CHUGAI

Roche Group

Annual Report 2019

Fiscal year ended December 31, 2019

INNOVATION
BEYOND IMAGINATION

CHUGAI PHARMACEUTICAL CO., LTD.

Contents

Bonus Video
***Saving Lives! Medic-boy's Big Adventure*:**
A Fun Guide to Advances in PHC

Personalized healthcare (PHC), which provides the most suitable medical care for each patient, is one of Chugai's initiatives to create shared value with patients and society. We have produced a bonus video about advances in PHC to accompany this report. Please enjoy the video, which presents PHC in a story that a wide range of stakeholders can understand.

https://www.chugai-pharm.co.jp/english/ir/ar2019/movie.html

Information on Chugai's Sustainability Initiatives

Chugai discloses its initiatives in a variety of media, including this printed report and its website. Please refer to the website for further details on initiatives presented in this report.

https://www.chugai-pharm.co.jp/english/sustainability

About the Cover

Representing Chugai's patient-centric approach to creating value, the design conveys our message: "It's not cancer. It's one person." We have also created corporate advertising that shares the same concept.

Mission Statement

Mission

Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world

Core Values

1. Patient Centric
   Make each patient's wellbeing our highest priority
2. Pioneering Spirit
   Pursue innovation by improving ourselves and thinking differently
3. Integrity
   Maintain the highest standards in all we do to create shared value with society

Envisioned Future

Become a top innovator for advanced and sustainable patient-centric healthcare, powered by our unique strengths in science and technology and the alliance with Roche

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At Chugai, our Mission Statement is the basis of everything we do. It is Chugai's most enduring and important concept, and represents our adherence to the Company's founding spirit and our founder's vow to "create drugs that benefit the world" in response to a medicine shortage following a major natural disaster. Our Core Values are the values that employees share and embody. They represent our commitment to maintaining the highest standards in all we do to meet the expectations and requirements of society as we pursue innovation with a pioneering spirit for the benefit of patients. In our Envisioned Future, we have set the goal of becoming a top innovator in the healthcare industry by going beyond the conventional scope of the pharmaceutical business in anticipation of future changes in the healthcare landscape. Chugai's vision of value creation is to fulfill its Mission Statement by creating shared value.

Chugai by the Numbers (2019)

Research

14

In-house products in the development pipeline
(As of January 31, 2020)

90[1]

Publications in academic papers and presentations at scientific conferences regarding Chugai's research findings
(2019)

4,976

Patents held (including pending applications)
(As of December 31, 2019)

Development and Pharmaceutical Technology

8

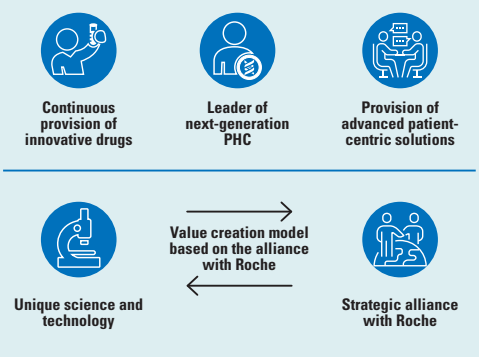
Breakthrough therapy designations[2]
(Cumulative as of January 31, 2020)

49

Pipeline projects
(As of January 31, 2020)

23

New products launched and new indications
(2015-2019)



Chugai's Unique Strengths

Using quantitative and comparable information and data, Chugai conducted an evaluation and analysis from the perspectives of value for patients and competitive advantage, and identified five strengths that are the source of its unique value.

Our unique science and technology is the base strength supporting the other four. It stems from our globally recognized discovery technologies and deep understanding of pathological mechanisms, and our strategic alliance with Roche, one of the world's leading pharmaceutical companies. The unique business model derived from these strengths has enabled us to achieve the top position in various areas by continuously providing innovative drugs, as well as to lead next-generation PHC as a pioneer. In addition, our initiatives to offer advanced patient-centric solutions, backed by a high level of expertise and provision of detailed information, have been well received.

Patient Access

No. 1 in Japan

Share of sales in the Japanese therapeutic antibody market (23.9%)[3] (2019)

69%

Proportion of sales from products that qualify for premium pricing (2019)

No. 1 in Japan

Satisfaction ranking based on healthcare professionals' assessments (Oncology; hospitals with 100 or more beds)[4] (2019)

Adequacy ranking for provision of safety information based on healthcare professionals' assessments (hospitals with 100 or more beds)[5] (2019)

Financial

¥686.2 billion

Revenues (2019)
No. 5 among pharmaceutical companies in Japan[6]

30.7%

Ratio of operating profit to revenues (IFRS)(2019)
No. 2 among pharmaceutical companies in Japan[6] (2019)

¥6.6 trillion

Market capitalization (As of February 29, 2020)
No. 1 among pharmaceutical companies in Japan[6]

1. Total of drug discovery and pharmaceutical technology
2. A system introduced in July 2012 by the U.S. Food and Drug Administration aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms
3. Copyright © 2020 IQVIA. Source: JPM 2019. Reprinted with permission. The scope of the market is defined by Chugai.
4. Source: INTAGE Healthcare Inc., CS Survey of Oncology, 2019. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
5. Source: INTAGE Healthcare Inc., 2019 questionnaire about safety information needs.
6. Financial results of pharmaceutical companies: (Chugai) Fiscal year ended December 31, 2019; (Other companies in the same industry) Fiscal year ended December 31, 2019 or March 31, 2019

Note: "Pharmaceutical companies" is defined as the top 10 Japanese domestic manufacturers of pharmaceuticals in terms of sales.
(Takeda Pharmaceutical Company Limited, Otsuka Holdings Co., Ltd., Astellas Pharma Inc., Daiichi Sankyo Company, Limited, Chugai Pharmaceutical Co., Ltd., Eisai Co., Ltd., Sumitomo Dainippon Pharma Co., Ltd., Mitsubishi Tanabe Pharma Corporation, Shionogi & Co., Ltd. and Kyowa Kirin Co., Ltd.)

Interview with the CEO

Society continues to expect and demand more from Chugai. There is only one way for us to create shared value with society that meets those expectations, and thereby increases our corporate value — we must pursue innovation.

To become a top innovator in the healthcare industry, Chugai will concentrate resources in innovation that contributes to the realization of advanced and sustainable patient-centric healthcare.

Q. What does Chugai aim to achieve?

Our goal is to contribute to the realization of advanced and sustainable patient-centric healthcare through innovation that is only possible at Chugai.

Chugai aims to be a top innovator in the healthcare industry that contributes to the realization of advanced and sustainable patient-centric healthcare.

This goal is also expressed in our Mission Statement, which we updated in 2019. In 2018, we achieved the "top pharmaceutical company" target we set for ourselves in 2009. From there, we wanted to establish a clear path going forward, which led to the revisions of our Core Values and Envisioned Future.

These revisions reflected our dialogue with various stakeholders. Although our founding commitment to benefiting patients and the medical community remains unchanged, society's expectations have changed considerably over the past 10 years. In addition to our responsibilities as the leading Japanese pharmaceutical company in therapeutic antibodies and oncology, our strong drug discovery capabilities have significantly raised expectations for our contribution to medicine worldwide. As of the end of

2019, for example, five products from Chugai research have received a total of eight breakthrough therapy designations.* Our value creation efforts are still focused on drugs, but we are broadening our contribution to patients through initiatives that maximize the value of drugs (Around the Pill) and healthcare services that transcend the boundaries of drugs (Beyond the Pill). Our market capitalization has increased six-fold in the last 10 years, which is further evidence of the expectations stakeholders have for us.

In this context, we have made the concept of creating shared value with stakeholders our basic management policy. One expectation that all our stakeholders have in common is for Chugai to deploy its high-level scientific and technological capabilities to create value for patients and society – to provide solutions that help solve social issues and lead to the advancement of society by innovating in ways that only Chugai can. Our employees must also have a clear understanding of this value creation path and our policy for sustainability.

* A system introduced in July 2012 by the U.S. Food and Drug Administration (FDA) aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms.

Q. What strategies is Chugai implementing based on that approach?

In IBI 21, we have designed strategies to share value with stakeholders and increase corporate value.

Mid-term business plan IBI 21, which started in 2019, includes Chugai's value creation strategies and growth strategies. The plan outlines a three-year strategic agenda that delineates our medium- and long-term growth story and issues for reform in light of the dramatic changes ahead in the external environment, the expectations for Chugai, and society's demands regarding sustainability, including the SDGs. To share value with stakeholders and thereby increase our corporate value, we have laid out five strategies for accelerating innovation, maximizing value globally, and strengthening our foundation for value creation, including human capital.

In these priority strategies, we will increase our focus on integrating our drug discovery technologies and biology to create innovative drugs while enhancing the value of the solutions we provide for addressing increasingly sophisticated and diverse needs. Personalized healthcare (PHC) will play a major role in making advanced and sustainable patient-centric healthcare a reality, and Chugai is taking the lead in promoting it as a pioneer of PHC in Japan. To concentrate more resources on this innovation, we will make changes to human resource development and our business structure, and work to strengthen sustainable platforms.

Q. How was Chugai's progress in 2019?

Our strategies progressed as planned, and financial results were good. Overall, it was a very productive year.

In 2019, the first year of IBI 21, we made good headway with each strategy.

One factor driving that progress is favorable growth in understanding and support of IBI 21 within the Company. When IBI 21 started, senior executives visited each business site to explain our strategies and engage in dialogue with employees. In a questionnaire afterward, many employees expressed empathy with the idea of creation of shared value, indicating strong resonance with management's goals. Since then, people have taken on new challenges with "patient-centric" as the key concept. I am pleased to see such a positive and vibrant atmosphere in the Company.

Departments and business functions are urgently implementing initiatives for each strategy. In research and development, projects for middle molecule drugs, which we are focusing on as a new modality, moved forward in 2019. Other projects also made steady progress, including regulatory filings for satralizumab (SA237) in Japan, the United States and Europe, and the start of a global phase III study of nemolizumab (CIM331), which we out-licensed to a pharmaceutical company other than Roche. Looking at the performance of the solutions we provided, the use of Hemlibra expanded in Japan and overseas, while new products such as Tecentriq performed well in Japan. In the pharmaceutical industry, a product with annual sales of more than U.S.$1 billion is called a blockbuster; Hemlibra became a major global product on that level just two years and two months after its launch. Our structural reforms also continued, including the transfer of long-term listed products and outsourcing of logistics and some other business operations. As for sustainable platforms, we strengthened our initiatives in supply chain management and environmental management.

One area of progress that deserves special mention is the promotion of advances in PHC. In 2019, we launched FoundationOne CDx Cancer Genomic Profile (F1CDx), a cancer genomic test. We also obtained an additional approval for F1CDx as a companion diagnostic for Rozlytrek, in tandem with the launch of this tumor-agnostic therapy. Comprehensive genomic profiling of patients with gene panel testing enables the optimal diagnosis for each patient. Symbolizing the advancement of PHC, this solution was a major step forward in expanding and promoting PHC.

The success of these various initiatives was reflected in significant growth in revenues and profit. Core EPS increased 73.3 percent compared with the previous year. We achieved record profit for the third consecutive year despite a challenging operating environment, indicating that we are on a strong growth trajectory.

▶ See "Overview of Mid-Term Business Plan IBI 21" on page 41.

Q. Please discuss Chugai's business model and the risks that you see for future growth.

We will take advantage of the unique business model we have built and deal appropriately with the various risks in a challenging operating environment.

I have confidence in the business model we have built. We will continue our policy of concentrating on innovation using our scientific and technological strengths under the strategic alliance with Roche. We will also maintain our earnings structure with business in Japan as our source of revenues, and global expansion of products from Chugai research as our source of growth.

However, the operating landscape will become extremely challenging in the years ahead. Even though we are currently enjoying growth momentum, a variety of risks exist.

In Japan, demands to reduce drug prices are becoming stronger as a result of strained healthcare finances, and with the rise of generics and biosimilars, we assume that domestic market growth will be either flat or negative. Fiscal pressure caused by shifting demographics is not exclusive to Japan, and measures to control healthcare costs in every advanced country will also require monitoring.

Technological progress in the life science field is expected to accelerate. Advances in areas such as cellular and genomic therapy and nucleic acid drugs are also expected, raising the possibility that innovative drugs with new modalities will emerge. The biggest risk for Chugai would be missing the wave of innovation. With limited resources, it is difficult to focus on every promising modality, but we are now laying the groundwork to enable us to flexibly participate in new modalities as necessary. We have chosen middle

Mid-Term Business Plan: 5 Strategies and Targets

Create Global Growth Drivers and Maximize Value

Strategy 1: Value Creation
Realize innovative drug discovery to cure and manage diseases

Strategy 2: Value Delivery
Deliver patient-centric solutions and maximize value of growth drivers

Strategy 3: Promote Advances in Personalized Healthcare (PHC)
Realize the further advancement of PHC and innovate R&D process by utilizing digital technology and data

Strengthen HR and Infrastructure That Support Chugai's Business

Strategy 4: Strengthen Human Capital and Conduct Fundamental Structural Reform
Develop high-caliber HR talent that supports innovation, and thoroughly reform costs, systems and processes

Strategy 5: Strengthen Sustainable Platforms
Simultaneously realize company growth and sustainable social development

Core EPS CAGR[1] (2018-2021)	Around 30%[2]

1. Compound annual growth rate (%)
2. Three years, based on constant exchange rate.
* Core EPS CAGR is calculated based on the assumption of no stock split with a scheduled effective date of July 1, 2020.

molecules as our next-generation modality, and it is essential for us to achieve promising outcomes in the next three to five years. Therefore, we are expediting our efforts to move a middle molecule drug into the clinical phase during IBI 21.

AI and digital technology will be key factors in Chugai's innovation, but we need to bear in mind risks such as the emergence of data oligopolies and the entry of businesses such as IT business into the healthcare industry. We have created a digital transformation roadmap toward 2030, but we will first accelerate upgrades of systems and infrastructure and connect them to areas such as AI drug discovery and efficiency in the value chain.

Regarding sustainable platforms, expectations and requirements regarding issues such as climate change countermeasures and human rights are increasing. Looking at other industries, it is clear that the pharmaceutical industry needs to step up its environmental efforts. Chugai has made environmental initiatives a priority in establishing material issues and Strategy 5 of IBI 21, and will place greater emphasis on dealing with long-term risks.

Looking overseas, China is a huge and growing market, but we are not considering expanding there independently. We will work to maximize the value of our in-house products in cooperation with Roche.

▶ See "The Risks behind Our Strategies" on page 36.

Q. What is Chugai's growth outlook?

After successfully completing IBI 21, we will look beyond with a broader view to maintain and enhance our growth trajectory.

Our focus during IBI 21 is the successful execution of our strategies. For 2020, the second year of the plan, we have set a four-point priority agenda: 1) Maximize the value of growth drivers; 2) Create next-generation growth opportunities; 3) Promote digital transformation and PHC; and 4) Conduct fundamental structural reform and strengthen sustainable platforms. Although the Japanese market is challenging, we forecast growth centered on overseas revenues. In light of this, as a quantitative target, we have raised our quantitative guidance for Core EPS CAGR from the high single digits to around 30 percent. In our dividend policy, we had been targeting a Core EPS payout ratio of 50 percent on average, but after considering future growth opportunities and funding plans, we changed that target to 45 percent in order to maintain stable dividend payments.

▶ See "Mid-Term Business Plan: 5 Strategies and Targets" on page 6.

Priority Agenda for 2020

Growth Factors

- Continuous creation of innovative global in-house products
- Global sales expansion of in-house products
- Accelerated penetration of new products in Japanese market
- Additional indications of existing products in Japan and overseas
- Enhancement of R&D and manufacturing facilities
- Establishment of platforms to support future growth, etc.

Risk Factors

- Biosimilars
- Generics
- Government pressure on pricing
- Environmental changes
- New modalities, etc.

1	Maximize the value of growth drivers	• Hemlibra: Achieve further market penetration • Tecentriq: Increase market share with additional indications • Satralizumab (SA237): Obtain approval and achieve rapid market penetration
2	Create next-generation growth opportunities	• Middle molecule project: Prepare for phase I trial • Antibody project: Start phase I trial for Switch antibody • Nemolizumab:[3] File for approval of atopic dermatitis in Japan, start multinational phase III study for prurigo nodularis • Crovalimab/SKY59: Start multinational phase III study for paroxysmal nocturnal hemoglobinuria
3	Promote digital transformation and PHC	• File for approval of FoundationOne Liquid • Promote AI in drug discovery and acquire and train digital talent • Accelerate collaboration with external partners
4	Strengthen sustainable platforms	• Implement and manage new HR system • Achieve higher scores in ESG

3. Maruho Co. Inc. is filing for approval of atopic dermatitis.
Galderma S.A. is conducting the global phase III study for prurigo nodularis.

We will maintain a strong growth trajectory by investing aggressively for the future beyond IBI 21. Creation of innovative drugs will remain the core of our business, but as a top innovator, we will deliver value with a broader view. This includes providing value beyond pharmaceuticals, developing more sophisticated solutions, and innovating through collaboration with players in diverse industries, such as the IT and digital sector. We expect profit growth to be fueled mainly by new growth drivers, progress in the development of middle molecule drugs, enhancement of drug discovery and productivity from the start of operation of new research facilities, and advances in next-generation PHC.

So, what is the key to maintaining this value creation? In my view, it all comes down to the pursuit of innovation.

Q. How will you promote innovation?

We will make Chugai a company that continues to innovate by concentrating resources in science, technology, and in human capital and corporate culture.

Chugai focuses on innovation in the creation of drugs. However, efforts to innovate are not limited to research and development operations alone. The whole company must concentrate on these efforts to be a company that continues to innovate.

That is why I am placing priority on science, technology, and on human capital and corporate culture, and we will concentrate resources in these areas. Science is the source of our value and provides the criteria for evaluating our activities. Technology is our strength and lifeline. And most important of all is our people. By strengthening talent management and diversity and inclusion (D&I) and aggressively investing in human capital, we want to create a corporate culture that fosters innovation.

D&I is a must for accelerating innovation. We have actively promoted D&I since the launch of a working team in 2010, and the ratio of female managers has risen steadily. But we still have more to do. In a few years, gender diversity may no longer be an issue of discussion in the Company, but right now we are in the phase of intentionally and intensively promoting it, and intend to step up related activities. We plan to devote further resources to diversity of nationality, which is another area where we need to improve.

In April 2020, we will introduce a new personnel system that prioritizes assigning the right people to the right positions. Under this system, instead of assessing the abilities and past contributions of employees, we will clearly define the requirements of all positions in the company to make it easier for employees to manage their own career development and challenge themselves in higher roles. By giving opportunities to capable employees, the personnel system itself will support innovation.

Q. In conclusion, what are your aspirations for Chugai's management?

Under the new management team, we are working to increase corporate value through an emphasis on dialogue.

Our approach of assigning the right people to the right positions also applies to people in management. In the recent changes in representative directors, the appointment of Dr. Osamu Okuda to the position of Representative Director, President and COO was a transparent process of selection from multiple candidates through discussions by the Nominating Committee. We also placed importance on a smooth transition. I have high hopes for Dr. Okuda in his new position because of his character, his abilities, and his record of achievements. He also played a central role in drafting the new Mission Statement and IBI 21, and fully shares my management philosophy. I intend to continue pursuing innovation under the new management team of Deputy Chairman Motoo Ueno, President Okuda and myself.

Chugai is well positioned for further value creation. Benefiting patients is connected directly to the value we share with stakeholders. Therefore, we remain committed to becoming a top innovator that contributes to the realization of advanced and sustainable patient-centric healthcare.

I will redouble my efforts to communicate this value creation path in a clear and simple way both in the Company and to external stakeholders. My efforts will focus on enhancing our corporate value through an emphasis on dialogue.

Look forward to even more innovation from us.

Message from the COO

Dedicated to creating value for each patient, we aim to become a top innovator that will lead the global healthcare industry.

Dr. Osamu Okuda
Representative Director, President and COO

Beginning My New Role as COO

I am Osamu Okuda, Chugai's newly appointed President and Chief Operating Officer.

With a history spanning more than 90 years, Chugai has established a unique business model through its strategic alliance with Roche, becoming an innovator in drug discovery that is unparalleled in Japan. My duty, as I see it, is to generate sustainable growth through a dedication to creating value for each patient, and to steer Chugai on a course toward becoming a globally recognized top innovator in the healthcare industry. I am honored to be entrusted with Chugai's future. I am also firmly resolved to take on this great responsibility.

Mid-term business plan IBI 21 is progressing steadily. In addition to focusing on successfully executing our strategies we will quickly and firmly implement the strategies of our strategic agenda with a medium- to long-term view to achieve sustainable growth.

Creation of Shared Value and Corporate Vision

Chugai has made creating shared value its basic management policy. This means aligning the value that we create with the value that society requires. We will meet society's demands by wholeheartedly concentrating even more resources than ever on dramatic innovation that changes the lives of patients.

To successfully execute our strategies, employees must truly understand the meaning of shared value. In 2019, we conducted workshops for approximately 900 mid-level managers, at which they engaged in dialogue with patients and their families and had discussions based on video letters from patients. Participating managers were reminded that their core business has value that can change patient's lives. We plan to devote further efforts to pursue shared value with employees.

What should Chugai do based on these ideas? Over the long term, the medical community is expected to converge on Value-Based Healthcare (VBHC). Eventually, only solutions that offer true value to patients and society – value that has been proven with data – will be adopted. To provide such high value, it is essential to further advance our drug discovery technology, which is one of our strengths, and deepen our understanding of the biology of diseases.

In this context, going forward I believe that we need to strengthen our pioneering spirit and our sensitivity to trends outside the Company and the industry. Our employees are highly focused on objectives and following through to completion. As healthcare and the required solutions change, our ability to detect what is happening outside the Company and in other industries will become increasingly important. Moreover, we will need a pioneering spirit to embrace new challenges, without being bound by our existing technologies and approaches. While the creation of innovative drugs is at the heart of our business, we will incorporate the most advanced technologies and team up with players in other industries to lead the development of new solutions.

I am fully committed to making Chugai a top innovator that will lead the global healthcare industry. We will think ideas through, create solutions that offer high value, and deliver them to patients based on the pioneering spirit of our Core Values. In the process, our employees will grow, and using the profit generated, we will create further groundbreaking solutions. This is the virtuous cycle I aim to establish.

Finally, everything we do is founded on integrity. We will strive to maintain an open and sincere dialogue with our stakeholders to meet the expectations and demands of society.

Our History and Shared Value

Chugai was founded in 1925 in response to the shortage of medicine after the Great Kanto Earthquake. Since then, we have consistently conducted business while sharing value with patients and everyone involved in providing healthcare. There have been six major turning points and important decisions in our history, and underpinning those decisions has always been our consideration of what kind of value we can create.

Turning Point 1

Shift to Prescription Pharmaceuticals

1960s

Japan's National Health Insurance system was established in 1961, enabling all citizens to enjoy stable healthcare. Under this system healthcare progressed, which in turn necessitated a broader range of pharmaceuticals to provide more treatment options. In response, Chugai shifted its business focus from manufacturing and sales of over-the-counter (OTC) drugs to prescription drugs. We also decided to concentrate on research and development in order to produce innovative medicines. As a result, our stagnating business performance began to recover.

Main Shared Value

Patients: Access to comprehensive medical care
Society: Expansion of treatment options; a stable healthcare system; further advances in the healthcare and pharmaceutical industries

Turning Point 2

Focus on Biopharmaceuticals

1980s

In the 1980s, although medical care was advancing, Chugai decided that establishing biotechnology was essential because it believed that unmet medical need could not be fully addressed with the chemically synthesized small-molecule drugs that were then mainstream. We invested resources in the research and development of biopharmaceuticals, which offered new approaches to diseases and promising therapies with high efficacy and safety. We also worked to establish mass-production technology, and in the early 1990s launched a biopharmaceutical that used gene recombination technology, creating the cornerstone of our later strengths.

Main Shared Value

Patients: Treatment options for a wide range of diseases; promising therapies with high efficacy
Society: Evolution and diversification of treatment methods; advancement of approaches to diseases; development of bioscience

Turning Point 3

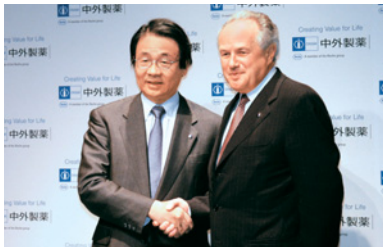
Strategic Alliance with Roche

Since 2000s

Seeking to benefit patients globally and accelerate innovation, in 2002 Chugai embarked on a strategic alliance with Roche, one of the world's leading pharmaceutical companies. From this alliance emerged a unique business model that leveraged the strengths of both companies. This model enabled us to in-license Roche products that had already been approved overseas, and to utilize Roche's cutting-edge expertise and infrastructure to expand our own value contribution. Subsequently, we transformed our revenue structure by reorganizing our business operations, research laboratories and plants.

Main Shared Value

Patients: Use of excellent Roche products (elimination of drug lag)
Society: Rapid expansion of treatment options; world-class quality in products and solutions



Turning Point 4

Promoting the Adoption and Advancement of PHC

When Herceptin was launched, there were numerous challenges in establishing PHC, but we worked to promote its adoption in cooperation with medical institutions, various groups, local governments and others. The advent of the next-generation of PHC brings with it expectations of treatment optimized for each patient, aided by advances in genetic analysis and drug discovery technologies. Chugai is pursuing various initiatives to promote advances in PHC as a pioneer in this approach to healthcare.

▶ See "Strategy 3: Promote Advances in PHC" on page 46.

Examples of Initiatives to Promote Adoption of PHC

- Drug discovery based on PHC
- Co-development of companion diagnostics
- Programs to improve screening procedure standards and screening rates
- Support for creation of guidelines
- Provision of various information; study sessions

Examples of Initiatives to Promote Advances in PHC

- Promotion of gene panel testing
- Expansion of tumor-agnostic therapies
- Cooperation with and support for medical institutions and governments to advance cancer genomic profiling
- Research that provides proof of value in advances in PHC

Turning Point 4

Promotion of PHC

Since 2000s

Personalized healthcare (PHC), in which the optimal treatment is provided based on the patient's genetic profile and other diagnostic information, is a current trend in healthcare that offers significant benefits to all stakeholders. Recognizing that the expansion of PHC would be essential in healthcare going forward, in the 2000s Chugai focused on advancement of PHC in Japan, starting with the launch of Herceptin and other products in-licensed from Roche. We are making major contributions as a PHC pioneer, not only through research and development but also through support activities such as providing information to healthcare professionals and creating guidelines.

Main Shared Value

Patients: Administration of drugs only when they are expected to be effective; improved quality of life; reduced burden
Society: Optimal treatments for each patient stratum; avoidance of unnecessary administration

Turning Point 5

Launch of Therapeutic Antibody and Continuous Creation of Innovative Drugs

Since 2000s

To further address unmet medical need, Chugai made large investments and in 2005 launched Actemra, the first therapeutic antibody created in Japan. Since then, we have produced a succession of innovative drugs by investing our resources in creating products from our own research and the advancement of technologies. So far, Chugai products have received breakthrough therapy designations from the U.S. FDA eight times. Chugai continues to maintain the top share* of the Japanese oncology and therapeutic antibody markets.

Main Shared Value

Patients: Superior efficacy and safety; groundbreaking outcomes
Society: Evolution of treatment paradigms; fuller treatment adherence and diagnosis; response to rare diseases

Source: JPM 2019. Reprinted with permission.
The scope of the market is defined by Chugai.

Turning Point 6

Commitment to Realizing Advanced and Sustainable Patient-Centric Healthcare

Since 2019

In view of the challenges facing the healthcare industry, including further responding to unmet medical need, structural changes in society, and strained healthcare finances, Chugai declared in 2019 that it would work toward becoming a top innovator for advanced and sustainable patient-centric healthcare based on creation of shared value. Although our basic idea has not changed since the Company was founded, this declaration represents our commitment to solving challenges facing society and achieving Chugai's own growth by contributing to the advance of healthcare, with patients at the center.

Shared Value from Realizing Advanced and Sustainable Patient-Centric Healthcare

Chugai has defined its shared value with each group of stakeholders that goes beyond simple cooperation.

▶ See "Analysis of Value Provided" on page 14.

Turning Point 5

Breakthrough Therapy Designations

The breakthrough therapy designation of the U.S. FDA is aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms. A drug must be highly innovative to receive the designation, but receiving it is valuable for various reasons. For example, a drug with this designation receives priority review, which shortens the development period, bringing the drug to patients as quickly as possible. Five Chugai products have received eight breakthrough therapy designations, which is further evidence of our strong drug discovery capabilities.

Chugai Products That Received Breakthrough Therapy Designation

Jun. 2013	Alecensa (treatment of people with ALK-positive metastatic NSCLC whose disease has progressed on crizotinib)
Jun. 2015	Actemra (systemic sclerosis)
Sep. 2015	Hemlibra (people 12 years of age or older with hemophilia A with factor VIII inhibitors)
Sep. 2016	Alecensa (first-line treatment of ALK-positive NSCLC)
Oct. 2016	Actemra (giant cell arteritis)
Apr. 2018	Hemlibra (hemophilia A without inhibitors)
Dec. 2018	Satralizumab (SA237) (neuromyelitis optica and neuromyelitis optica spectrum disorder)
Dec. 2019	Nemolizumab (CIM331) (pruritus associated with prurigo nodularis)

▶ See "Focus 1: Evolution of Antibody Engineering Technologies" on page 50.

Value Creation Model

Mission Statement

— Innovation all for the patients —

Mission

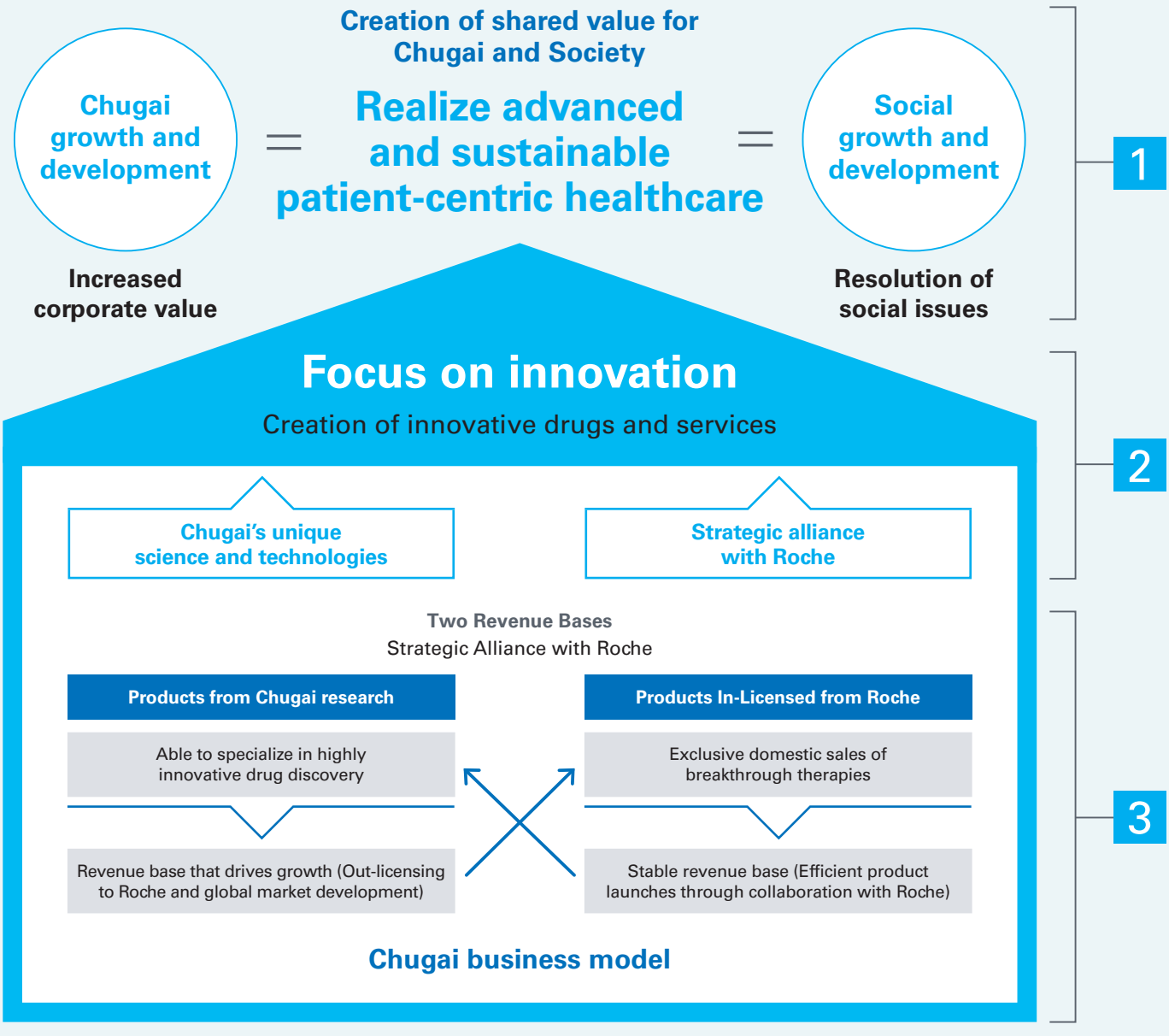
Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world

Core Values

Patient Centric – Pioneering Spirit – Integrity

Envisioned Future

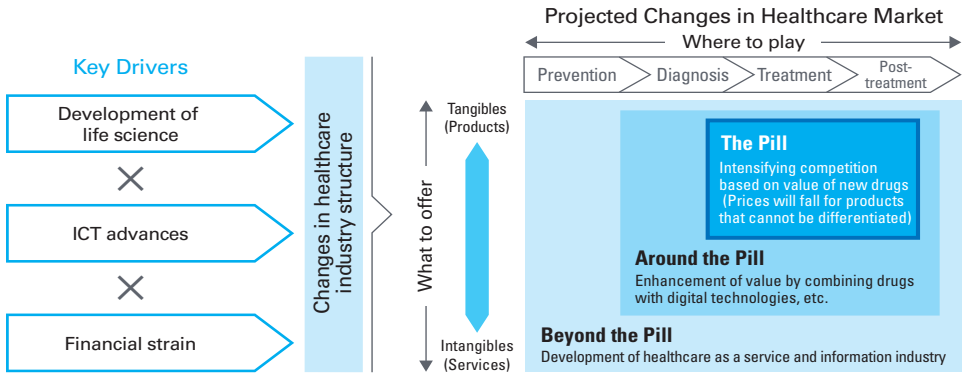
Become a top innovator for advanced and sustainable patient-centric healthcare, powered by our unique strengths in science and technology and the alliance with Roche



Chugai has adopted "creating shared value" as its basic management policy, in line with its philosophy of growing together with its various stakeholders by solving social issues through business activities.

The goal of this shared value, which is also part of our Envisioned Future, is to realize advanced and sustainable patient-centric healthcare. Healthcare is facing significant change, driven by dramatic advances in life sciences and digital technology, and healthcare issues will become increasingly sophisticated and diverse. The contribution of the healthcare industry will also expand to encompass needs not just in the treatment phase, but throughout the patient's lifetime from prevention and diagnosis to post-treatment, including the provision of solutions "beyond the pill."(See diagram below.)

Expanding Scope from "The Pill" to "Around the Pill" and "Beyond the Pill"



Meanwhile, the financial strain on healthcare systems due to the growth and aging of populations worldwide is an issue that must be resolved to ensure the sustainability of those systems.

Our thinking on solutions to these issues is closely aligned with the Sustainable Development Goals (SDGs) adopted by the United Nations. We are working on 10 of the SDGs in addition to "3. Good health and well-being," the development goal we are focusing on the most. We also endorse initiatives such as the Task Force on Climate-related Financial Disclosures (TCFD) and the Carbon Disclosure Project (CDP), which reflects top management's strong commitment to addressing climate change and other global issues. ▶ See "Strengthen Sustainable Platforms" on page 48.

The top priority goal directly linked to our Mission (3), the four goals required to achieve it (8, 9, 12 and 17) and the six goals that form the basis of our business activities (5, 6, 10, 13, 15 and 16)

The key to creating shared value is to focus on innovation. As technology progresses and the financial strain on healthcare systems increases, only solutions that offer true value for patients will be pursued. In such an environment, companies will need to innovate continuously in order to survive. Chugai will focus its resources on innovation, powered by its unique capabilities in science and technology and the strategic alliance with Roche.

We believe that Chugai's unique business model makes such value creation possible. It is vital that we make full use of this business model that combines two revenue bases – products from Chugai research, which drive growth, and products in-licensed from Roche, which generate stable revenue.

On the following pages, we analyze and examine each component of our value creation model.

In addition, we have established 25 material issues in eight categories to be given priority in our efforts to create shared value. ▶ See "Chugai's Material Issues" on page 37.

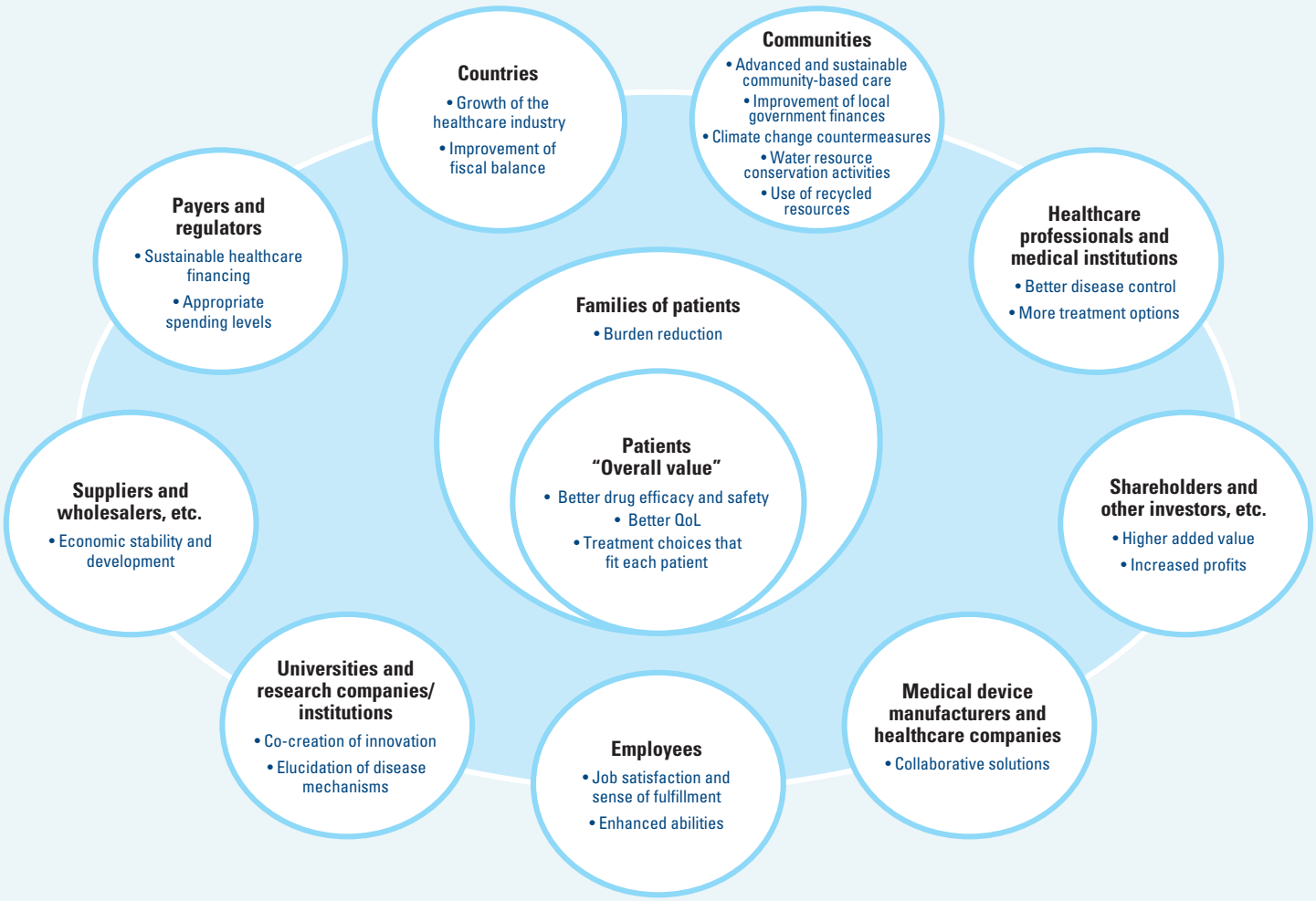
1
▶ See "Analysis of Value Provided" on page 14.

2
▶ See "Examination of Innovation" on page 16.

3
▶ See "Analysis of Business Model" on page 18.

Value Creation Model

1 Analysis of Value Provided



Helping to build a framework for healthcare while sharing value with stakeholders will be essential for realizing advanced and sustainable patient-centric healthcare.

Chugai carefully examined the kinds of value that will be important to create and share with each group of stakeholders, and established indicators to quantify and measure changes in value. (See the diagram above and the table to the right.)

For example, drug efficacy and safety is of the utmost importance for patients. In addition to the prescription and use of our products in Japan, we also place importance on the treatment outcome and safety information relating to patients worldwide that we obtain through the Roche Group's network. Other key types of shared value include patients' quality of life and the ability to provide treatment consistent with patients' personal values. As a leading company in Japan in the oncology field and the hospital market, Chugai has also established key indicators such as treatment adherence rates and treatment outcomes by disease area in each region.

While examining and considering these indicators, Chugai will strive to embody advanced and sustainable patient-centric healthcare as the value it aims to provide, and visualize progress toward that goal.

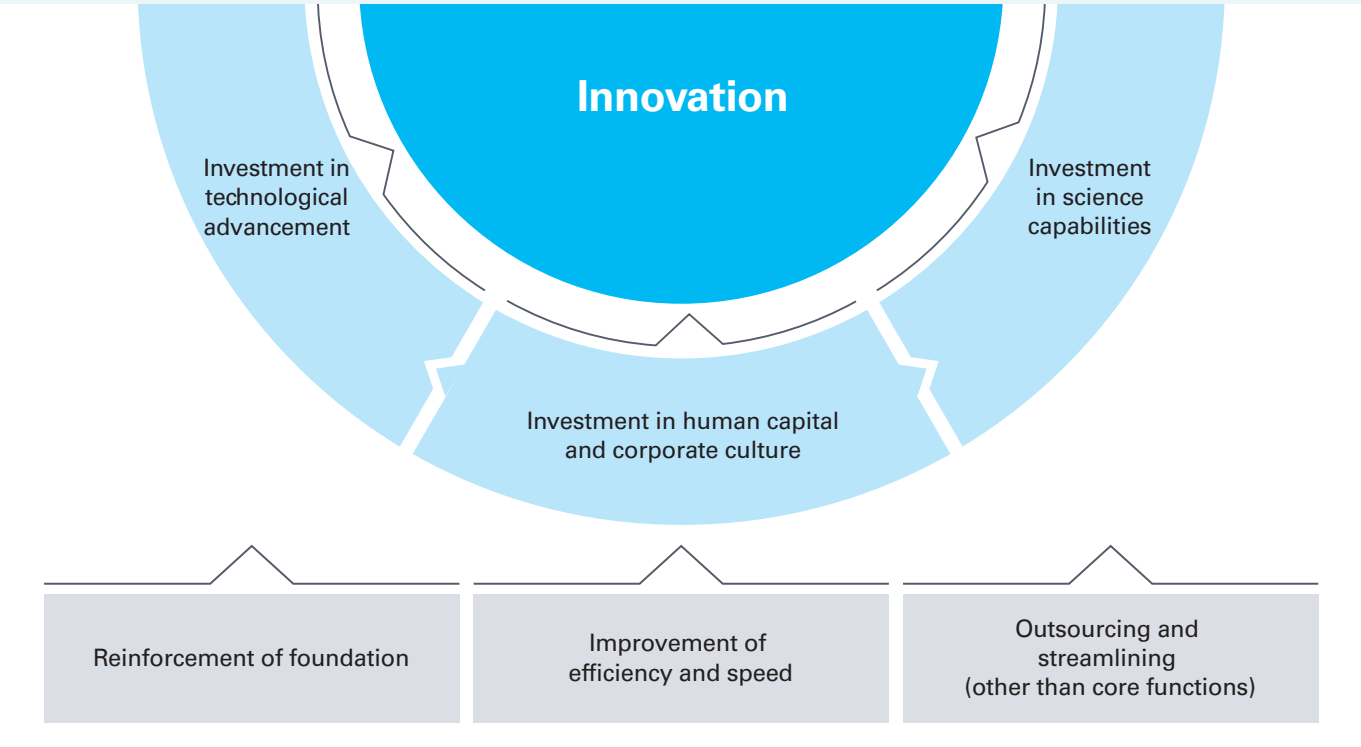
Statistics for Key Global Chugai Products (including cooperation with Roche)

Actemra	Alcensa	Hemlibra
Total of more than 1,000,000 patients treated Approved in over 110 countries	Approved in over 85 countries	Total of more than 6,000 patients treated Approved in over 90 countries

Value Shared with Stakeholders and Key Value Indicators

Stakeholder	Shared Value	Value Indicators	
		Indicators Used by Chugai	External Indicators
Patients	• Better drug efficacy and safety • Better QoL • Treatment choices that fit each patient	• Number of new products launched and additional indications • Number of safety information reports • Number of development projects and products based on PHC	• Treatment outcomes in each disease area • Treatment adherence rate • Medication and post-treatment care costs
Families of patients	• Burden reduction	• Number of development projects and products based on PHC	• Total cost of care for patients
Healthcare professionals and medical institutions	• Better disease control • More treatment options	• Number of new products launched and additional indications	• Treatment outcomes in each disease area • Number of standard of care guidelines
Communities	• Advanced and sustainable community-based care • Improvement of local government finances • Climate change countermeasures • Water resource conservation activities • Use of recycled resources	• Number of liaison activities • Energy consumption • Eliminate use of specific fluorocarbons • Waste recycling ratio	• Treatment adherence rate • Drug costs in hospital market • Environmental-related assessments
Countries	• Growth of the healthcare industry • Improvement of fiscal balance	• Revenues • Income taxes paid	• Growth rate of healthcare industry • Taxable capacity of the industry
Payers and regulators	• Sustainable healthcare financing • Appropriate spending levels	• Number of new products launched and additional indications • Number of development projects and products based on PHC	• Health insurance costs
Universities and research companies/ institutions	• Co-creation of innovation • Elucidation of disease mechanisms	• Number of joint research projects • Number of research agreements/ alliances	• Number of clinical studies in main disease areas
Suppliers and wholesalers, etc.	• Economic stability and development	• Sales • Number of risk evaluations	• Growth rate of healthcare industry
Medical device manufacturers and healthcare companies	• Collaborative solutions	• Number of cooperative solution development projects	• Growth rate of healthcare industry
Employees	• Job satisfaction and sense of fulfillment • Enhanced abilities	• Employee awareness surveys • Productivity indicators	• Diversity and inclusion-related indices
Shareholders and other investors, etc.	• Higher added value • Increased profits	• Core EPS CAGR • Payout ratio	• ESG rating • Market capitalization

2 Examination of Innovation



In an environment characterized by financial strain on healthcare systems and changing social structures, it is inevitable that only solutions that offer true value will be pursued. Pharmaceutical companies cannot demonstrate value to society without innovating, yet innovation is not easy and requires substantial investment of resources. According to one study,[1] the cost to research and develop a drug, including the cost of failures, is more than $2.5 billion. The top five global pharmaceutical companies spend roughly ¥1 trillion annually on research and development.[2]

Chugai's research and development activities are very efficient, partly because Chugai utilizes Roche's research infrastructure and the companies jointly conduct global studies. Considering the outlook for the healthcare market, however, creating an environment and corporate culture for further innovation is an urgent issue. We need to transform our business structure so we can focus every available resource on innovation. Based on these circumstances, Chugai will examine exactly what kind of innovation to focus on, as explained below.

Chugai has decided it will focus investment of resources on innovation in three areas: technological advancement, science capabilities, and human capital and corporate culture.

Resource investment in technological advancement will encompass everything directly related to innovation, such as our drug discovery modalities – antibodies, small molecules and middle molecules – as well as identification of targets, formulation, device technologies, and development of research material technologies. Development of life science technologies is accelerating, and it will be important to not only acquire the latest data analysis technology, but also to take advantage of outside resources, including cooperation with specialized institutions and companies.

As for investment in science capabilities, main areas of focus will include research in pathology and the visualization of value. In addition to Chugai's own research, our comprehensive collaboration agreement with IFReC and other open innovation with academia will be essential. Resource investment in this area will encompass not only research and development but also analysis of real-world data[3] and epidemiological demonstration of product value.

Human capital and corporate culture are the basis of innovation and the prime resources driving the evolution of technology and science. As such, investment in these areas is an absolute must. Over its history, Chugai has changed its business structure and business areas and overcome numerous difficulties through innovation, and that DNA has been inherited by our employees. Building on this foundation, we will focus on priorities such as investing in human resource development and recruiting, accelerating diversity and inclusion, and fostering a corporate culture of constantly pursuing innovation.

To enable these investments of resources, we first need to establish the infrastructure and find the necessary resources.

We will do this in three ways. First, we will reinforce the foundation of various functions such as clinical development, regulatory affairs, and sales and marketing, while enhancing our technological base and research platform, including cooperation with Roche.

Second, we will improve efficiency and speed. This will be essential in focusing our limited funds, time and personnel on innovation. Accordingly, we have begun initiatives such as rationalization, including the use of robotic process automation (RPA), as well as digitalization and the introduction of AI, in addition to the productivity improvement projects that individual departments have been carrying out on their own.

Third, we will review our business structure, outsourcing and streamlining of non-core functions. This will help to free up capital for innovation. With measures including the transfer of long-term listed products and review of processes for every function, we will work to establish a sustainable and resilient profit structure.

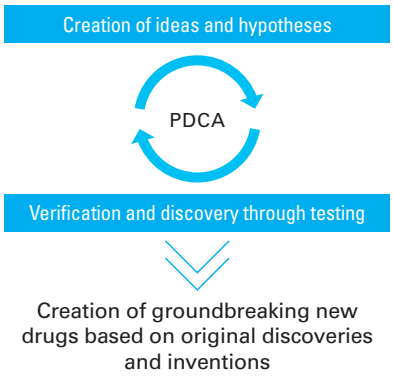
1. Source: DiMasi, J.A. et al., *Journal of Health Economics* 47 (2016): 20-33
2. Calculated by Chugai from 2019 financial results of the companies
3. Data from clinical practice

Example 1: Development Background of Switch Antibody™

The idea of Switch antibody engineering technology for solving the problem of on-target toxicity* was conceived in 2010, but it took nearly 10 years to perfect. Proving the concept and designing the technology for optimization was exceptionally difficult not only because the technology was for creating an antibody with an original mode of action, but also because the antibody had no established precedent and was highly complex. Despite these challenging conditions, and although it was a process of trial-and-error, the antibody engineering technology discovery process moved forward because of our organizational culture in which various divisions cooperate and enthusiastically engage in positive, creative discussions for impressive drug discovery. In addition, we made investment decisions to concentrate resources on that effort. It became a model case of innovation through the advanced combination of core analytical technologies, the pharmacology function and antibody engineering technologies, while deepening our understanding of biology.

▶ See "Focus 1: Evolution of Antibody Engineering Technologies" on page 50.

* Toxicity in which there is excessive pharmacological action when the antibody binds to the target molecule. Toxicity remains a challenge in creating therapeutic antibodies.



Example 2: TACTICS – A System for Allocating 20 Percent of Research Workloads to Idea Creation

The Research Division started an initiative called "TACTICS" in 2019 to promote innovation. This system involves approximately half of our researchers across the division, and requires that they allocate at least 20 percent of their workloads to the generation, testing and verification of new ideas. Respecting the autonomy of researchers, the division leaves the specific details of activities to their discretion. The intention is to systematically concentrate on innovation by focusing our human resources and their time on the generation and verification of ideas. It is clear that idea creation will be even more vital in the healthcare industry going forward. Based on the theme of "Innovation in Drug Discovery through the Transforming Fusion of Biology (Science) and Technology," and with TACTICS underpinning our efforts, we intend to foster an organizational culture that is focused on talent development and continuous innovation.

3 Analysis of Business Model

Win-Win Relationship with Roche

Independent management (stock listing maintained)

Concentrate on innovation through an emphasis on originality and diversity

Access emphasizing economies of scale and regional optimization

Products from Chugai research
Global marketing utilizing Roche's network

Products in-licensed from Roche
Development and marketing in Chugai's territory (Japan, South Korea and Taiwan)

Advantages for Roche

- Handling of innovative drugs created by Chugai
- Presence in Japan, one of the world's largest markets
- Marketing that matches Japan's business environment
- Increase in the Roche Group's corporate value

Contractual arrangements regarding Chugai and Roche products

- Chugai has right of first refusal on the development and marketing of Roche products in Japan
- Roche has right of first refusal on the development and marketing of Chugai products outside Japan
  - Worldwide except in Chugai's territory
  - Chugai offers all development projects to Roche in the early PoC stage
  - Co-promotion rights in the U.K., Germany, France, etc. (Discussions about China on a drug-by-drug basis)

Features and Outcomes by Business Model Function

Area/Function	Features of Business Model	Outcomes of Relationship and Cooperation with Roche
Management	• Stock listing maintained by guaranteeing independence • Minority interests ensured • Management with a broad, long-term view	• Basic Agreement emphasizes Chugai's management independence and maintenance of stock listing. • Executive directors, independent outside directors, and directors concurrently sitting on Roche's Board of Directors each comprise one-third of Chugai's Board of Directors. • Joint committees with Roche and close consultation between senior managers take place routinely. Chugai and Roche share and confirm each other's mission, values and direction.
Research	• Concentration on innovation through independent decision-making • Efficient research activities • Acceleration of efforts driven by friendly rivalry within the Group	• Activities are based on Chugai's independent decision-making, including selection of research projects and investment of resources. • Chugai can use Roche's research infrastructure, including its large, high-quality compound library. • In the Roche Group, a culture of friendly competition between the research divisions of each company provides mutual motivation.
Clinical Development	• Optimal timing of collaboration with Roche • Efficient and rapid global marketing utilizing the Roche Group's infrastructure • Access to latest market information globally	• While Roche has right of first refusal on the global development of Chugai products, Chugai has exclusive development and marketing rights to Roche products in Japan. • Out-licensing of products from Chugai research is immediately offered to Roche upon achievement of early PoC (changed in 2014). This has enabled faster development by reducing "white space" in the development process. • Participation in global studies conducted by Roche for in-licensed and out-licensed products that extend worldwide. Chugai manages clinical trials in Japan. • Chugai is establishing its own independent global development system in order to quickly achieve early PoC.
Pharmaceutical Technology and Production	• Optimization of global production system • Conformance with the world's most advanced management standards • Information-sharing in the areas of supply chain management and environment, health and safety (EHS)	• In principle, products from Chugai research are manufactured by Chugai and exported to Roche, but for Actemra, technology has been transferred to Roche Group production bases. • Roche, which manufactures and markets products worldwide, shares its knowledge on the latest GxP compliance. • In addition to incorporating Roche's expertise in supplier due diligence and management, Chugai and Roche keep each other informed about EHS management of production bases.
Marketing/ Medical Affairs/ Drug Safety	• Provision of solutions tailored to regional characteristics • Sharing of various information with Roche and establishment of common infrastructure for safety information	• Chugai provides solutions in each territory with a focus on local healthcare systems and regional characteristics. • However, when necessary Chugai and Roche share information and cooperate across regions in marketing strategy, generation of evidence and other matters for each product. • Safety information on each product is collected and analyzed in real time in cooperation with Roche.

Chugai's Business Model

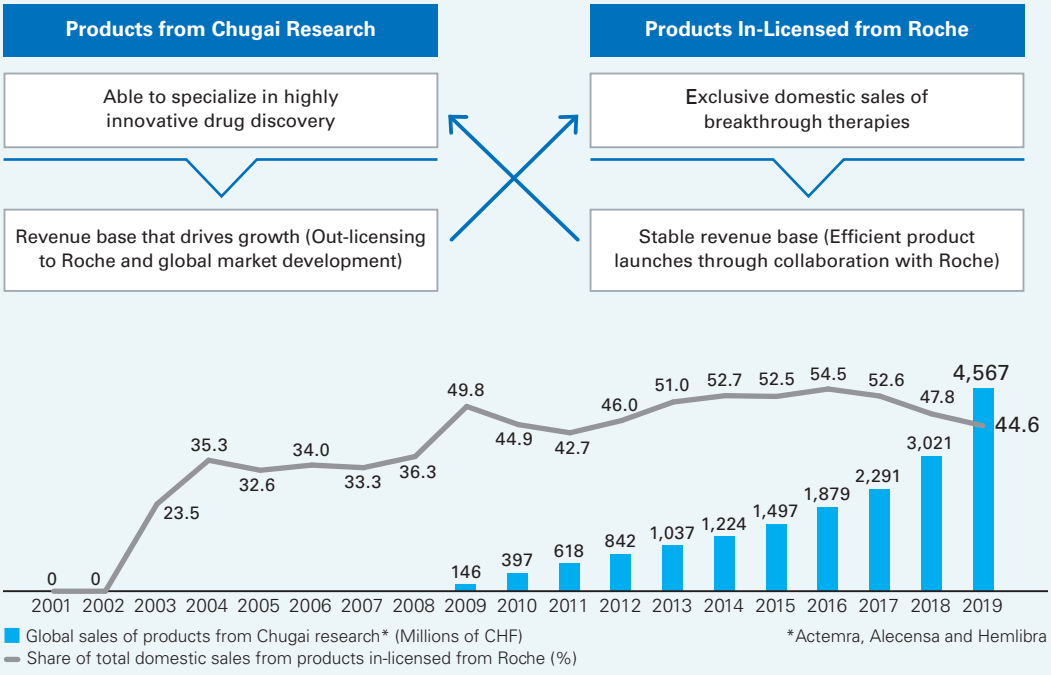
Chugai's business model, in which Chugai is a member of the Roche Group while maintaining autonomy and management independence, allows us to concentrate on innovation through an emphasis on originality and diversity, thereby contributing to the enhancement of Chugai's corporate value as well as the growth of the Roche Group. This unprecedented business model was viewed with considerable skepticism when the alliance began, but is now seen as the foundation for Chugai's growth.

The business model has continued to evolve over the years since the strategic alliance began in 2002, but further innovation will be essential in achieving advanced and sustainable patient-centric healthcare.

A summary of this business model, which is founded on a win-win relationship with Roche, shows how we are cooperating and what value is being generated in each function.

▶ See "Features and Outcomes by Business Model Function" on page 18.

Two Revenue Bases (Products from Chugai Research and In-Licensed from Roche)



Based on its unique business model, Chugai has established two revenue bases – products from Chugai research and products in-licensed from Roche. This model creates a sustainable cycle in which stable revenue from products in-licensed from Roche enables Chugai to make a concentrated investment in innovation, which accelerates continuous creation of innovative products, and the subsequent out-licensing of these products to Roche contributes in turn to Roche's growth over the long term and enables Roche to further invest in research and development. Completing the cycle, Chugai can then launch innovative new products in Japan that arise from Roche's powerful research infrastructure and wide-ranging partnerships.

To achieve steady and strong growth, it is important for both of these revenue bases to grow, and since 2012 the share of total domestic sales from products in-licensed from Roche has stayed relatively stable, as initially planned. On the other hand, global sales of products from Chugai research supplied through Roche's network have grown rapidly, with overseas approvals obtained for Actemra in 2009, Alecensa in 2015 and Hemlibra in 2017.

This revenue structure, in which products from Chugai research and products in-licensed from Roche are both growing while global expansion of products from Chugai research serves as a growth driver, is evidence that our business model through the strategic alliance with Roche is successful.

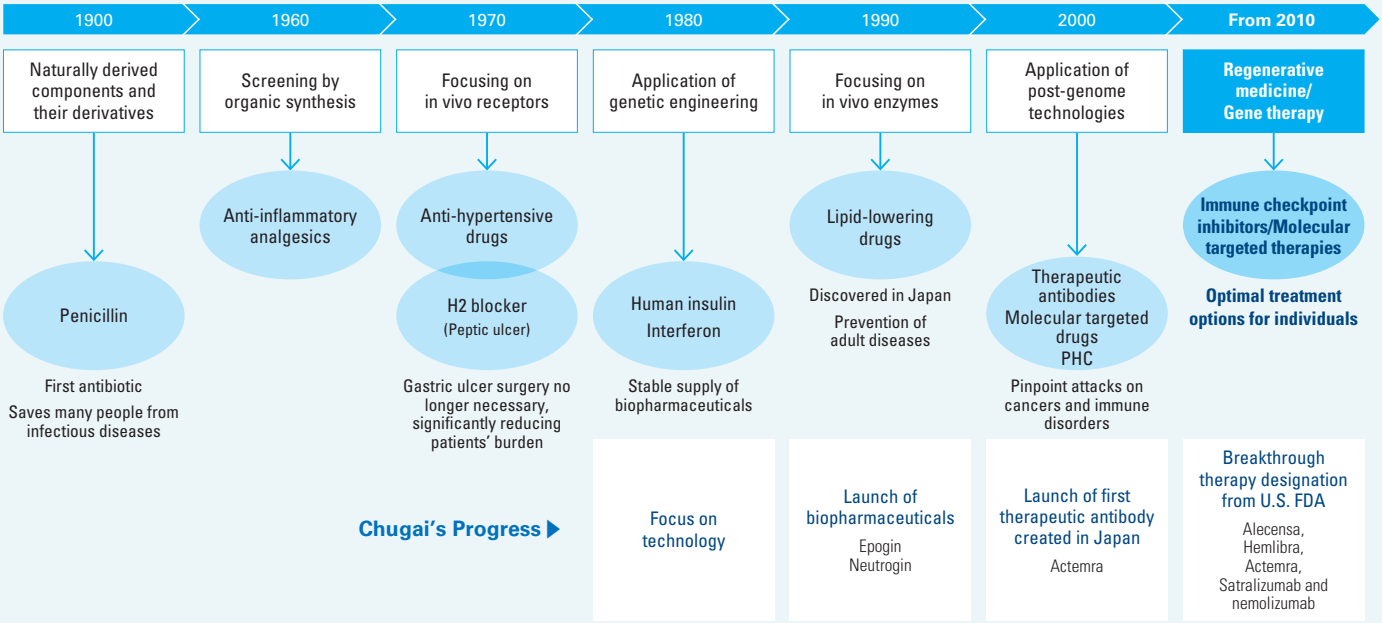
Chugai's Unique Strengths

- Continuous provision of innovative drugs
- Leader of next-generation PHC
- Provision of advanced patient-centric solutions
- Unique science and technology
- Strategic alliance with Roche

▶ See "Chugai by the Numbers (2019)" on page 2.

For Reference: The Pharmaceutical Industry and Chugai's Business

Evolution of Drug Therapy



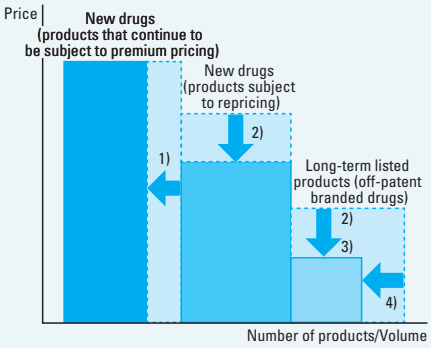
Since the discovery of penicillin in 1928, drug therapy around the world has advanced in line with scientific developments. Specifically, better understanding of in vivo disease mechanisms and the development of genetic engineering technologies and genomic analysis have led to the creation of a large number of innovative drugs. Since the 2000s, the expansion of molecular targeted therapies targeting the proteins and genes that cause diseases has enabled good treatment outcomes even for diseases that were previously considered difficult to treat or control, such as rheumatoid arthritis and breast cancer.

In recent years, further advances have been made in the treatment of cancer, which will affect almost one of every two people in developed countries at some point in their lives. Immune checkpoint inhibitors, a new cancer immunotherapy, are a prime example. These drugs target the signals produced by cancerous tissues that block the immune system's activity. By inhibiting these "brake" signals, immune checkpoint inhibitors allow the immune system to function normally so they can attack the cancer cells. Another promising new trend in cancer treatment is cancer genomic profiling. Cancer treatments have typically been classified according to the organ where the cancer occurs (lung, stomach, etc.) or the tissue type (adenocarcinoma, squamous cell carcinoma, etc.), but as genetic mutations have become better understood, treatment classification has extended beyond conventional classification. Selecting treatments according to the the genetic mutation pattern (tumor-agnostic treatment) has gained wider acceptance. This approach, combined with the development of next-generation sequencers and other technologies that make it possible to read large quantities of gene sequences rapidly, enables the genetic profiles of patients to be comprehensively analyzed, which is expected to lead to more advanced PHC.

Chugai has made an important contribution to these advances in healthcare. In the 2010s, we developed and launched Alecensa, an innovative targeted molecular therapy, and in 2018 we obtained approval in Japan for Tecentriq, an immune checkpoint inhibitor. In 2019, we obtained approval in Japan for Foundation One CDx Cancer Genomic Profile, a cancer genomic test that enables gene panel profiling, and launched Rozlytrek, a tumor-agnostic therapy approved for all solid tumors with a specific gene mutation. Chugai will continue its pursuit of innovation with a focus on realizing more advanced PHC.

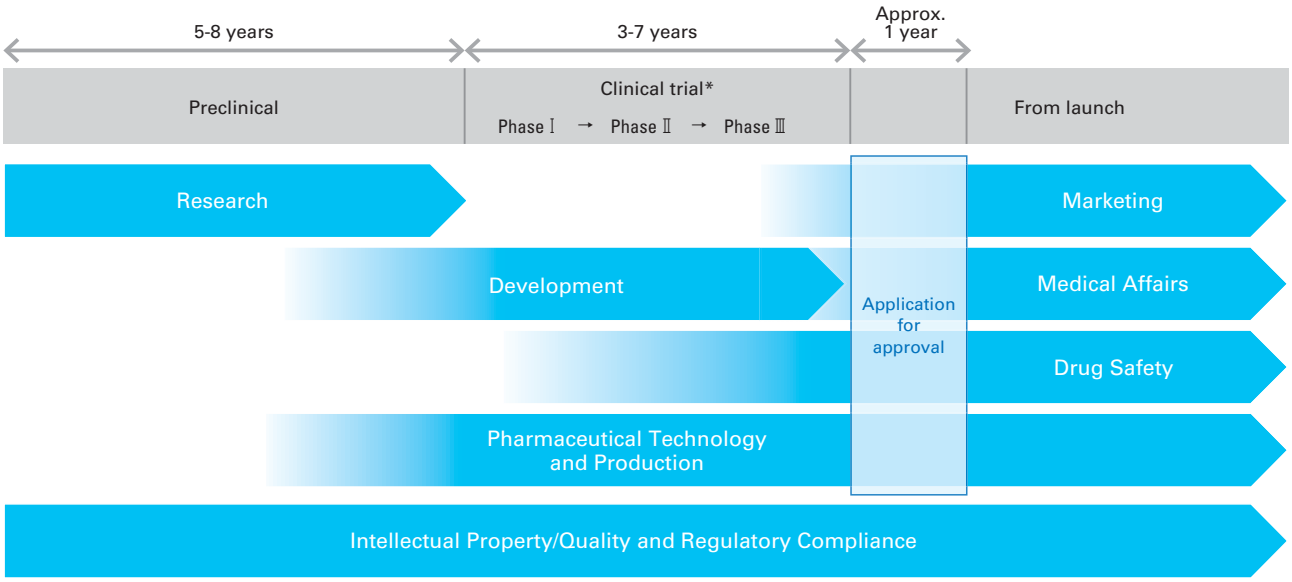
Although innovative drugs are being created, the drug pricing system is a serious risk for the future of the pharmaceutical industry, particularly in Japan. In Japan, fundamental reforms were made to the NHI drug pricing system in 2018 as a measure to curb rising healthcare costs. The number of innovative drugs subject to premium pricing to promote the development of new drugs was reduced, and evaluation of innovation became stricter. Moreover, the markets for other products have shrunk as a result of the introduction of quarterly drug repricing based on market expansion in addition to regular drug price revisions and policies to promote the use of generics. Manufacturers of both new drugs and long-term listed products have been hit hard by these reforms. There is concern that the reforms could discourage innovation in Japan and impede the advancement of medical care and patient access to treatments.

Impact of Fundamental Reforms of Drug Pricing System



System Reforms
1) Reducing the number of products subject to premium pricing
2) Yearly repricing
3) Measures to reduce prices of long-term listed products
4) Promotion of generics

Chugai's Business Process



To provide innovative drugs, Chugai conducts its business largely according to the flow in the diagram above. Research encompasses work from searching for target molecules to selection and optimization of drug candidates. Development consists of conducting clinical trials to prove the efficacy and safety of drug candidates based on the evidence obtained in research, as well as activities to obtain the necessary data for regulatory approval of drugs. Pharmaceutical Technology and Production involves the establishment of production processes for the drug candidates selected in research, as well as work to expedite commercialization and stable supply of high-quality products. Marketing entails the provision of solutions by sharing information with healthcare professionals and acting as a liaison between healthcare facilities. Medical Affairs involves generating and disseminating scientific evidence for products after they have been launched. Drug Safety encompasses the collection, evaluation, and timely and appropriate provision of safety data to help ensure the proper use of drugs. In addition, we have built a system for providing sophisticated solutions according to regional characteristics through the appropriate division of labor and collaboration among Marketing, Medical Affairs and Drug Safety operations. Activities related to all of these processes are the functions of Intellectual Property and Quality and Regulatory Compliance.

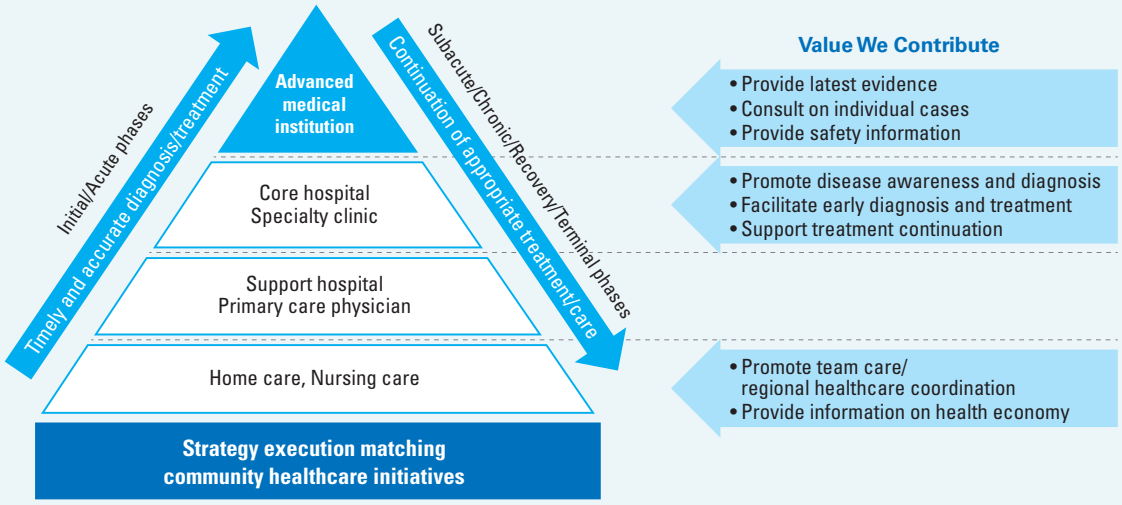
*A study to verify the safety, efficacy and other characteristics of a drug in human subjects. Studies conducted for the purpose of filing an application for approval are called clinical trials.

Phase Ⅰ: Performed on a small number of healthy volunteers (or, for certain disease areas and diseases, on patients) to assess the drug's safety and the process by which it is absorbed, distributed, metabolized and eliminated by the body.

Phase Ⅱ: Performed on a small number of consenting patients to determine the safest and most effective dosage and the dosing regimen.

Phase Ⅲ: Performed on a large number of consenting patients to verify the efficacy and safety of the new drug in comparison with existing drugs or a placebo.

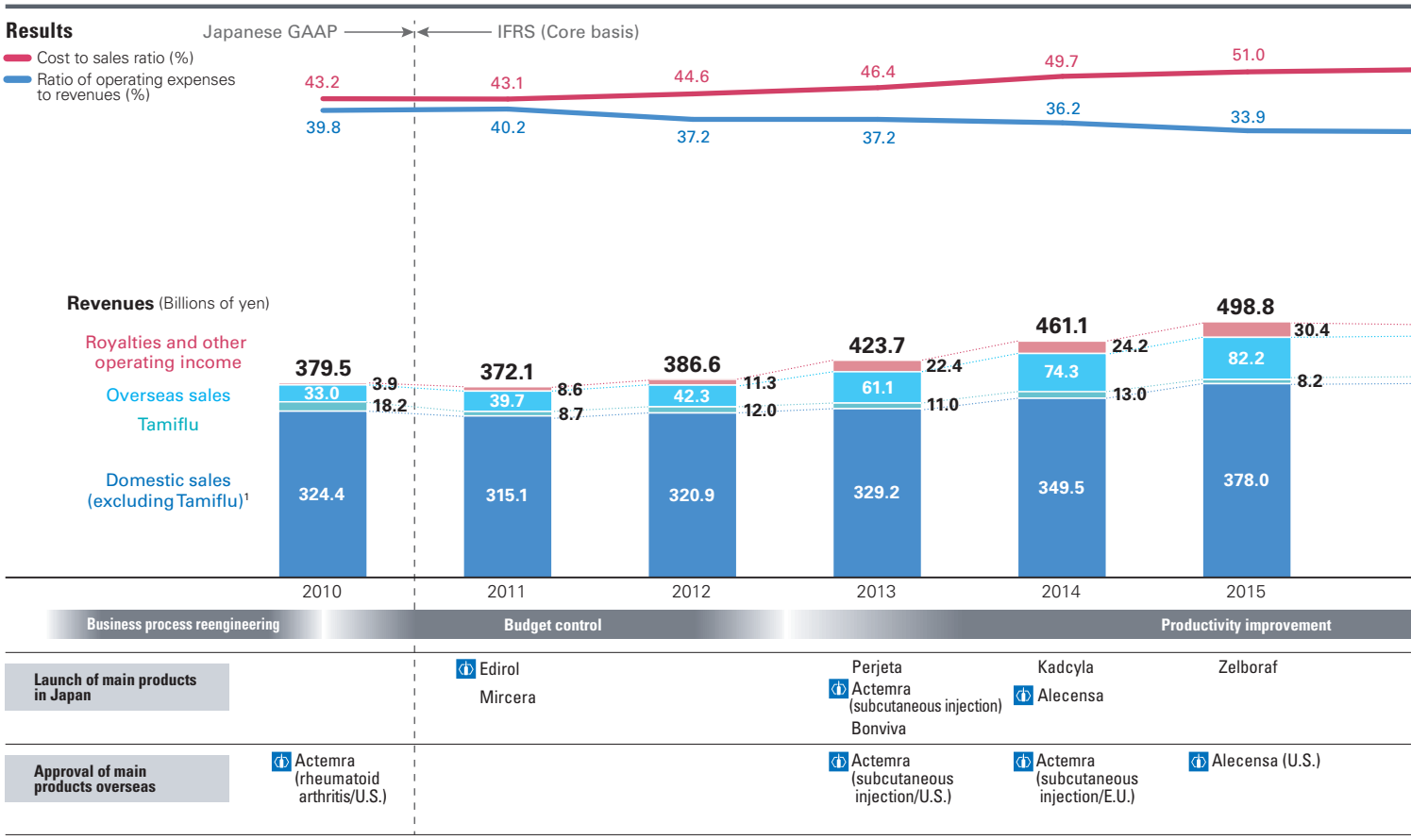
Chugai's System for Providing Solutions in Japan



Financial and Pre-Financial Highlights (IFRS)

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/Years ended December 31

Financial Indicators (Core Basis)

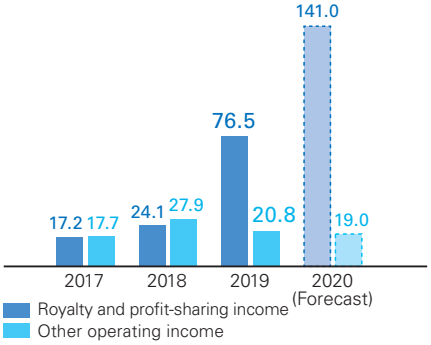


Chugai product

1. From 2017, domestic sales include Tamiflu.

Royalty and Profit-Sharing Income/ Other Operating Income

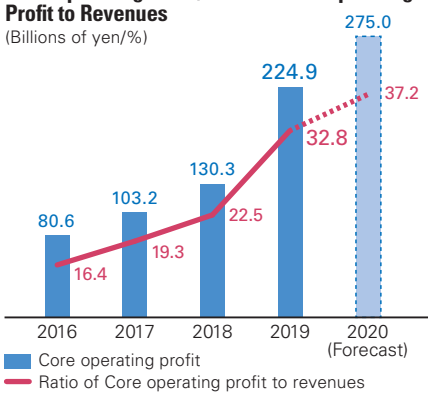
(Billions of yen)



Royalty and profit-sharing income, which is linked to sales of Chugai (in-house) products by Roche outside Japan, increased significantly in 2019 due to the solid global penetration of Hemlibra. Other operating income, which consists of non-recurring income, temporarily increased in 2018 due to one-time income recognized from the transfer of long-term listed products.

Core Operating Profit/Ratio of Core Operating Profit to Revenues

(Billions of yen/%)

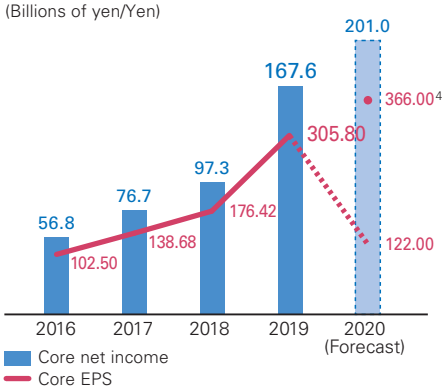


The ratio of Core operating profit to revenues is consistently high because of the low ratio of operating expenses to revenues. This ratio should rise further because of increasing ROOI[2] and the declining cost to sales ratio in recent years. In 2020, we expect our fourth consecutive year of record Core operating profit due to factors including an increase in royalty income from Roche relating to Chugai product Hemlibra.

2. Royalties and other operating income

Core Net Income/Core EPS

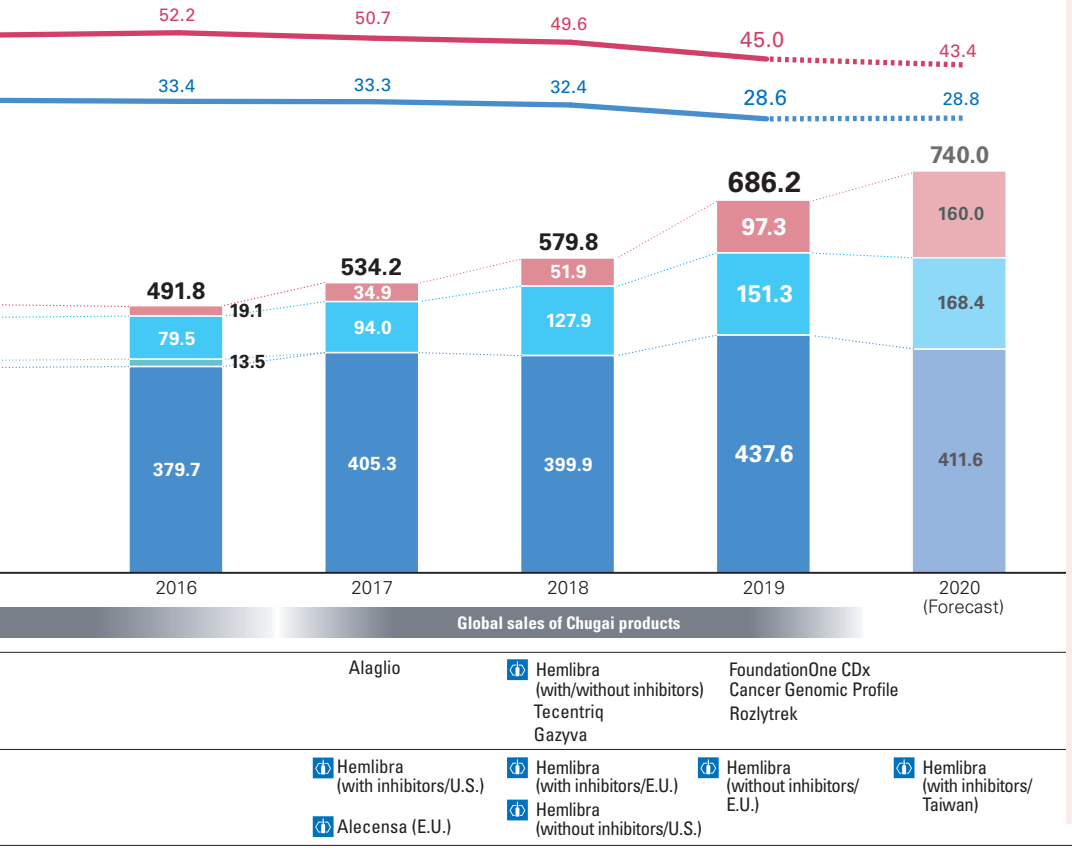
(Billions of yen/Yen)



In mid-term business plan IBI 21, Chugai set Core EPS CAGR over three years as a quantitative target. In light of strong sales of global products developed in-house, Chugai revised its target Core EPS CAGR from the high single digits[3] to around 30 percent[3] (assuming no stock split).

3. Based on constant exchange rates for the three-year period
4. Based on the assumption of no three-for-one split of ordinary shares, with a scheduled effective data of July 1, 2020.

About Core Basis Results
Chugai reports its results on a Core basis from 2013 in conjunction with its decision to adopt IFRS. Core basis results are the IFRS basis results adjusted by excluding non-Core items, and are consistent with the concept of Core basis results disclosed by Roche. Core basis results are used by Chugai as internal performance indicators for representing recurring profit trends both internally and externally, and as indices for establishing profit distributions such as returns to shareholders. No items have been excluded from the IFRS balance sheet and cash flows, as the Core basis results concept only applies to the income statement.

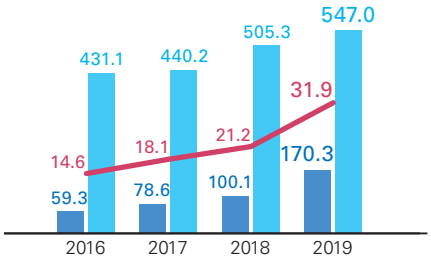


Chugai has substantially improved its cost structure in view of the increase in the cost to sales ratio due to the increase in products in-licensed from Roche following the signing of the strategic alliance between the two companies. We have now secured high profitability by continuously achieving a ratio of operating expenses to revenues at a level that compares favorably with the world's leading pharmaceutical companies. Our cost to sales ratio has been improving steadily in recent years due to the solid performance of Chugai global products, which have a lower cost to sales ratio than those in-licensed from Roche.

We have generated record revenues for three consecutive years due to factors including solid sales of mainstay products and of new products Hemlibra and Tecentriq in Japan, exports of Chugai products Actemra and Alecensa to Roche, and an increase in royalty and profit-sharing income from Hemlibra. In 2020, we forecast that sales and earnings will increase because exports of Hemlibra to Roche and increased royalties from Roche will more than offset a year-on-year decrease in domestic sales due to NHI drug price revisions and intensified competition resulting from the launch of biosimilars and generics.

Core Operating Profit (after Taxes)/ Net Operating Assets/Core Return On Invested Capital

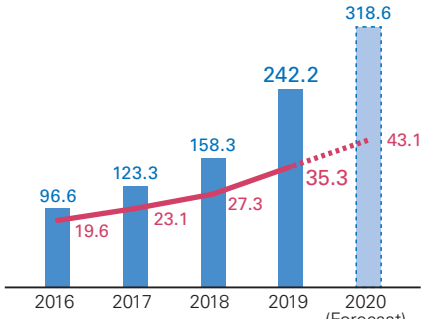
(Billions of yen/%)



Chugai has been using Core ROIC[5] as a financial KPI since 2019 in order to give greater consideration to long-term investment efficiency. NOA (2) increased significantly due to aggressive strategic investments such as Chugai Life Science Park Yokohama, but faster growth in Core operating profit after taxes (1) has resulted in consistent increases in Core ROIC (1÷2).

Overseas Revenues/Overseas Revenues Ratio

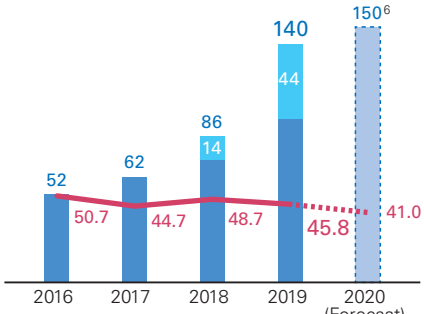
(Billions of yen/%)



Overseas revenues increased steadily with the growth in global sales of Chugai products. While we expect Actemra to become a mature product, we forecast that the overseas revenues ratio will continue to increase because of products including Hemlibra, for which global sales exceeded CHF 1 billion in its third year of sales; Alecensa, which continues to penetrate the European market; and satralizumab, which we expect to launch in 2020.

Dividends per Share/Core Payout Ratio

(Yen/%)



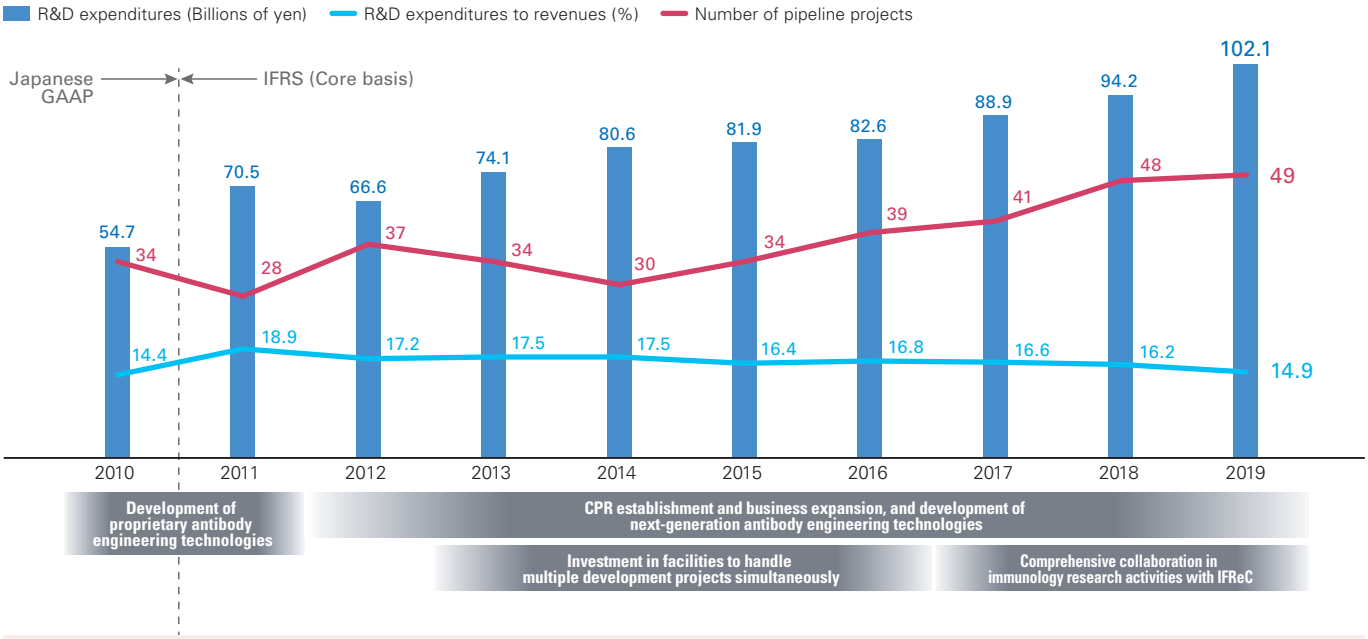
Regarding shareholder returns, Chugai's target Core EPS payout ratio was 50 percent on average. After taking into account future investment opportunities and funding plans, from 2020 we have changed to a target Core EPS payout ratio of 45 percent on average to maintain our policy of a stable allocation of profit.

5. Return on invested capital: Indicates how efficiently a company uses capital invested for business activities (invested capital) to generate profit.

6. Based on the assumption of no stock split

Research, Clinical Development, Pharmaceutical Technology and Production

R&D Expenditures/R&D Expenditures to Revenues/Pipeline Projects

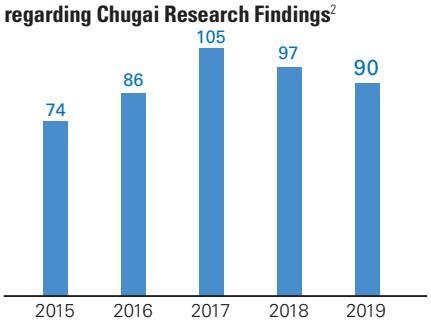


As revenues grow, Chugai increases investment in research and development. In addition to the steady creation of innovative drugs, our research findings have the potential to contribute to the advancement of healthcare and the pharmaceutical industry worldwide. Our policy is to proactively conduct speedy research and development in light of the competitive environment, as well as to make upfront investments in digital technologies such as AI to establish and strengthen our competitiveness, while keeping growth in overall operating expenses within the rate of revenue growth, as a general principle.

Under our strategic alliance with Roche, we have been promoting new drug development with higher success rates and greater efficiency by collaborating in ways such as examining and deciding on which Roche products to in-license based on the results of early-stage clinical trials. In recent years, we have maintained a robust pipeline, with several products from Chugai research having moved into the clinical phase, including in-house products from Chugai Pharmabody Research (CPR),[1] which has expanded its operations to accelerate the creation of innovative therapeutic antibodies.

1. Established in Singapore in 2012

Publications in Academic Papers and Presentations at Scientific Conferences regarding Chugai Research Findings[2]

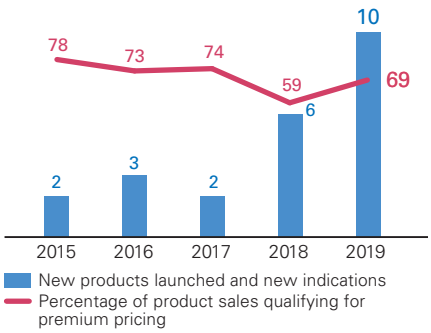


Chugai develops innovative medicines that allow it to differentiate itself from competitors by continuously establishing proprietary drug discovery technologies and applying them to development candidates while promoting research on commercialization for high quality and high added value. We will continue to generate research findings that may contribute to the overall advancement of healthcare, presenting those findings at scientific conferences and publishing them in academic papers.

2. Total of drug discovery and pharmaceutical technology

New Products Launched and New Indications/ Percentage of Product Sales Qualifying for Premium Pricing

(Number/%)

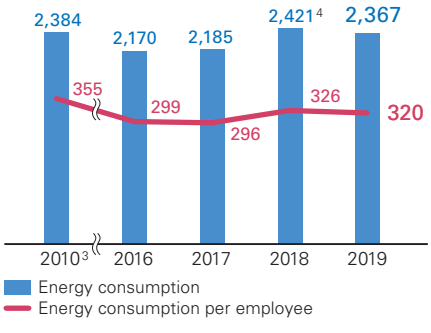


In 2019, the number of new product launches and indications expanded year on year due to the launch of FoundationOne CDx Cancer Genomic Profile (F1CDx) and Rozlytrek, additional indications for mainstay oncology product Tecentriq and for Actemra, and the expanded use of F1CDx as a companion diagnostic. With our stable revenue base from the efficient in-licensing of Roche products for the Japanese market, we will continue to concentrate on the creation of innovative medicines.

Note: Products subject to special market-expansion repricing (2016, 2017: Avastin) are counted as products qualifying for premium pricing because they were assumed to meet the conditions for such pricing in the relevant fiscal years.

Energy Consumption/ Energy Consumption per Employee

(Thousands of GJ/GJ per employee)

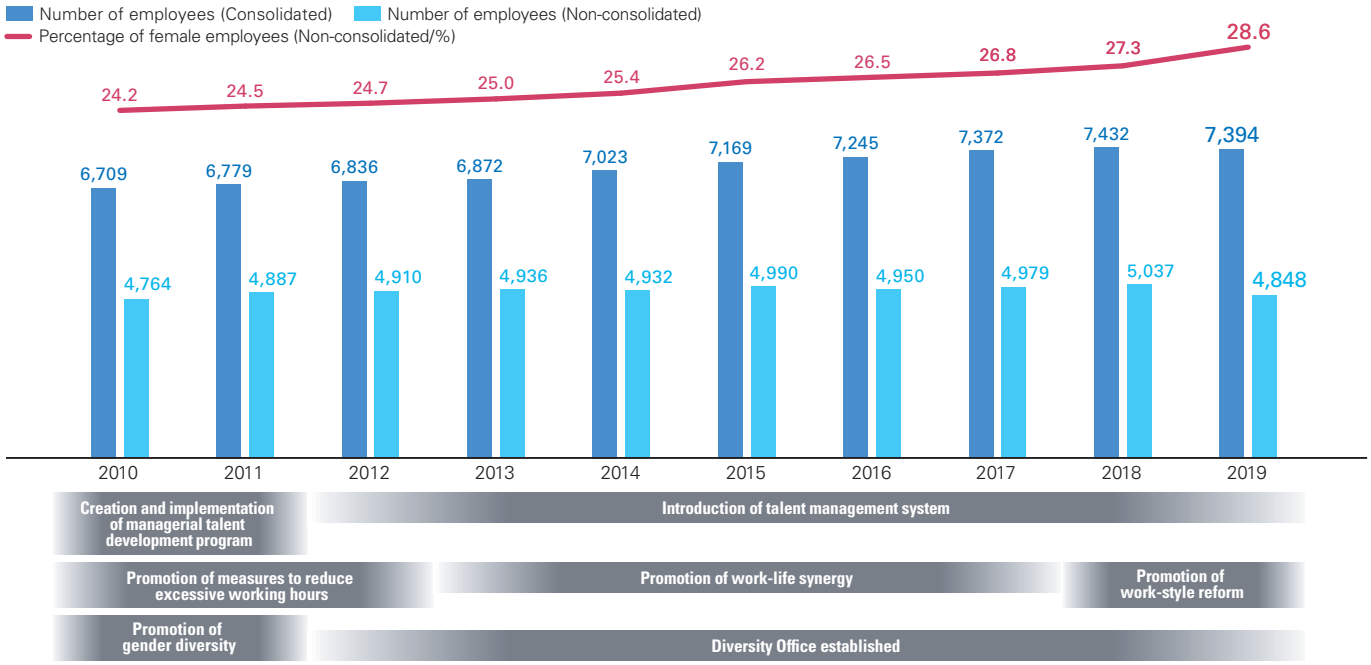


Energy consumption decreased 2.3 percent year on year in 2019 due to factors including progress in an energy use visualization system and energy conservation project. As Chugai enhances its production system for new drugs, it is also working to reduce energy consumption as one of its tasks, based on its Code of Conduct, which includes "Protection of the Global Environment."

3. Benchmark year for mid-term environmental goals
4. Includes 40,000 GJ of overseas consumption

Human Resource Management

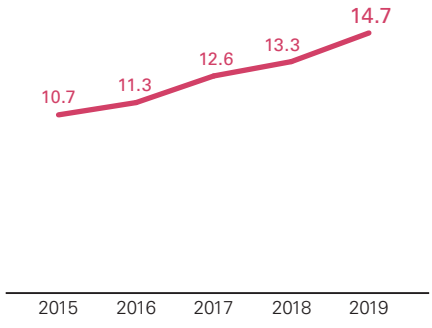
Employees/Ratio of Female Employees



The basic philosophical tenet of Chugai's human resource strategies is that people are an invaluable asset that drives a company's growth and progress. Therefore, our policy is to promote the hiring, development and use of diverse human resources regardless of gender or nationality. We place value on the pursuit of innovation and creativity for delivering innovative drugs to patients around the world, and are therefore committed to diversity and inclusion as one of our human resource strategies because we recognize that innovation arises from diverse values and expertise. We will maintain an environment that enables diverse employees to fully exercise their capabilities, and foster an organizational culture that generates innovation.

Ratio of Female Managers[5]

(Non-consolidated/%)



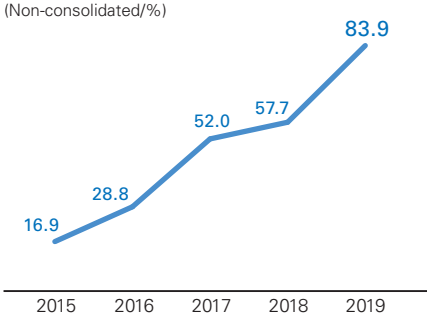
To promote the success of women in the workplace, we set a target ratio of female managers of 16 percent or higher by the end of 2021 (non-consolidated employee basis[6]). The ratio of female managers is increasing, but we are aiming for further success by implementing measures to support career development among women, and we plan to further accelerate our initiatives to develop female leaders.

Note: Ratio of Female Managers (Non-consolidated employee basis)
2018: 12.6% 2019: 13.7%

5. Number of female managers as a percentage of the total number of managers
6. Calculated based on Chugai Pharmaceutical (non-consolidated) employees, including employees assigned to affiliated companies and external companies. On the other hand, non-consolidated basis is calculated based on the definition in the Company's *Yuka Shoken Hokokusho* (Securities Report).

Percentage of Male Employees Taking Childcare Leave[7]

(Non-consolidated/%)

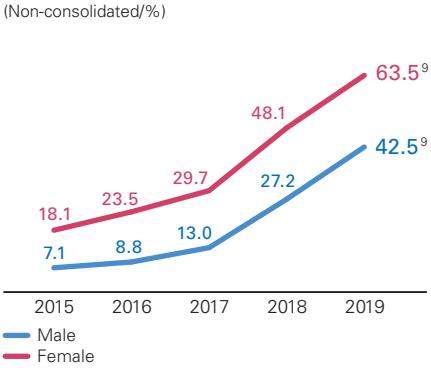


Chugai aims to improve productivity and increase flexibility in work styles to achieve work-life synergy. The number of male employees taking childcare leave is increasing. We are encouraging male employees to take childcare leave through awareness-raising activities targeting men with newborn children and their supervisors and by providing their supervisors with a handbook containing guidance on key management points.

7. Number of male employees taking childcare leave as a percentage of all male employees with newborn children

Percentage of Employees Using the Telecommuting System[8]

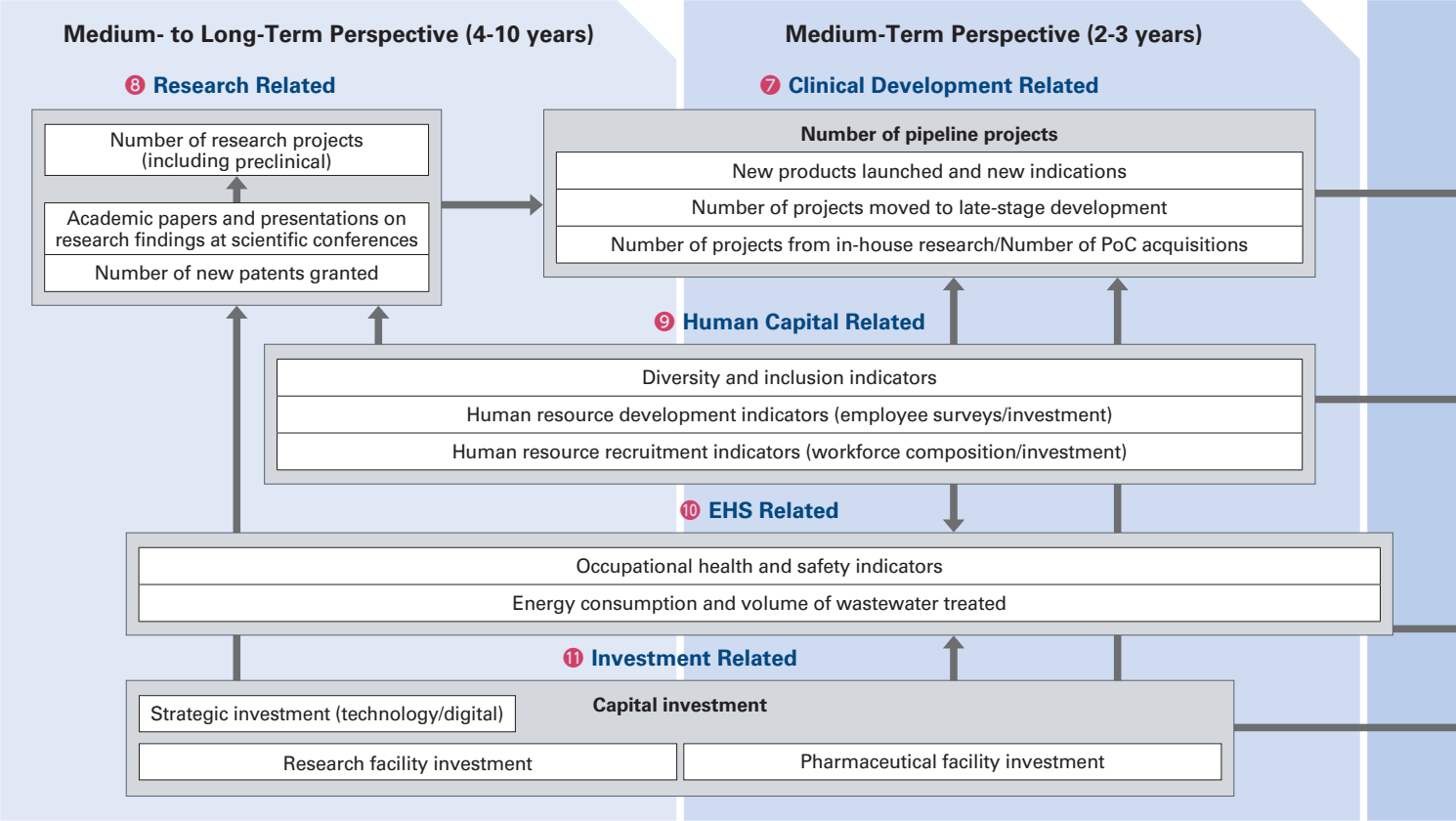
(Non-consolidated/%)



Originally introduced in 2012 for childcare and nursing care, the telecommuting system has expanded to include use for productivity improvement. In 2019, we enhanced flexibility by enabling users to record 15-minute increments, and expanded eligibility to employees who work remotely, such as MRs. We will continue to empower even more flexible work styles.

8. Percentage of eligible employees
9. Excluding MRs and other employees who work outside Chugai offices

Relationships of Indicators



Financial Performance

Given the characteristics of its business model, Chugai considers the Core EPS growth rate and, from the perspective of the cost of capital/stock, Core return on invested capital (ROIC) to be two particularly important KPIs. We believe that raising the level of these KPIs will enhance our corporate value over the medium to long term.

❶ IBI 21 Guidance

The ratio of Core operating profit to revenues (profit margin) in Chugai's main business and the growth of that margin in absolute terms are the most important indicators for enhancing corporate value. Accordingly, we use Core EPS CAGR – a KPI that presents these indicators from the viewpoint of shareholders – as guidance in IBI 21. This KPI is related to ❸ Growth Indicators and ❹ Profitability Indicators.

❷ Internal Management Indicators

In managing the performance of each division, Chugai uses Core ROIC because both stock and flow perspectives are important. Core ROIC consists of ❹ Profitability Indicators and ❺ Efficiency Indicators.

❸ Growth Indicators

Growth indicators are one measure of the value that Chugai's products and services provide globally. In addition to total revenues, we also emphasize new products, as well as overseas sales and royalty income from Chugai products as indicators of future growth, among others.

❹ Profitability Indicators

Operating profit and the ratio of Core operating profit to revenues play the largest role in enhancing Chugai's Core EPS. The cost to sales ratio, which changes with the share of Chugai products in the sales mix, affects profit, as do R&D expenditures, which fluctuate according to the progress of research projects and technology development. The ratio of operating expenses to revenues is an indicator for measuring continuous improvement through measures including cost structure review and productivity enhancement.

❺ Efficiency Indicators

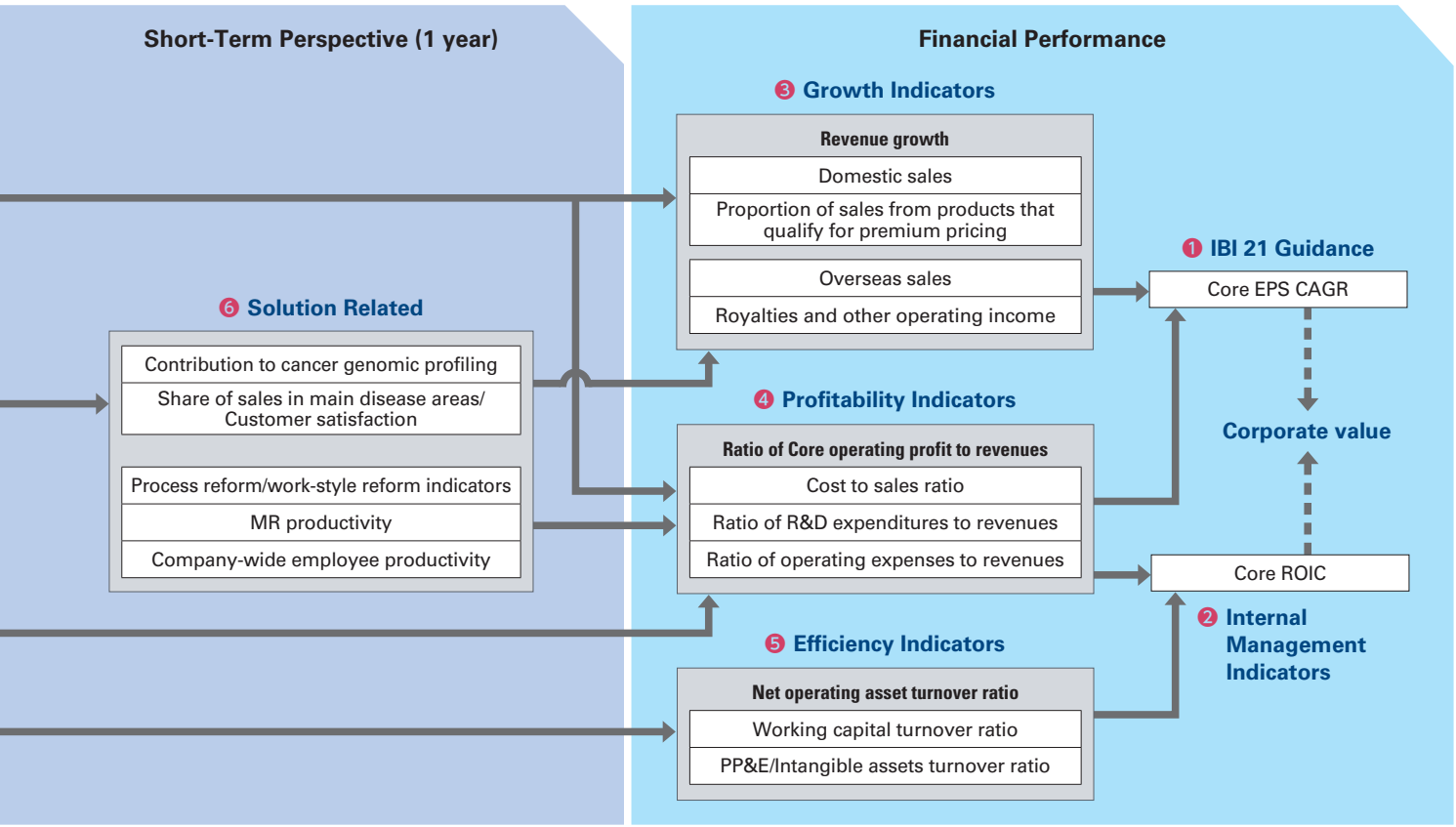
Biopharmaceuticals, an area of strength for Chugai, have a relatively lengthy manufacturing process. Consequently, there are certain limitations on increasing turnover to fulfill our pharmaceutical supply obligations. However, we are placing priority on managing working capital and property, plant and equipment (PP&E) turnover as essential indicators in improving capital efficiency.

Activity Indicators (Short-, Medium- and Medium-to-Long-Term Perspectives)

Indicators that affect corporate value and financial performance are roughly divided by category and temporal perspective. The activity indicators mainly expected to yield results over the short term (1 year), medium term (2-3 years), or medium to long term (4-10 years) are outlined in ❻ through ⓫, below.

❻ Solution Related

We use these indicators to monitor the successful execution of our strategies from



a short-term (1 year) perspective. Share of sales in main disease areas and productivity are important indicators related to ❸ Growth Indicators, ❹ Profitability Indicators and ❺ Efficiency Indicators.

❼ Clinical Development Related

With the increasing difficulty of drug discovery, the richness of the development pipeline will have a significant impact on Chugai's sales and profit in the short, medium and medium to long term, and will determine the extent of corporate value it creates. In managing our pipeline, we focus not just on the number of projects, but on their quality and progress.

❽ Research Related

In the case of manufacturers of innovative drugs, the results of a research project usually take four to ten years to be reflected in business performance, and in the case of technological infrastructure and pathological research even longer management timelines may be involved. The principal quantitative indicators that Chugai manages include the number of research projects, but it also uses indicators such as the number of academic papers and presentations at scientific conferences, and the number of new patents granted to measure research results.

❾ Human Capital Related

Chugai strongly believes that the levels of each indicator mentioned above change according to factors such as recruitment, allocation and development of human resources, and the organizational culture. Therefore, we focus on managing factors such as the amount of human capital investment and various indicators based on an all-employee survey and human resource database. We also set detailed targets for indicators related to diversity and inclusion to create a culture conducive to innovation, and take measures to improve the level of those indicators.

❿ EHS Related

Chugai takes a comprehensive approach to managing environmental and occupational health and safety (EHS) issues. The risks involved in these areas are considerable, and will have an impact on the results of medium- to long-term research and development, pharmaceutical technology, marketing and other operations, but the impact on production-related activities will be especially large. To continue reinforcing our robust value chain from the standpoint of ESG, we closely monitor indicators concerning climate change, energy, water, health and productivity management, occupational injuries and other matters.

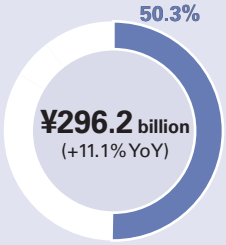
⓫ Investment Related

Investment in pharmaceutical technology and production aligned with strategies, including production facilities capable of handling new drug discovery technologies and facilities for manufacturing investigational drugs in tandem with clinical development, affects clinical development and business results in the medium term. The pharmaceutical value chain, including research, is affected by investment to expand our research infrastructure and enhance efficiency. It is also affected by investments in new technology and digital technology. However, the results of these investments typically do not become apparent for four years or more, a medium- to long-term span.

Review by Disease Area

Oncology

Sales and Percentage of Total Sales



Opportunities and Risks

Opportunities

- Cancer is the largest area of unmet medical need[1] (the leading cause of death in Japan).
- PHC is expected to advance further due to factors including insurance coverage for cancer genomic profiling.
- Phase Three of the Basic Plan to Promote Cancer Control Programs is promoting delivery systems for cancer genomic profiling.

Risks

- Intensifying global competition for cancer immunotherapies including anti-PD-1/PD-L1 immune checkpoint inhibitors
- Return of premium for new drug creation for mainstay products
- Entry of large pharmaceutical companies into biosimilar[2] markets

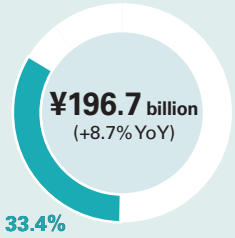
Review of 2019 Performance

Sales in Japan increased 6.6 percent year on year to ¥240.5 billion due to factors including steady market penetration of the new product Tecentriq and mainstay product Perjeta, despite a decrease in sales of products including Rituxan, mainly due to the significant impact of biosimilars.

Overall sales, including overseas sales, increased 11.1 percent to ¥296.2 billion supported by factors including substantial growth in Alecensa exports to Roche, which increased 54.3 percent to ¥44.6 billion. Alecensa, a product from Chugai research, continued to penetrate first-line markets, primarily in Europe and the United States.

Bone and Joint Diseases/ Autoimmune Diseases

Sales and Percentage of Total Sales[3]



Opportunities

- The emergence of biologics has dramatically improved the effectiveness of rheumatoid arthritis (RA) treatment, and the treatment goal is shifting to remission (a symptom-free state).
- The number of osteoporosis patients is increasing yearly as populations age.
- There are many potential osteoporosis patients because the treatment rate and adherence to treatment remain low.

Risks

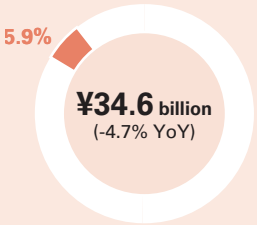
- Intensifying global competition in the RA market
- Slower growth due to the maturing of Actemra in the medium to long term
- The emergence of biosimilars that compete with biologics

Sales in Japan increased 7.9 percent year on year to ¥108.4 billion, driven by the solid performance of mainstay products Actemra, a product from Chugai research for treatment of RA and other diseases, and Edirol, another product from Chugai research and the top brand in oral osteoporosis drugs.

Overall sales, including overseas sales, increased 8.7 percent to ¥196.7 billion. Overseas sales from exports of Actemra, which is approved in more than 110 countries and is distributed through Roche, increased a steady 9.9 percent to ¥86.5 billion.

Renal Diseases

Sales and Percentage of Total Sales



Opportunities

- Due to the enhanced measures to address chronic kidney disease (CKD) by the Ministry of Health, Labour and Welfare, screening rates are increasing among potential patients and people who have not been screened.
- Early intervention in potential patients is improving the treatment rate of renal anemia.
- Renal anemia is divided into the dialysis stage and the pre-dialysis stage, and the number of patients treated in the pre-dialysis stage is trending upward every year.

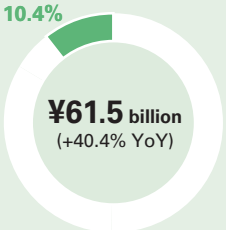
Risks

- Intensifying competition in the renal anemia market due to a reduction in fee points for dialysis as part of medical fee revisions
- Intensifying competitive environment due to a competing biosame and other generics

Sales in Japan decreased 4.7 percent year on year to ¥34.6 billion. Sales of Oxarol, an agent for secondary hyperparathyroidism, and Mircera, a long-acting erythropoiesis stimulating agent, decreased in part because of NHI price revisions and the impact of a competing biosame[4] in the renal anemia market.

Other Diseases

Sales and Percentage of Total Sales



Opportunities

- The burden on people with hemophilia A and caregivers due to the development of inhibitors and frequent need for administration is an issue.
- Neurology is an area of very high unmet medical need, with many pathologies and syndromes.
- Medical fee points have been increased to promote more kidney transplants, and treatment needs for kidney transplants in Japan are rising.
- Need to improve patients' quality of life because in addition to skin deterioration, itching associated with atopic dermatitis disrupts sleep.

Risks

- Intensifying global competition due to the limited number of known molecular targets
- Possibility of few target patients despite high unmet medical need

In Japan, sales of Hemlibra, a Chugai product for treating hemophilia A, increased 740.0 percent year on year to ¥25.2 billion. Market penetration of Hemlibra for patients without inhibitors significantly exceeded our initial forecast. Ordinary sales of anti-influenza agent Tamiflu decreased 26.7 percent year on year to ¥7.4 billion, and sales for government stockpiles increased 540.0 percent to ¥3.2 billion.

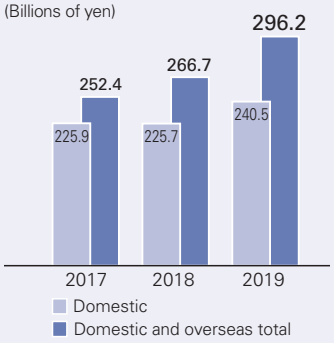
Overall sales in the other diseases category, including overseas sales, increased 40.4 percent year on year to ¥61.5 billion. Included in that total were exports of Hemlibra to Roche, which increased 43.5 percent year on year to ¥3.3 billion.

1. Medical need that is not adequately met due to a lack of effective treatments
2. Successor products to biopharmaceuticals whose patent term has expired. They have the same quality, effectiveness and safety as the original product, but are made by manufacturers other than the manufacturer that developed the antecedent biopharmaceutical.
3. Bone and joint diseases only

Sales

Domestic market share in oncology: No. 1[5]

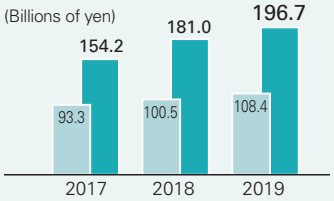
(Billions of yen)



Domestic market share in osteoporosis: No. 1[5]

Domestic market share in RA: No. 2[5]

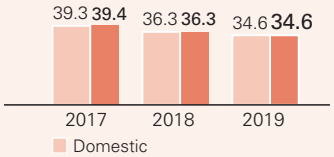
(Billions of yen)



Note: Graph shows sales for bone and joint diseases only.

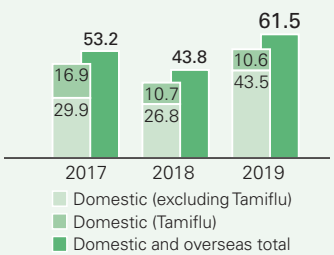
Domestic market share in renal diseases: No. 2[5]

(Billions of yen)



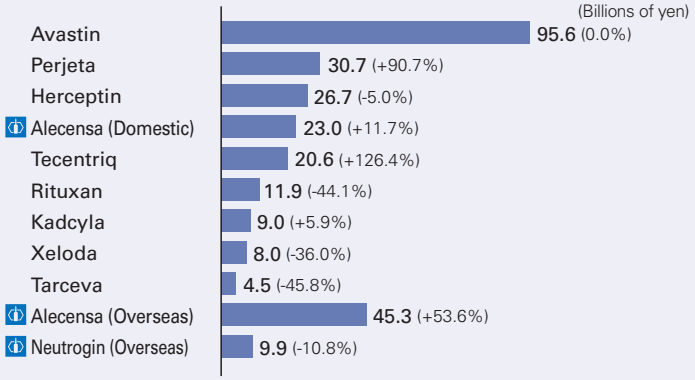
Other Diseases

(Billions of yen)



Sales of Major Products

(Billions of yen)



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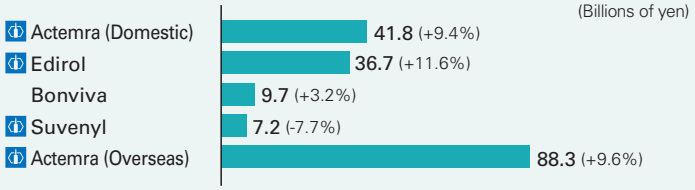

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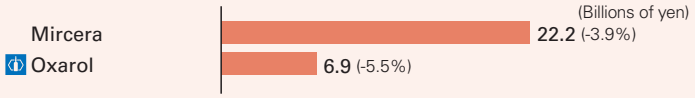

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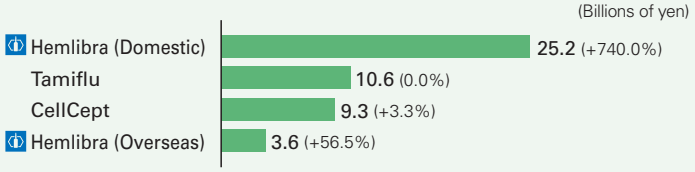


Development Pipeline

(Including additional indications)

- Φ AF802 (Alecensa)
- RG435 (Avastin)
- RG3502 (Kadcyla)
- RG7446 (Tecentriq)
- RG7440
- RG7596
- Φ GC33
- Φ ERY974
- RG7421
- RG6264
- RG7802
- RG7828
- RG7461
- RG6058
- Φ ED-71 (Edirol)
- Φ NRD101 (Suvenyl)
- RG7845
- RG7880
- Φ EOS789
- RG1450
- RG7916
- Φ SKY59
- Φ PCO371
- RG7716
- Φ GYM329
- RG7935
- Φ SA237
- Φ AMY109
- RG7906
- RG6042
- Φ NXT007
- RG6100
- RG7314

4. A successor biopharmaceutcal that is the same as its antecedent in terms of active pharmaceutical ingredients manufacturing method, etc. Only the packaging is different.
5. Copyright © 2020 IQVIA. Source: JPM 2019. Reprinted with permission. The scope of the market is defined by Chugai. The analysis is conducted by Chugai.

Φ Products from Chugai research

Development Pipeline (As of January 30, 2020)

Development Code (*Additional Indication)	Indication	Status: Phase Ⅰ / Phase Ⅱ / Phase Ⅲ / Filed / Approved	Approved/Filing Date [Planned Year of Filing]
Oncology			
RG6268	Solid tumors [*NTRK* fusion gene-positive]	Approved	2019/6
	Non-small cell lung cancer (NSCLC)	Filed	2019/3
RG7446*	Small cell lung cancer	Approved	2019/8
	Breast cancer	Approved	2019/9
	NSCLC (adjuvant)	Phase Ⅲ	[2022 or later]
	NSCLC (neoadjuvant)	Phase Ⅲ	[2021]
	Urothelial carcinoma	Phase Ⅲ	[2020]
	Muscle invasive urothelial carcinoma (adjuvant)	Phase Ⅲ	[2020]
	Renal cell carcinoma	Phase Ⅲ	[2020]
	Renal cell carcinoma (adjuvant)	Phase Ⅲ	[2022 or later]
	Early breast cancer	Phase Ⅲ	[2021]
	Ovarian cancer	Phase Ⅲ	[2020]
	Hepatocellular carcinoma	Phase Ⅲ	[2020]
	Hepatocellular carcinoma (adjuvant)	Phase Ⅲ	[2022 or later]
	Head and neck carcinoma (maintenance)	Phase Ⅲ	[2022 or later]
RG3502*	Breast cancer (adjuvant)	Filed	2019/8
RG435*	Renal cell carcinoma (combination with RG7466)	Phase Ⅲ	[2020]
	Hepatocellular carcinoma (combination with RG7466)	Phase Ⅲ	[2020]
	Hepatocellular carcinoma (adjuvant/combination with RG7466))	Phase Ⅲ	[2022 or later]
	Small cell lung cancer (combination with RG7466)	Phase Ⅲ	[2022 or later]
RG7440	Prostate cancer	Phase Ⅲ	[2021]
	Breast cancer	Phase Ⅲ	[2020]
RG7596	Diffuse large B-cell lymphoma (DLBCL)	Phase Ⅲ	[2020]
RG6264	Breast cancer (fixed-dose combination, subcutaneous injection)	Phase Ⅲ	[2021]
AF802 (RG7853)*	NSCLC (adjuvant)	Phase Ⅲ	[2022 or later]
GC33	Hepatocellular carcinoma	Phase Ⅰ	
ERY974	Solid tumors	Phase Ⅰ	
RG7421	Solid tumors	Phase Ⅰ	
RG7802	Solid tumors	Phase Ⅰ	
RG7828	Hematologic tumors	Phase Ⅰ	
RG7461	Solid tumors	Phase Ⅰ	
RG6058	Solid tumors	Phase Ⅰ	
Bone and Joint Diseases			
ED-71	Osteoporosis	(China)	2018/2
NRD101	Knee osteoarthritis/Shoulder periarthritis	(China)	[2020]
Renal Diseases			
EOS789	Hyperphosphatemia	Phase Ⅰ	
Autoimmune Diseases			
RG7845	Rheumatoid arthritis	Phase Ⅰ	
RG7880	Inflammatory bowel disease	Phase Ⅰ	
Neurology			
SA237 (RG6168)	Neuromyelitis optica spectrum disorder (NMOSD)	Filed	(U.S.) Aug. 2019, (E.U.) Aug. 2019, (Japan) Nov. 2019
RG1450	Alzheimer's disease	Phase Ⅲ	[2022 or later]
RG6042	Huntington's disease	Phase Ⅲ	[2022 or later]
RG7916	Spinal muscular atrophy (SMA)	(Ⅱ/Ⅲ)	[2020]
RG7935	Parkinson's disease	Phase Ⅰ	
GYM329 (RG6237)	Neuromuscular disease	Phase Ⅰ	
RG7906	Psychiatric disorders	Phase Ⅰ	
RG6100	Alzheimer's disease	Phase Ⅰ	
RG7314	Autism spectrum disorder	Phase Ⅰ	
Other Diseases			
ACE910 (RG6013)	Hemophilia A (Non-inhibitor)	Approved	(E.U.) Mar. 2019 / (Taiwan) Oct. 2019
RG7716	Diabetic macular edema	Phase Ⅲ	[2021]
	Neovascular age related macular degeneration (nAMD)	Phase Ⅲ	[2022 or later]
SKY59 (RG6107)	Paroxysmal nocturnal hemoglobinuria (PNH)	(Ⅰ/Ⅱ)	
NXT007	Hemophilia A	(Ⅰ/Ⅱ)	
PCO371	Hypoparathyroidism	Phase Ⅰ	
AMY109	Endometriosis	Phase Ⅰ	

Designates change in status in 2019 and thereafter

Note: In principle, completion of first dose is regarded as the start of clinical studies in each phase.

	Generic Name/Product Name	Origin (Collaborator)	Mode of Action
	entrectinib/Rozlytrek	Roche/Nerviano Medical Sciences	ROS1/TRK inhibitor (Oral)
	atezolizumab/Tecentriq	Roche	Engineered anti-PD-L1 monoclonal antibody (Injection)
	trastuzumab emtansine/Kadcyla	Roche	Anti-HER2 antibody-tubulin polymerization inhibitor conjugate (Injection)
	bevacizumab/Avastin	Roche	Anti-VEGF (vascular endothelial growth factor) humanized monoclonal antibody (Injection)
	ipatasertib/Product name undetermined	Roche/Array BioPharma	AKT inhibitor (Oral)
	polatuzumab vedotin/Product name undetermined	Roche	Anti-CD79b drug conjugate (Injection)
	trastuzumab, pertuzumab/Herceptin, Perjeta	Roche	Anti-HER2 humanized monoclonal antibody/HER2 dimerization inhibitory humanized monoclonal antibody (Injection)
	alectinib/Alecensa	In-house (Roche)	ALK inhibitor (Oral)
	codrituzumab/Product name undetermined	In-house	Anti-glypican-3 humanized monoclonal antibody (Injection)
	Generic and product names undetermined	In-house	Anti-glypican-3/CD3 bispecific antibody (Injection)
	cobimetinib/Product name undetermined	Roche/Exelixis	MEK inhibitor (Oral)
	cibisatamab/Product name undetermined	Roche	Anti-CEA/CD3 bispecific antibody (Injection)
	mosunetuzumab/Product name undetermined	Roche	Anti-CD20/CD3 bispecific antibody (Injection)
	Generic and product names undetermined	Roche	Anti-FAP humanized antibody-engineered IL-2 variant fusion protein (Injection)
	tiragolumab/Product name undetermined	Roche	Anti-TIGIT human monoclonal antibody (Injection)
	eldecalcitol/Edirol	In-house	Activated vitamin D_3 agent (Oral)
	purified sodium hyaluronate/Suvenyl	In-house	Sodium hyaluronate (Injection)
	Generic and product names undetermined	In-house	— (Oral)
	fenebrutinib/Product name undetermined	Roche	BTK inhibitor (Oral)
	Generic and product names undetermined	Roche	Human IL-22 fusion protein (Injection)
	satralizumab/Product name undetermined	In-house (Roche)	Anti-IL-6 receptor recycling antibody (Injection)
	gantenerumab/Product name undetermined	Roche/MorphoSys	Anti-amyloid-beta human monoclonal antibody (Injection)
	Generic and product names undetermined	Roche/Ionis Pharmaceuticals	Antisense oligonucleotide targeting *HTT* mRNA
	risdiplam/Product name undetermined	Roche/PTC Therapeutics	SMN2 splicing modifier (Oral)
	prasinezumab/Product name undetermined	Roche/Prothena	Anti-α-synuclein monoclonal antibody (Injection)
	Generic and product names undetermined	In-house (Roche)	Anti-latent myostatin sweeping antibody (Injection)
	Generic and product names undetermined	Roche	— (Oral)
	semorinemab/Product name undetermined	Roche/AC Immune	Anti-tau humanized monoclonal antibody (Injection)
	balovaptan/Product name undetermined	Roche	Vasopressin 1a receptor antagonist (Oral)
	emicizumab/Hemlibra	In-house (Roche)	Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody (Injection)
	faricimab/Product name undetermined	Roche	Anti-VEGF/Ang2 bispecific antibody (Injection)
	crovalimab/Product name undetermined	In-house (Roche)	Anti-C5 recycling antibody (Injection)
	Generic and product names undetermined	In-house	Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody (Injection)
	Generic and product names undetermined	In-house	PTH1 receptor agonist (Oral)
	Generic and product names undetermined	In-house	— (Injection)

Sustainability and Growth Strategies

Valuable Suggestions from Dialogues in 2019 That Should Be Reflected in Management

Investor Suggestions ⇔ Chugai's Response

Export Scheme for Chugai Products

The export scheme for products out-licensed to Roche, and the sales amounts and trends of exports, are difficult to understand because they are complex. In particular, Hemlibra is a blockbuster product, so I would like to know the details that go into determining the forecast.
(Sell-side analyst)

Present a diagram of the export scheme in the presentation materials for financial results, and disclose royalty and profit-sharing income and other operating income separately. Also disclose projected royalty income related to Hemlibra.

ESG Meeting

At the first ESG meeting Chugai Pharmaceutical plans to hold, it would be useful if it covered topics aligned with investor needs. It's also important to make this an ongoing event and to regularly report on progress.
(Buy-side analyst and fund manager)

Will cover topics of particular interest based on preliminary interviews with the commenting analysts, who are deeply knowledgeable of ESG issues, and on preliminary online questionnaires sent to people who register for the meeting. Also, planning themes for future ESG meetings, assuming that this event will continue.

Explanation of R&D

Chugai is an R&D-driven pharmaceutical company, so to get detailed explanations, I would like you to hold R&D presentations separately from regular financial results presentations.
(Buy-side analyst)

Held an information meeting on antibody technologies in December 2019. In addition to explaining Chugai's research strategy, the meeting introduced innovative antibody technologies established using our antibody engineering capabilities, one of Chugai's strengths.

Expert Suggestions ⇔ Chugai's Response

Supply Chain Management

- Human rights themes in Japan have typically focused on discrimination and human rights awareness, but it is important to consider the human rights of workers more broadly. Besides the in-house training you already conduct, you should also conduct due diligence at suppliers.
  (NPO and Advisory Committee)

Reaffirmed the effectiveness of plans formulated internally. Created a comprehensive supplier evaluation system that includes human rights, environmental and occupational health and safety perspectives. Drew up targets for 2030 and three-year milestones, and began due diligence.

Climate Change Risk

- Climate change and other environmental risks are increasingly important worldwide, but the pharmaceutical industry has yet to place a high priority on such risks, and there are still no collaborative activities. These efforts, however, will likely accelerate overall.
  (Chugai International Council, other external reviews, etc.)

Moved up our initiatives regarding endorsement of the TCFD recommendations and implementation of scenario analysis, plans for which had been included in IBI 21. Also analyzed trends in other industries. Plan to announce results of TCFD scenario analysis in 2020.

Employee Suggestions ⇔ Chugai's Response

From Workshop on "Patient-Centric"

I realized that what I had thought of as "patient-centric" is really "treatment-centric," and that for patients, the treatment of their disease is only one aspect of their lives.
(Employee/Manager)

Listening to what patients say is extremely important. We are unable to contact patients directly, but collecting their views through key opinion leaders alone is insufficient. I would like to think about what we can do as a top innovator, based on the rules and regulations.
(Employee/Manager)

Recognized that this workshop brought substantial changes to employees. Will engage in discussions with patient groups, and reconsider how we approach business activities that incorporate feedback from patients.

IBI 21 – From a Site Visit by Top Executives

I was able to understand and appreciate the Company's vision for the future, its approach to human resources, and so on. The scope of direct dialogue with executives is expanding, and the ripple effect is growing.
(Employee)

The implications of strategies and so on made sense, but I could not fully understand the specifics of such points as the envisioned personnel system and the ideal MR profile.
(Employee)

Top executives will continue to conduct regular site visits and dialogue with employees. Plan to provide detailed explanations on personnel-related matters at information meetings and other forums.

Message from the Deputy Chairman

We will further accelerate our initiatives for creating shared value based on the needs and expectations of shareholders.

Motoo Ueno
Representative Director &
Deputy Chairman
In charge of Sustainability Dept.,
Audit Dept.

Chugai's Sustainability and Growth Strategies

Realizing better human health around the world – the goal expressed in Chugai's Mission – is a universal desire. Since it was founded, Chugai has consistently pursued solutions to this challenge in cooperation with various stakeholders. However, in order to accomplish our Mission in an increasingly uncertain and complex operating environment, it will be important to demonstrate our path to value creation more clearly. Therefore, in 2019, we set out a basic management policy of creating shared value with our stakeholders to realize advanced and sustainable patient-centric healthcare.

Our stakeholders – healthcare professionals, research institutions, partners, the governments and regulatory agencies that support healthcare systems, communities, countries, and employees – all place importance on contributing to patients. Committing to patient-centric value (outcomes) will enable Chugai to carry out value expansion initiatives together with stakeholders.

Corporate sustainability is vital to the creation of sustainable healthcare and a sustainable society. In order to solve social issues, corporations such as Chugai must grow over the medium and long term, allocating various resources to new investments. This is precisely the idea behind the Sustainable Development Goals (SDGs) that Chugai has committed to supporting. The time horizons for goals and targets are different, but sustainability and growth strategies should be looked at from the same viewpoint.

Chugai established its material issues and formulated mid-term business plan IBI 21 based on this approach. IBI 21 is a three-year roadmap for the sustainable growth and development of society and the Company, and incorporates Strengthen Sustainable Platforms as Strategy 5 for achieving that objective. It is highly significant that initiatives that had been carried out at the departmental level are now being reflected in our Company-wide management strategy.

Dialogue with Stakeholders

One aspect that we are giving more emphasis to in IBI 21 is dialogue with stakeholders. Since we are committed to the idea of shared value, we must understand the needs and expectations of stakeholders in order to create such value. The speed, degree of achievement, and other aspects of strategy execution will be determined by the needs and expectations of society, and the level of those needs and expectations will vary according to our presence and influence on society.

In establishing our material issues and formulating our strategies, we placed importance not just on internal discussions but on dialogue with external stakeholders, and held extensive discussions with the Chugai Sustainability Advisory Committee and outside experts. We will maintain an ongoing dialogue with them to confirm our progress.

In 2019, we engaged in dialogue with internal and external stakeholders as planned. Our first ESG meeting was held in June 2019. This meeting and the interview with investors that preceded it were very worthwhile, as they gave us an opportunity to sound out the hopes and expectations of investors and the media directly. We plan to continue holding ESG meetings, introducing themes that go a step further and include reports on our progress. As a new initiative, we also conducted training and workshops on the SDGs for interested employees. Feedback was positive, with employees saying the programs helped them to think about the significance of working to achieve the SDGs. Afterward, we held an SDG contest in which all employees were invited to submit ideas for contributing to the achievement of the SDGs. The number of ideas exceeded expectations.

Establishment of Material Issues and Progress of Establishing Sustainable Platforms

In 2020, we established and announced targets and indicators for measuring material issues (see "Chugai's Material Issues" on page 37). Of course, there are some items that can't be verified sufficiently at this stage, such as those that are not suited to quantitative measurement. But in all of our corporate activities, setting targets is essential. We will continue to consider setting and disclosing appropriate targets as we conduct examinations and verification in order to share our priorities in corporate activities both internally and externally.

Our strategy of strengthening sustainable platforms is also moving forward. In quality management, for example, we have upgraded Company-wide quality requirements and taken other measures such as holding meetings on quality to further instill a quality mindset in response to more stringent demands for data integrity from authorities in recent years. In supply chain management, we are conducting due diligence based on the comprehensive evaluation system for suppliers that we established in 2019. In healthcare access, our efforts include joining the World Federation of Hemophilia Humanitarian Aid Program together with Roche and a program to support diagnosis and treatment of non-communicable diseases in Myanmar.

We are making progress as planned in each category, as these examples illustrate. At the same time, our presence in the industry and market capitalization changed in 2019. I sense that stakeholders' needs and expectations are rising, so we need to further accelerate the execution of each of our strategies. One area we are focusing on is the global environment, particularly climate change. Based on the TCFD recommendations, we are currently strengthening governance regarding our response to climate change, analyzing risks and opportunities, and conducting scenario analysis that considers aspects such as the financial impact of these risks and opportunities. Going forward, we will step up our efforts in analysis, countermeasure design, and information disclosure. We plan to set our next medium-term targets in 2020, and are preparing to set ambitious goals for climate change countermeasures that match those in the Paris Agreement. Implementing such measures over the long term will also be important, so we are considering proactively setting longer-range goals such as for 2050.

I believe that one of the outcomes of our efforts to create shared value is that we will gain a precious asset – relationships of trust at a high level with each group of stakeholders. Based on this trust, we should be able to create further shared value. I will conduct management that helps Chugai evolve into a company where each and every employee works toward fulfilling its Mission with awareness of relationships with stakeholders and the Company's value creation path.

Relationship between Stakeholders and Material Issues

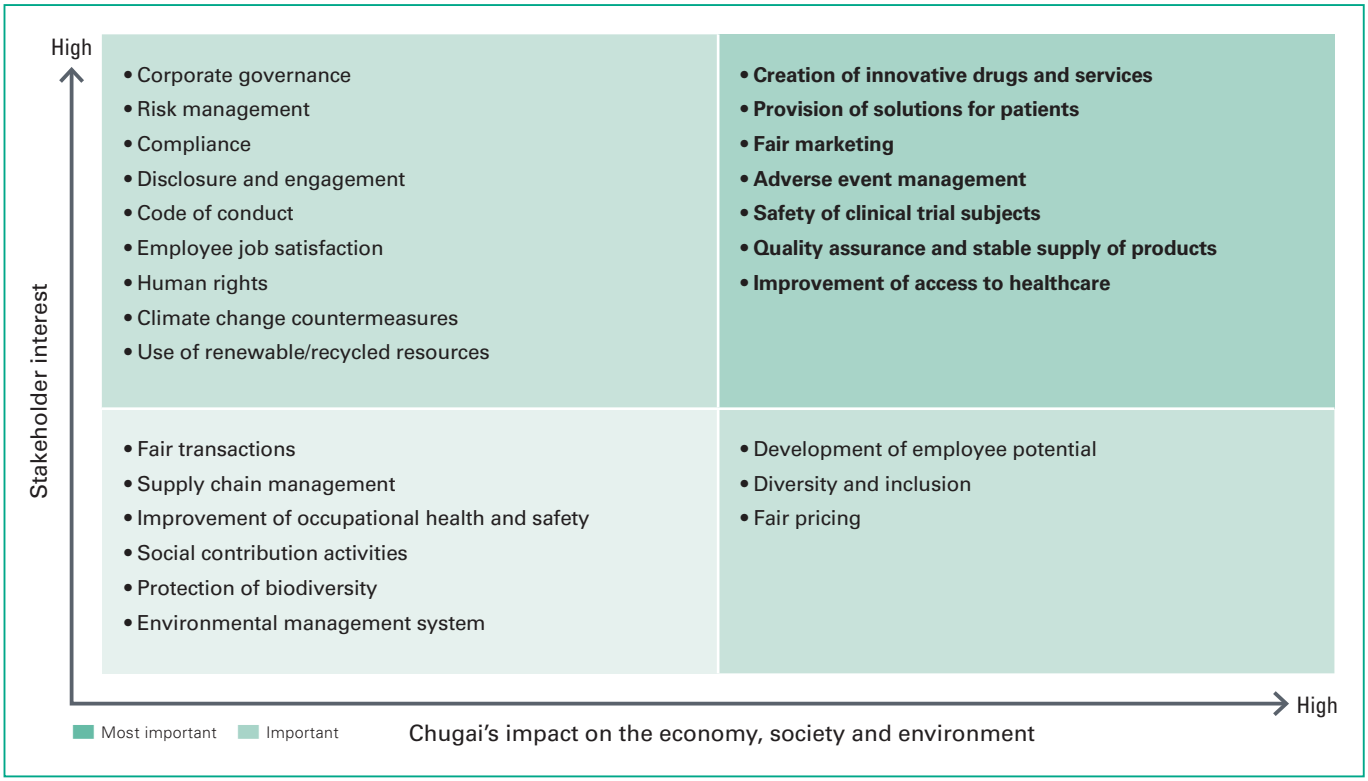
Patients and families of patients	Creation of innovative drugs and services/Provision of solutions for patients/Adverse event management/Quality assurance and stable supply of products/Safety of clinical trial subjects/Improvement of access to healthcare
Healthcare professionals and medical institutions	Creation of innovative drugs and services/Provision of solutions for patients/Fair marketing/Adverse event management/Quality assurance and stable supply of products
Shareholders and other investors, etc.	Corporate governance/Risk management/Compliance/Code of conduct/Disclosure and engagement
Employees	Human rights/Employee job satisfaction/Development of employee potential/Diversity and inclusion/Improvement of occupational health and safety
Payers and regulators	Fair pricing/Creation of innovative drugs and services
Suppliers and wholesalers, etc.	Supply chain management/Fair transactions
Countries	Creation of innovative drugs and services/Fair pricing/Improve access to healthcare
Communities	Provision of solutions for patients/Fair pricing/Social contribution activities/Climate change countermeasures/Use of renewable/recycled resources/Protection of biodiversity/Environmental management system
Universities and research companies/institutions	Creation of innovative drugs and services/Provision of solutions for patients
Medical device manufacturers and healthcare companies	Creation of innovative drugs and services/Provision of solutions for patients

The Risks behind Our Strategies

Principal Risks Associated with Strategies	Specific Risk Scenarios	Impact on Enhancement of Corporate Value	Response
❶ Product Environment	• Changes in treatment paradigms due to new life science technologies such as cell and gene therapy and therapeutic nucleic acids • Launch of innovative products by competitors and increasing speed of market penetration of biosimilars and generics • Changes in the competitive environment due to factors such as capital alliances between competitors • Emergence of a digital oligopoly due to the entry of IT platform companies into the healthcare industry	• Decline in competitiveness of products • Decline in market position • Drug price reductions • Cost of measures to respond to new modalities • Increase in costs associated with introduction of new technologies, enhancement of competitiveness and data utilization	**Upgrade and Diversify Value Provided** • Identify and accelerate development of new drugs that have a competitive advantage (❶, ❷) • Flexibly adopt new life science technologies, modalities and digital technologies (❶, ❷) • Pursue and provide proof of "true value" for patients (❶, ❷, ❸) • Realize personalized healthcare (PHC) that is more advanced and offers high value to both patients and society (❶, ❷, ❸, ❹) **Enhance Competitiveness** • Change to a profit structure that creates sufficient resources for innovation (❶, ❷, ❸) • Develop human resources by enhancing their responsiveness to environmental change (❶, ❷) **Enhance Sustainability** • Conduct initiatives in priority areas that take into account SDGs and issues in healthcare overall (❸, ❹, ❺, ❻) • Promote evolution of ESG activities throughout the value chain (❹, ❺, ❻) • Contribute through cooperation with other companies and organizations (❶, ❷, ❸, ❹, ❺, ❻)
❷ Research and Development of New Products	• Increasing difficulty of identifying new drug targets due to intensifying R&D competition • Further increase in R&D expenditures for creating new drugs • Decline in success rate of new drug candidate projects due to higher level of innovation required	• Delays in creating in-house products • Rising R&D expenditures and pressure on earnings • Additional costs for new supplemental technology	
❸ Healthcare System	• Stronger measures to reduce drug prices in response to rising healthcare costs and strain on finances in each country • Fundamental changes in health insurance coverage for drugs • Advance of Value-Based Healthcare (a model in which only solutions that offer true value are pursued)	• Decrease in sales volume • Increase in marketing costs to expand sales volume • Decrease in profitability	
❹ Supply Chain	• Risk of supply delays or disruptions due to natural disasters or other causes • Compliance, environmental, human rights or other ESG-related risks of suppliers throughout the supply chain	• Loss of public trust • Additional costs to restore and maintain the supply system • Decrease in sales volume • Shift in market share	
❺ Human Rights	• Slowness in taking action to address human rights issues, including workplace environment, health and safety • Risks related to human rights violations, harassment and other issues throughout the supply chain	• Loss of public trust • Deterioration of employees' physical and mental health and decline in human resource capabilities • Decrease in sales volume • Shift in market share	
❻ Global Environment	• Occurrence of unexpected contamination or its collateral damage by harmful substances • More stringent environmental regulations in the future • Delay in autonomously and proactively engaging in climate change measures • Insufficient response to expectations and requirements of society concerning environmental protection activities • Greater difficulty of temperature and quality control in product manufacturing, storage and logistics due to rising outdoor temperature • Malfunction of production equipment due to technical problems related to temperature control • Disruption of business activities due to damage to the logistics network and production facilities caused by abnormal weather or meteorological disasters • Relocation of factories or other sites due to the rising sea level • Water shortages and deterioration of water quality due to drought	• Expenditures for remedial measures and compensation for damages related to environmental pollution or for other reasons • Restrictions on business activities due to regulations, increase in energy costs associated with production, and rise in prices of procured products • Unplanned spending to comply with regulations • Increase in capital investment costs related to the introduction of new technologies • Increase in investment due to decline in reputation among customers and capital markets, and impact of lower brand image on stock price and acquisition of human resources • Increase in expenditures related to temperature control • Impact on management from suspension or considerable delay in product supply • Expenses incurred to handle lawsuits arising from lower quality	

Chugai's Material Issues

Specification of Material Issues

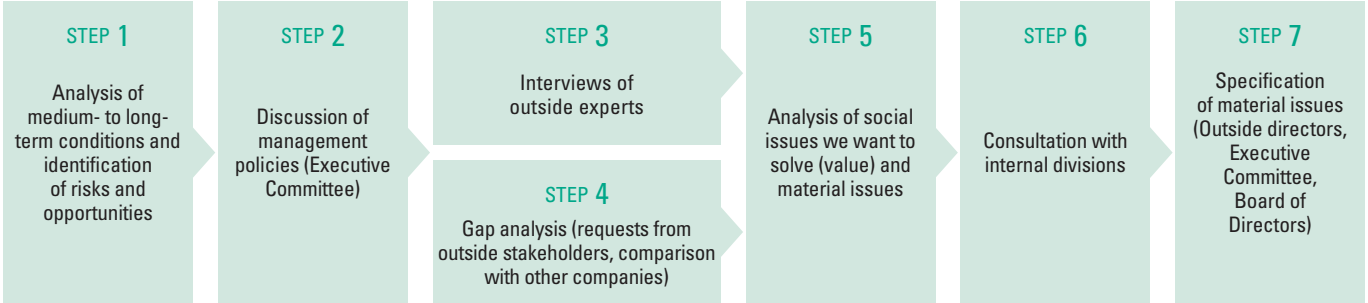


Chugai has adopted creating shared value with stakeholders as its basic policy. We identified 25 material issues that should be given priority.

These issues were identified through a multifaceted analysis that incorporated objective views from outside experts. Together with these issues, we formulated relevant targets (see following page for details). These material issues may be adjusted in response to changes in the external environment or the evolution of Chugai's business activities, and we plan to update them periodically. Sustainability is part of our business strategy, and we consider it important to carry out our activities with an integrated and strategic view.

In establishing material issues, we analyzed the future market environment, referred to the SDGs and other external initiatives and guidelines, and comprehensively identified the issues that society expects Chugai to address. We also scrutinized items for which Chugai is not sufficiently meeting expectations. We conducted an objective analysis that incorporated outside views, and narrowed the list of issues to those for realizing Chugai's Envisioned Future. Based on that process, we specified 25 material issues.

Process for Establishing Material Issues



Targets and Indices for Material Issues

Chugai has established material issues together with the targets it wants to achieve over the medium to long term for creating shared value. At the same time, because the promotion of these targets will require measures spanning all departments of the Company, we have also designated departments in charge of supervision and core execution. In addition, in 2019 we decided to reorganize and disclose our evaluation items as indices for measuring progress and degree of achievement of each target (only some are actual numerical values). By communicating to society the evaluation items we have set and the specific matters we will focus on, we aim to generate dialogue going forward. We will review the evaluation indices as necessary in line with the promotion of our strategies, and continue to consider disclosing actual numerical values.

Economy

Category	Material Issue	Target	Indicators	Department/Unit in Charge
Sustainable healthcare	Creation of innovative drugs and services	Create innovative drugs	• Number of projects and products based on PHC • Number of new product launches and additional indications	Project & Lifecycle Management Unit Research Div. Translational Research Div. Clinical Development Div.
	Provision of solutions for patients	Realize patient-centric healthcare	• Market share in therapeutic area • Customer satisfaction	Marketing & Sales Div. Medical Affairs Div. Drug Safety Div.
	Fair marketing	Marketing in compliance with national guidelines	—	Marketing & Sales Div. Project & Lifecycle Management Unit
	Fair pricing	Pricing that reflects drug and service value	—	External Affairs Dept.
	Adverse event management	Perform appropriate pharmacovigilance activities and promote proper drug use	• Customer satisfaction	Drug Safety Div.
	Quality assurance and stable supply of products	Ensure quality and stable supply of products and services	—	Quality & Regulatory Compliance Unit Pharmaceutical Technology Div.

Governance

Category	Material Issue	Target	Indicators	Department/Unit in Charge
Corporate governance	Corporate governance	Realize sustained growth and corporate value	• Review of Board of Directors effectiveness	General Affairs Dept.
	Risk management	Perform risk assessment and evaluate responses	—	General Affairs Dept.
	Disclosure and engagement	Earn market trust through appropriate information disclosure	• Annual ESG meeting for institutional investors and media	Corporate Communications Dept.
Ethics and compliance	Compliance	Appropriately manage compliance risks	• Compliance monitoring	Sustainability Dept. Quality & Regulatory Compliance Unit
	Code of conduct	Promote understanding and awareness of Chugai Group Code of Conduct (CCC)	• CCC and human rights training in Japan: twice a year	Sustainability Dept.
	Fair transactions	Ensure compliance with trading laws and regulations and build fair and transparent business relationships	—	Purchasing Dept. Sustainability Dept.
Supply chain management	Supply chain management	Perform comprehensive supplier evaluations	• Risk assessment of major CMOs	Sustainability Dept. Pharmaceutical Technology Div. Purchasing Dept.

Environment

Category	Material Issue	Target	Indicators	Department/Unit in Charge
Global environment	Climate change countermeasures[1] (energy, etc.)	Minimize impact on global environment	• Reduce energy consumption per employee by 20% vs 2010 • Eliminate use of specific fluorocarbons • Fuel economy of sales vehicles: ≥16 km/L	Sustainability Dept.
	Use of renewable/ recycled resources[1] (water, waste, etc.)		• Zero waste emissions (≥99% recycling of waste): 3 sites	Sustainability Dept.
	Protection of biodiversity (environmental burden mitigation)		• Wastewater measurement using whole effluent toxicity testing: 5 sites	Sustainability Dept.
	Environmental management system	Third-party assurance of performance data	• Expand verification items and scope (Overseas sales companies)	Sustainability Dept.

1. Target for December 31, 2020

Social

Category	Material Issue	Target	Indicators	Department/Unit in Charge
Human resources	Employee job satisfaction[2]	Develop work environment where employees can continue their careers	• Rate of paid leave taken: ≥80% • Telecommuting participation rate[3]: 35% • Employee awareness survey	Human Resources Management Dept.
	Development of employee potential	HR recruitment and training to realize strategic targets and accelerate innovation	• Number of next-generation leader candidates	Human Resources Management Dept. Human Capital Development Dept.
	Diversity and inclusion[2]	Create new value through diverse talents	• Ratio of female managers[4]: 16% • Ratio of female managers (With subordinates)[4]: 15%	Human Resources Management Dept.
	Improvement of occupational health and safety	Maintain and enhance safe work environment and employee health	• Prohibit smoking during work by December 31, 2021	Sustainability Dept.
Human rights	Human rights	Respect human rights of all persons involved in business	• Human rights due diligence on contractors	Sustainability Dept.
	Safety of clinical trial subjects	Conduct clinical trials under high ethical and scientific standards with safety	—	Translational Research Div. Clinical Development Div. Drug Safety Div.
Social responsibility	Social contribution activities	Develop networks in key areas	• Set for each program	Sustainability Dept.
	Improvement of access to healthcare	Improve access to healthcare including drug development	• Set for each program	External Affairs Dept.

2. Target for December 31, 2021
3. Non-consolidated basis
4. Non-consolidated employee basis

Previous Mid-Term Business Plans

Sunrise 2012
(2008-2012)

Business environment
- Emphasis on unmet medical need
- Stronger pressure to contain healthcare costs

Formulation and launch of the "top pharmaceutical company" goal[1]

Strategies
- Strengthen portfolio management
- Exhibit strategic marketing functions
- Maximize Company-wide productivity

Results and issues
- Established high profitability
- Continuous stream of in-house candidates into clinical development
- Developed and established recycling antibody engineering technology and other proprietary antibody engineering technologies
- Promoted PHC

Quantitative guidance

2012 targets	Result
Revenues: ¥460 bn →	**¥391.2 bn**
Operating profit: ¥80 bn →	**¥76.4 bn**
Operating profit margin: 17.4% →	**19.5%**

ACCEL 15
(2013-2015)

Business environment
- Evolution of discovery technology
- Stricter drug approval requirements
- More severe impact from drug price revisions

Prepare the foundation for achieving the "top pharmaceutical company" goal

Strategies
- Increase marketing productivity
- Accelerate global development
- Continuously generate innovative projects
- Further strengthen management infrastructure

Results and issues
- Product growth exceeding market average
- Advances in global development of in-house products including Alecensa
- Strengthened R&D structure with expansion of CPR,[2] establishment of TCR Division,[3] etc.
- Enhanced functions for providing solutions

Quantitative guidance

3-year target	Result
Core EPS[4] CAGR[5] (2012-2015): Mid to high single digit →	**18.3%**[6]

IBI 18
(2016-2018)

Business environment
- Advances in life science
- Increasing difficulty of creating new drugs
- Fierce global competition

Realization of the "top pharmaceutical company" goal

Strategies
- Acquisition and implementation of competitiveness at a top global level
- Selection and concentration strategy for acceleration of growth (Set 13 priority issues in 5 areas: Drug discovery, development, pharmaceutical technology, marketing & sales/medical affairs/ drug safety, and Company-wide)

Results and issues
- Achieved record-high results
- Continuously created therapeutic antibody projects and enhanced the middle molecule drug creation technology platform
- Prepared for approval and accelerated growth of Hemlibra and Tecentriq
- Created a structure for providing solutions by region

Quantitative guidance

3-year target	Result
Core EPS CAGR (2015-2018): Low single digit →	**17.1%**[7]

1. A vision for Chugai to be realized in the second half of the 2010s. It sets numerical targets including ranking within the top three major Japanese pharmaceutical companies, the number-one domestic presence in our strategic disease areas, and expansion of global presence, and qualitative targets including becoming a company that receives the support and trust of all stakeholders and conducts independent activities.
2. Chugai Pharmabody Research Pte. Ltd. Established in Singapore in 2012.
3. Translational Clinical Research Division. Partially reorganized into the Translational Research Division in October 2018.
4. Diluted earnings per share attributable to Chugai shareholders on a Core basis
5. Compound annual growth rate
6. Based on average exchange rates for 2012
7. Based on average exchange rates for 2015

Overview of Mid-Term Business Plan IBI 21

IBI 21

INNOVATION BEYOND IMAGINATION

Quantitative Outlook

Core EPS CAGR
(2018-2021)

Around 30%*

- We will make essential investment for future growth, while maintaining the momentum of growth achieved during IBI 18, and realize sustainable profit growth and expansion of corporate value.
- We will target a Core EPS payout ratio of 45 percent on average.

* Three years, based on constant exchange rate.
Note: Core EPS CAGR is calculated based on the assumption of no stock split with a scheduled effective date of July 1, 2020.

Mid-Term Business Plan: 5 Strategies

We aim to accelerate the development of society and Chugai by generating innovation centered on innovative new drugs with the following five strategies under the themes "create global growth and maximize value" and "strengthen HR and infrastructure that support Chugai's business."

Create Global Growth Drivers and Maximize Value

Strategy 1: Value Creation
Realize innovative drug discovery to cure and manage diseases

Strategy 2: Value Delivery
Deliver patient-centric solutions and maximize value of growth drivers

Strategy 3: Promote Advances in Personalized Healthcare (PHC)
Realize the further advancement of PHC and innovate R&D process by utilizing digital technology and data

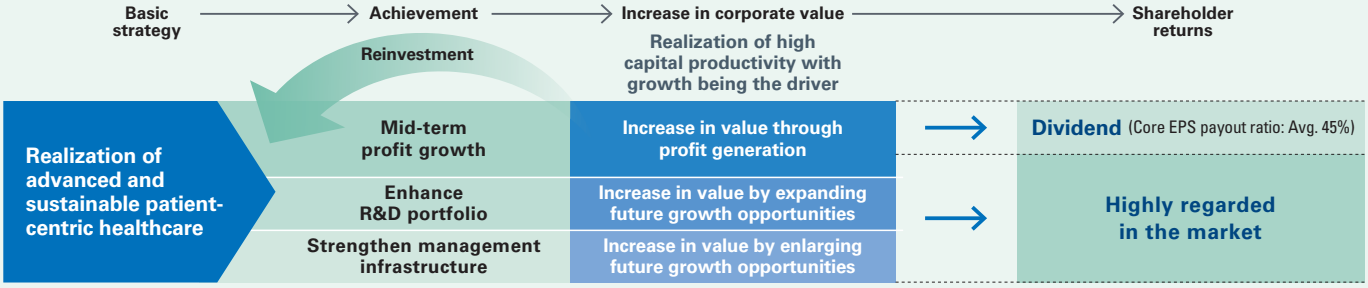
Strengthen HR and Infrastructure That Support Chugai's Business

Strategy 4: Strengthen Human Capital and Conduct Fundamental Structural Reform
Develop high-caliber HR talent that supports innovation, and thoroughly reform costs, systems and processes

Strategy 5: Strengthen Sustainable Platforms
Simultaneously realize company growth and sustainable social development

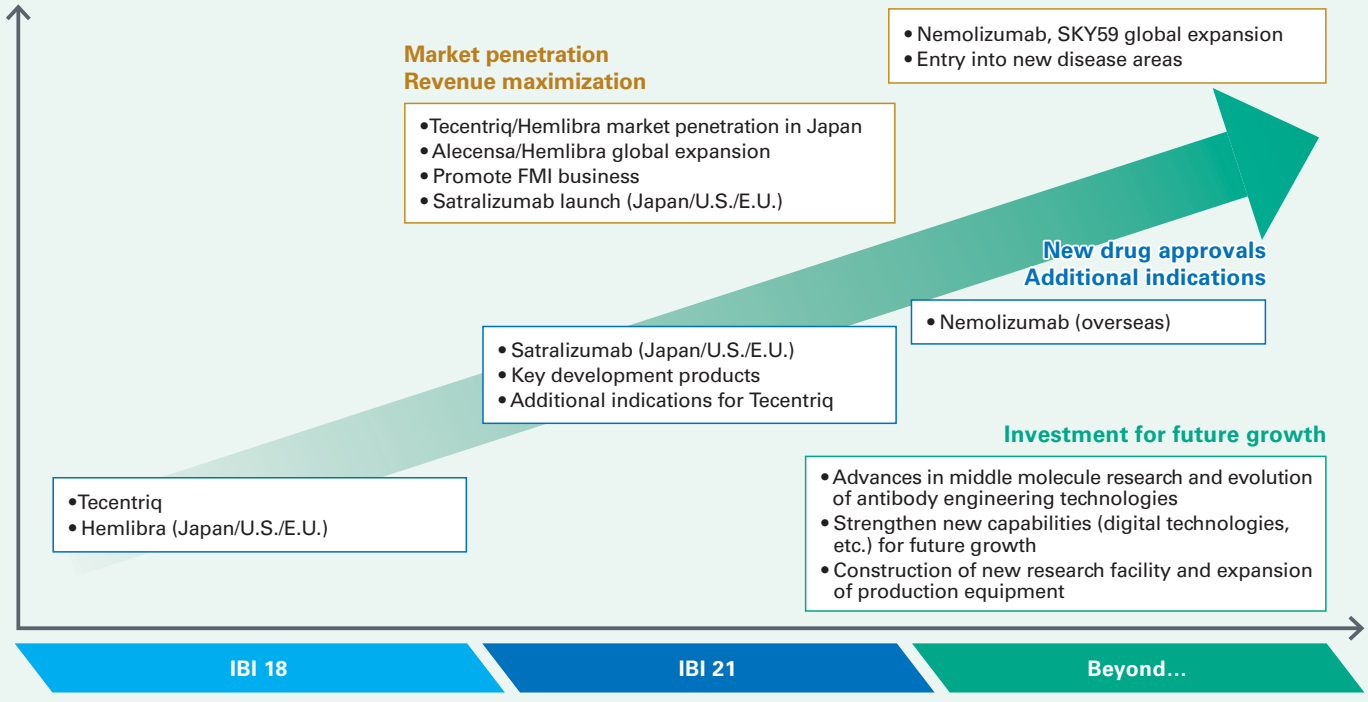
Based on its five strategies, IBI 21 aims to accelerate the advancement of society and Chugai by generating innovation focused on novel drugs. In quantitative terms, we are targeting a Core EPS CAGR of around 30 percent (assuming constant exchange rates) for the three years of the plan, and will allocate resources and make management decisions with emphasis on profitability and capital productivity, including evaluation based on capital costs. Our policy on shareholder returns is to aim for a dividend payout ratio of 45 percent of Core EPS on average to provide stable dividends, taking into account the balance between shareholder returns and the internal reserves necessary for increasing corporate value. In January 2020, we raised the quantitative outlook from the previous high single digits in anticipation of future business expansion, and changed from the previous target Core payout ratio of 50 percent on average to 45 percent to maintain our policy of stable dividends.

Basic Principles of Increasing Corporate Value and Shareholder Returns



IBI 21 Growth Outlook

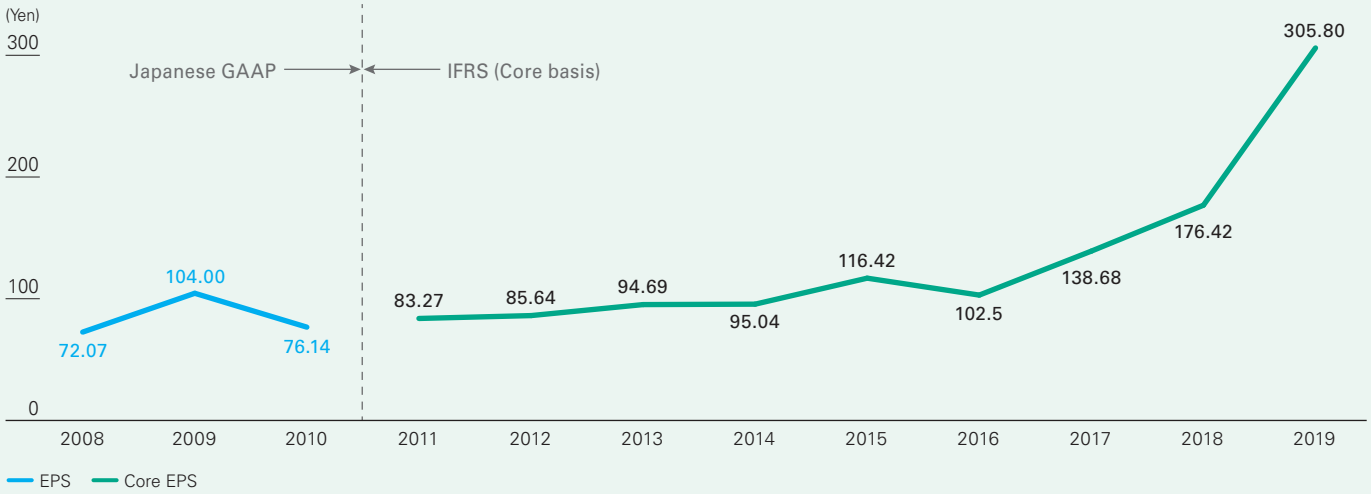
In addition to market penetration of growth drivers in Japan and overseas, the approval and launch of satralizumab will support further growth.



Progress of IBI 21

Strategy 1 Value Creation	• Hemlibra: Obtained approval in Europe for hemophilia A without inhibitors • Rozlytrek: Obtained approval in Japan for *NTRK* fusion gene-positive solid tumors, filed for *ROS1* fusion gene-positive NSCLC • Nemolizumab: Received breakthrough therapy designation from the U.S. FDA for the treatment of pruritus associated with prurigo nodularis • Telomelysin: Concluded exclusive licensing and capital tie-up agreements with Oncolys BioPharma Inc. • Satralizumab (SA237): Filed applications in Japan, the U.S. and Europe for treatment of neuromyelitis optica spectrum disorder • OWL833: Out-licensed to Eli Lilly and Company and began phase I clinical trial
Strategy 2 Value Delivery	• Steady market uptake of Hemlibra, Tecentriq and other new products • Global sales of Hemlibra reached about ¥150.0 billion
Strategy 3 Promote Advances in PHC	• Launch of FoundationOne CDx Cancer Genomic Profile in Japan • Approval for expanded use of FoundationOne CDx Cancer Genomic Profile as a companion diagnostic for Rozlytrek • Established Digital & IT Supervisory Division (Strategies 1, 2 and 3)
Strategy 4 Strengthen Human Capital and Conduct Fundamental Structural Reform	• Transferred the businesses of two long-term listed products • Outsourced pharmaceutical distribution and packaging operations • Implemented early retirement incentive program • Completed design of new personnel system (Started operation on April 1, 2020)
Strategy 5 Strengthen Sustainable Platforms	• Strengthened initiatives for each ESG theme and set targets for each material issue • Held ESG meeting • Selected as a component of the Dow Jones Sustainability Asia Pacific Index

EPS/Core EPS

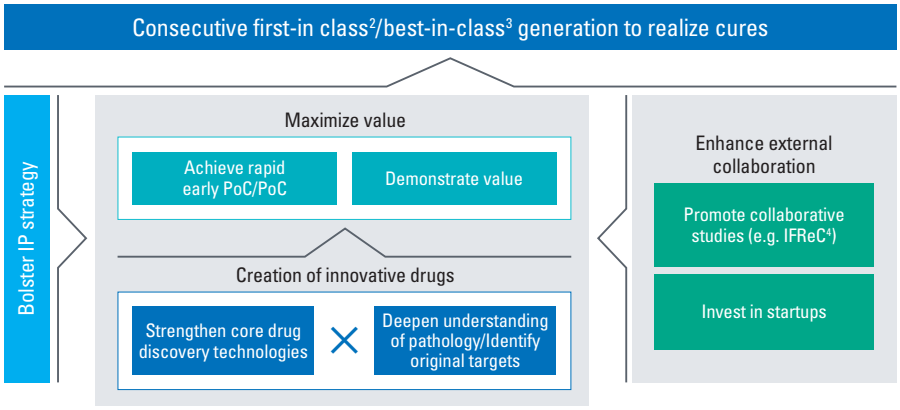


Strategy 1
Value Creation

Realize innovative drug discovery to cure and manage diseases by fusing our core drug discovery technologies and biology, and by achieving rapid proof of concept (PoC).

Strategic Points

- Strengthen core drug discovery technologies
- Deepen understanding of pathology/ Identify original targets
- Achieve rapid early PoC/PoC[1]
- Demonstrate value
- Bolster intellectual property (IP) strategy



1. PoC is confirmation that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.
2. An original drug that is highly novel and useful, and will significantly change the therapeutic system
3. A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target
4. Osaka University Immunology Frontier Research Center

Creation of Innovative Drugs

As part of IBI 21, we are attempting drug discovery at a whole new level under the theme, "Realize innovative drug discovery to cure and manage diseases."

Continuous creation of innovative drugs drives Chugai's growth, and our prioritized investment of management resources has established a cutting-edge technology platform. Under IBI 21, we are exploring the potential for cure or full recovery at an earlier stage resulting from the synergy between advances in drug discovery technology and a deeper understanding of the biology underlying pathologies, which will lead to the identification of original targets.

For drug discovery modalities, we have technologies to create therapeutic antibodies, small molecule drugs and middle molecule drugs. Therapeutic antibody projects made smooth progress in 2019, including the start of clinical development of NXT007, the next generation of Hemlibra. We are also developing a series of proprietary new antibody engineering technologies including Switch antibody engineering technology. We will start clinical trials of a project that applies Switch antibody engineering technology during 2020, and will accelerate the utilization of new antibody engineering technologies as we work to create a new mode of action.

For middle molecule drugs, an area where we have been working to establish a modality platform as a core technology for next-generation drug discovery, we at last expect to see projects entering the pipeline. Measures will include developing non-clinical data, clinical protocols and upgrading our supply system with the aim of commencing a phase I clinical trial during IBI 21.

Deepening Our Understanding of Biology and Open Innovation

As we deepen our understanding of biology, we will cultivate targets and modes of action by establishing an integrated disease database and conducting research using fresh human tissue among other measures. Concurrently, we will conduct joint research with IFReC, the University of Tokyo Center of Innovation (COI) and the National Cancer Center at on-site laboratories. We will also collaborate with other research institutions in Japan and overseas.

Moreover, in fusing technology and biology to enable a higher level of drug discovery, generating insights is key. We will continue to innovate by making full use of the TACTICS system we launched in 2019, which allocates at least 20 percent of approximately half of our researchers' workloads to idea creation.

Maximizing Value

For new drug candidates, we will promote development with world-class quality and speed by evolving the development process through ongoing enhancement of our organizations for translational research and investigational drug production. At the same time, we will work to further evolve manufacturing technologies for middle molecule drugs, step up quality control, quality assurance and regulatory functions in accordance with global standards, and strengthen our strategies for intellectual property, including technology patents.

Progress was steady at each stage of the development pipeline in 2019, and we intend to continue working to accelerate development of each project, including nemolizumab (CIM331) and SKY59.

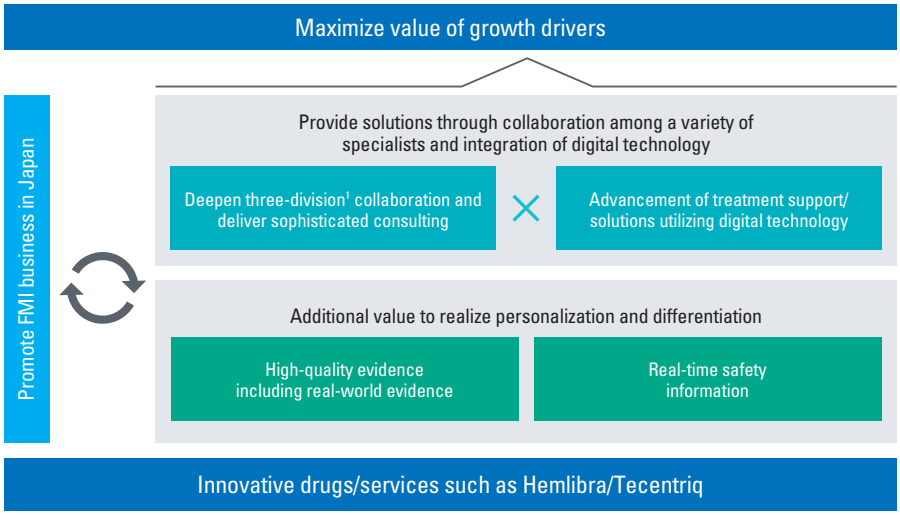
To prove the value of our products, we are working to establish a system that can collect, analyze and manage various data from the development stage, including in areas such as quality of life and healthcare economics. We have already designed new outcome technologies and indicators using wearable devices and image analysis to demonstrate value for patients, and are verifying the results for the purpose of implementation in clinical trials.

- See "Focus 1: Evolution of Antibody Engineering Technologies" on page 50.
- See "Research" on page 78.
- See "Close-Up 1: Advancing Middle Molecule Drugs to the Clinical Phase" on page 82.

Strategy 2
Value Delivery

Maximize value of growth drivers (innovative drugs and services) through patient-centric consulting and enhanced digital solutions.

Strategic Points
- Maximize value of growth drivers
- Work to realize patient-centric healthcare
- Provide effective and efficient solutions



1. Marketing, Drug Safety and Medical Affairs

Maximizing the Value of Growth Drivers for Patients

In a changing healthcare landscape characterized by demographic shifts and advances in life science and digital technology, the industry as a whole is expected to be seen as an ecosystem in which various stakeholders converge as one community that shares the goal of maximizing value for patients. To an increasing extent, making a contribution to patients requires a healthcare company to go beyond simply providing pharmaceuticals to offer comprehensive solutions that coordinate the functions of marketing, medical affairs and drug safety.

Under IBI 21, we will maximize the value of our growth drivers by providing solutions that include enhancing safety information and further incorporating digital technology to accurately meet increasingly sophisticated and diverse needs. Specifically, we will focus our efforts and resources on new products and growth drivers including Tecentriq, Hemlibra and satralizumab (SA237). We will achieve further growth and take every opportunity such as the smooth market introduction of Hemlibra and Edirol in China in cooperation with Roche.

In 2019, we conducted a wide-ranging rollout for Hemlibra, which obtained approval for the additional indication of hemophilia A without inhibitors. This included consulting activities for healthcare professionals and the provision of safety information to minimize the risk of adverse events. As a result, we made headway in both evaluations from and uptake by healthcare providers. We also made steady progress in expanding use of Tecentriq for non-small cell lung cancer and other indications.

Going forward, we intend to accelerate uptake of and obtain approval for Hemlibra in more countries as we promote further market penetration. We will also file for additional indications for Tecentriq, which is expected to be used in combination with existing therapies and to be effective for a wide range of cancers. For satralizumab (SA237), we filed applications in Japan, the United States and Europe in 2019, and will now focus on obtaining approval, a smooth launch and market penetration.

Advancing the Delivery of Effective and Efficient Solutions

Chugai is working on both functional and systemic enhancements in order to provide more sophisticated solutions and higher added value, which it considers essential for maximizing the value of its growth drivers. Accordingly, in our value delivery strategy we are enhancing organic collaboration with various specialists and incorporating digital technology for more advanced provision of information. We are promoting a more collaborative framework among the marketing, medical affairs and drug safety divisions, and we plan to utilize this framework to propose solutions that incorporate digital technology through cooperation between these three divisions and the Digital & IT Supervisory Division that we inaugurated in 2019.

In medical affairs, we will generate high-quality evidence, including evidence derived from real-world data (RWD), in addition to continuing post-marketing clinical studies. In drug safety, we will combine RWD with our existing post-marketing surveillance and safety information database tools to visualize safety evidence in real time. In marketing, on the basis of these various forms of data, we have developed a database tool that is adaptable to local healthcare delivery systems, and we will use it to propose treatment plans optimized for each patient.

- See "Focus 2: Digital Transformation" on page 52.
- See "Marketing" on page 83, "Medical Affairs" on page 85 and "Drug Safety" on page 86.
- See "Close-Up 2: Maximizing the Value of Hemlibra" on page 89.

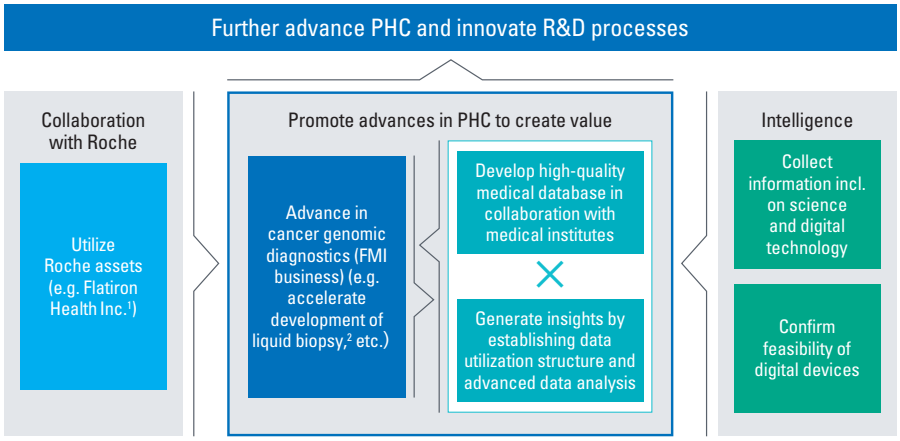
Strategy 3

Promote Advances in PHC

Realize further advancements in PHC and innovate R&D processes by utilizing digital technology and data.

Strategic Points

- Enable patient-centric PHC
- Establish a digital intelligence platform



1. A company that provides oncology-specific electronic health record systems and has a comprehensive database developed in collaboration with medical institutions. It became a member of the Roche Group in 2018.
2. Unlike a conventional biopsy, which uses an endoscope and needle to take a tissue sample, liquid biopsy is a technology that uses blood or other fluid samples to make a diagnosis and a prediction of therapeutic response.

Enabling Patient-Centric PHC

Chugai is a pioneer in PHC in Japan and a member of the Roche Group, a global leader in personalized medicine. Under IBI 21, we are focusing on promoting the next stage of PHC to provide the best treatment for each patient.

PHC, which administers treatments only to selected patients who are expected to benefit from them, is the main approach for realizing advanced and sustainable patient-centric healthcare, offering value for patients, healthcare finances and society. Backed by the recent dramatic progress in genomic medicine and data analysis technology, comprehensive genomic profiling has become possible. A representative example is our FMI business, which uses the technology of Roche Group member Foundation Medicine Inc. (FMI) to promote PHC through cancer genomic profiling. In 2019, we launched FoundationOne CDx Cancer Genomic Profile (F1CDx), a system for comprehensive cancer-related genomic profiling using next-generation sequencing, and also obtained approval for its use as a companion diagnostic for tumor-agnostic therapy Rozlytrek, which was also launched in 2019.

We will encourage and cooperate with regulatory authorities, scientific conferences, participating facilities and other parties to improve access to cancer genomic profiling and pursue synergies with Rozlytrek and other PHC-based products to accelerate uptake of cancer genomic diagnostics.

As an addition to the conventional biopsy method, we are also preparing to submit an application for a liquid biopsy test that reduces the burden on patients and raises the efficiency of medical facilities. We consider liquid biopsy to be a key factor for accelerating uptake of cancer genomic diagnostics, and are conducting focused efforts with the aim of filing an application during 2020.

Moreover, the evolution of digital devices and other developments have made it possible to obtain an immense amount of patient information in a timely manner, and to rapidly quantify a wide range of benefits for patients, including aspects such as quality of life as well as drug efficacy and safety. In close cooperation with government and academia, and in collaboration with the Roche Group, including Flatiron Health Inc., Chugai will help to collect real-world data (RWD), including cancer-related genomic information, and to establish a comprehensive database for regulatory compliance.

Establishing an Intelligence Platform Based on Digital Technology

For Chugai, innovation requires the use and upgrade of digital technologies, including the introduction of AI technology in drug discovery and all other functions, sophisticated data analysis, and RWD-based research and development. Our aim of building and reinforcing a Company-wide platform for utilization of digital technologies under IBI 21 is a theme that runs through Strategies 1, 2 and 3. In 2019, we formulated our vision for achieving digital transformation by 2030. As part of this vision, during 2020 we are laying out and getting to work on the priority areas for innovation in the drug discovery and development process and the value chain. We will concurrently invest management resources in acquiring and developing specialists, strengthening technologies and reforming our corporate culture to build and reinforce our platform for utilization of digital technologies.

Bonus Video

Saving Lives! Medic-boy's Big Adventure

https://www.chugai-pharm.co.jp/english/ir/ar2019/movie.html

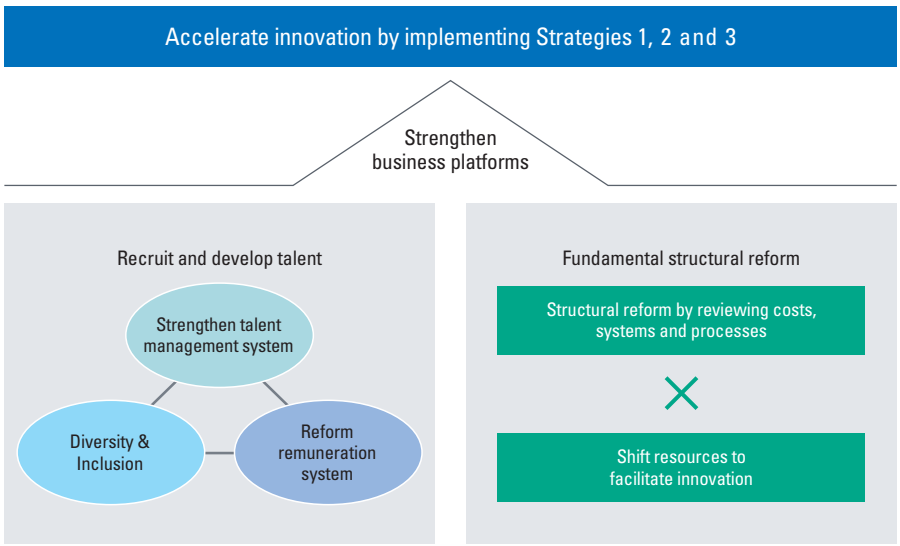
▶ See "For Reference: The Pharmaceutical Industry and Chugai's Business" on page 20.

▶ See "Focus 2: Digital Transformation" on page 52.

Strategy 4
Strengthen Human Capital and Conduct Fundamental Structural Reform

Recruit and develop diverse and high-caliber talent that supports innovation, and conduct fundamental structural reforms.

Strategic Points
- Develop and recruit talent from a medium- to long-term perspective
- Shift to a robust profit and cost structure



Developing and Recruiting Talent from a Medium- to Long-Term Perspective

Our people are an invaluable asset that drives Chugai's growth and progress. As we implement IBI 21 Strategies 1, 2 and 3, we will further strengthen human resource management from a medium- to long-term perspective, aiming to recruit, develop and assign diverse, high-caliber human resources who will drive innovation. In particular, to meet stakeholder expectations and create value in a rapidly changing business environment, it is important for employees to be able to think on their own in carrying out strategies with high quality and speed, in an organization that encourages taking on new challenges.

For a human resource strategy based on this stance, we have revised human resource requirements, and promote talent management and position management to assign the right people to the right positions. We also quickly identify and develop leaders and high-level specialists who can play a key role in implementing strategies. In addition, by further promoting diversity and inclusion, we will foster an organizational culture that is conducive to innovation, and encourages the active participation of diverse employees.

Based on these priority issues, we designed a new personnel system in 2019 (operation started in April 2020) that assigns the right people to the right positions with the aim of building a corporate culture that encourages taking on new challenges. This personnel system defines and communicates the duties, performance responsibilities and human resource requirements for all positions in the Company, and determines compensation based on the value of each position, thus facilitating independent career development and promotion. We will also abolish the age limit for management personnel to enable assignments regardless of age.

In formulating IBI 21, we conducted a survey to identify human resource issues. It indicated that our management system and our level of employee engagement were at a high level compared with other global companies, but also that our work environments and organizational culture, though comparing favorably to our domestic competitors, still showed room for improvement at the global level. We will therefore set detailed organizational reform tasks for each division and implement the PDCA cycle, in addition to making our survey results a key performance indicator for the final year of IBI 21.

Transforming Our Profit Structure by Conducting Fundamental Structural Reform

Chugai has established a profit structure comparable to that of major global pharmaceutical companies by conducting measures such as improving productivity to optimize costs, reducing its expense ratio and transferring the business rights of long-term listed products. However, given the increasingly severe business environment for pharmaceutical companies, including measures to curb drug prices, transforming our profit and business structure to allow a greater concentration of resources on innovation is a major issue in achieving sustainable growth.

Therefore, in order to raise funds and concentrate management resources for innovation, we will reorganize systems, fundamentally reform our business processes and cost structures, and take firm steps to streamline operations, including the introduction of digital technology and robotic process automation. We will also flexibly and proactively invest to upgrade core functions and capture growth opportunities.

In 2019, we worked to reform our cost structure by outsourcing operations that will not be part of future core businesses and functions. This enables us to increase automation and raise efficiency. We also made capital investments, including in our new research site Chugai Life Science Park Yokohama, and conducted new function and solution design measures. We will continue to conduct timely structural reform.

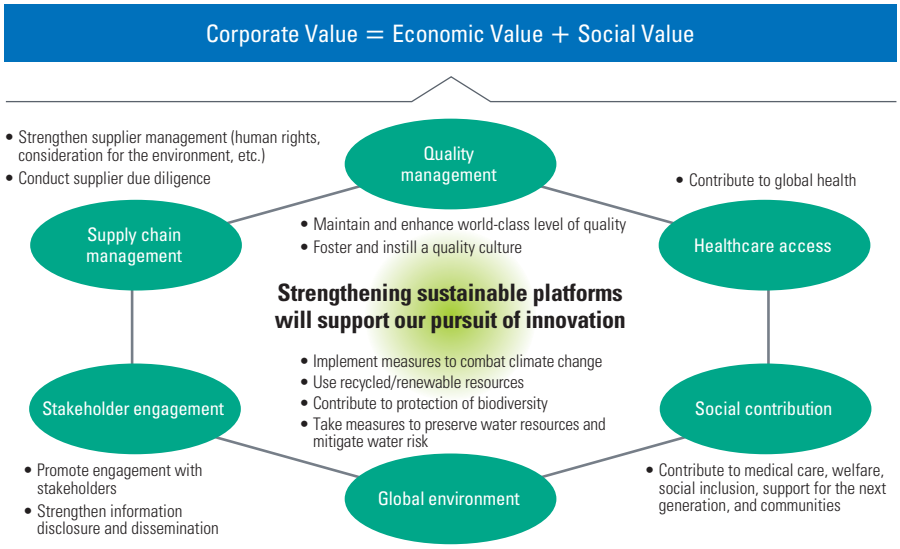
▶ See "Message from the CFO" on page 54.
- Concentration and Selection Are the Key to Structural Reform
- Main Fundamental Structural Reforms in 2019
- Balancing Investment for Value Creation and Shareholder Returns

▶ See "Human Resources" on page 90.

Strategy 5

Strengthen Sustainable Platforms

With the aim of improving corporate value continuously, we have specified six priority categories that support our drive for innovation, based on expectations and requests from society, Chugai's impact on the economy, society and environment, and stakeholder interest.



Strengthening Sustainable Platforms for Creating Shared Value

Chugai identified material issues for creating shared value with its stakeholders, in light of growing expectations and demands for the sustainability of the global environment and social systems, in addition to its contribution to patients and healthcare. In formulating Strategy 5 of IBI 21, "Strengthen Sustainable Platforms," we specified six areas from among the medium- to long-term material issues for the sustainable platforms that should be prioritized during the plan.

Progress was steady in 2019 as relevant divisions worked together in each area. We have set targets for each category of the material issues, but we will continue to examine the appropriateness and adequacy of the targets as we enhance external disclosure to be able to accurately share our progress toward the targets both inside and outside the Company.

Material Issues in Six Categories

Quality Management

We will work to maintain and enhance our world-class level of quality, a key factor in the value of our products and services. In light of recent demands for data integrity, we are working in particular on organizing quality requirements for cross-divisional management of good practice guidelines and regulations (GxP) for pharmaceuticals.

At the same time, going beyond GxP in the belief that each employee's awareness of quality in their daily duties has a profound impact on quality in the four areas of products, information, processes, and human resources, we will hold quality meetings in each division and overseas subsidiary to foster a quality mindset in our workplaces.

Supply Chain Management

It is essential to work with suppliers to help resolve social issues such as poverty, growing inequality, environmental problems and worsening working conditions. Chugai has therefore established guidelines and a comprehensive evaluation system for conducting supplier management in the areas of human rights and the environment, in addition to its existing efforts for stable supply and quality control. In 2019, we used this evaluation system in conducting due diligence based on the principles of the Pharmaceutical Supply Chain Initiative (PSCI). Specifically, we are setting priorities in the event that human rights and environmental risks materialize, based on factors such as the impact on the Company and society and the difficulty of selecting alternatives, and conducting risk assessments.

Healthcare Access

Up to now, Chugai has contributed to global health through the GHIT Fund and Access Accelerated, and we will expand our activities as a core theme of IBI 21. In 2019, we joined the World Federation of Hemophilia Humanitarian Aid Program together with the Roche Group. In addition, employees visited Myanmar to collect feedback and better understand the needs for our local projects, which include the promotion of safer hospital childbirth and maternity healthcare, and measures for people living with noncommunicable diseases. Since the nature of specific issues varies by country and region, we will continue to conduct activities that closely match actual circumstances in each location.

Social Contribution

At the start of IBI 21, we formulated Chugai's basic stance on social contribution and set five priority themes for Chugai's engagement: medical care, welfare, social inclusion, support for the next generation, and local communities. In 2019, we designed measures for each theme and worked to enhance the substance of our activities. In the area of social inclusion, based on our experience in promoting para-sports, we sponsored art exhibitions, concerts, workshops and other events where everyone could express themselves freely, whether disabled or not, to realize an inclusive society looking ahead. In the area of communities, our activities included working with a non-profit organization to support the early operation of emergency shelters in areas damaged by a series of typhoons in 2019, and we intend to further enhance these activities going forward.

Global Environment

In addition to actively contributing to measures to combat climate change, increase the use of renewable and recycled resources and protect biodiversity, we also work to mitigate water risk and preserve water resources, which are especially critical to the pharmaceutical industry. We set and have been advancing toward mid-term environmental goals for 2020, when we will set the next mid-term environmental goals.

An area of particular focus among global environmental issues is combating climate change, and to improve environmental performance we are employing state-of-the-art design in the construction of Chugai Life Science Park Yokohama, with the intention of enhancing our management system and measures. In response to the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD), we conducted a scenario analysis in 2019 based on the TCFD framework, which considered topics including strengthening governance for climate change countermeasures as well as an analysis of risks and opportunities and their financial impact. We announced our support for the TCFD recommendations in February 2020, and will continue working to further address climate change risks and opportunities and enhance information disclosure. In addition, our progress in combating climate change has been positively evaluated, receiving a Carbon Disclosure Project (CDP) score of "B" in 2019, up two ranks from the previous year. We are not satisfied with this score, and will continue to step up our efforts.

Stakeholder Engagement

More proactive dialogue and engagement with individual stakeholders is a central part of our drive to create shared value. Other priorities will include strengthening disclosure and information dissemination, two-way communication, and creating new dialogue opportunities.

As a new initiative in 2019, we held an ESG meeting for shareholders, investors and the media in June. Representative Director & Deputy Chairman Motoo Ueno, who is in charge of the Sustainability Department, received a great deal of valuable feedback from dialogue with attendees. We plan to continue holding presentations in the future.

- See "Message from the Deputy Chairman" on page 34.
- See "Chugai's Material Issues" on page 37.
- See "Targets and Indices for Material Issues" on page 38.
- See "Quality and Regulatory Compliance" on page 87, "Human Rights" on page 93, "Environment, Health and Safety" (Mid-Term Environmental Goals) on page 94, and "Social Contribution and Global Health" on page 97.

Gap Analysis of ESG Surveys and Progress

When identifying the material issues that it must address in order to create shared value, Chugai conducted a gap analysis between its ESG initiatives and the evaluation items in global ESG surveys used for the Dow Jones Sustainable Indices, MSCI indexes, and FTSE Russell indices, among others. These external surveys reflect at a high level the advanced ESG initiatives that investors demand. We have decided to continuously conduct gap analyses against these surveys, using the items in them as benchmarks to quantitatively and objectively gauge the changing expectations and demands of society and to identify issues. In this way, we are enhancing our foundation for sustainable growth.

In 2019, our ESG evaluation showed improvement in multiple categories, as illustrated in the chart on the left, and our overall score also rose. However, in comparison with highly-rated companies globally, we still have more to do. In 2020 and beyond, we will continue to set priorities to strengthen sustainable platforms, and carry out new initiatives in the areas of climate change risk mitigation and healthcare access.

Main Categories in Which Chugai Improved in 2019 External Evaluations

Category	Assumed Reasons for Improved Evaluation
Supply chain management	Formulated Supplier Code of Conduct Formulated guidelines for assessment of EHS compliance risk
Human rights	Formulated Human Rights Statement
Global environment	Received external assurance audit of water consumption
Healthcare access	Formulated Basic Approach to Global Health
Material issues	Identified material issues and disclosed the process for doing so
Social contribution	Formulated Basic Concept of Social Contribution Activities

Policies for Initiatives during IBI 21 (Planned)

Policy	Categories
Further enhancement of initiatives	Supply chain management, human rights, global environment, material issues
Promotion of new initiatives	Analysis of climate change risks and opportunities, healthcare access, corporate governance, tax strategy, talent development

FOCUS 1
Evolution of Antibody Engineering Technologies

Maximize the value of drug targets → **Create drugs for undruggable targets and modes of action**

From 1990	From 2005	From 2008	From 2012	From 2018
Humanized antibodies	**Engineering to create best-in-class antibodies** • Stability improvement • Pharmacokinetic improvement • Deimmunization beyond humanization • ADCC[1]/ADCP[2] enhancement	**Engineering to create antibodies with unique modes of action** • Bispecific antibody • Recycling antibody® • Sweeping antibody® • FcγRIIb selective Fc • T cell redirecting antibody (TRAB®)	**Engineering to confer disease tissue/cell specificity** • Switch Antibody™ • Second-generation TRAB® • Others	**Engineering to expand sites of action**

1. Antibody-dependent cellular cytotoxicity 2. Antibody-dependent cellular phagocytosis

Positioning of Antibody Engineering Technologies at Chugai

Chugai has three modalities (therapeutic approaches) in drug discovery research: small molecules and antibodies, in which it has proven strengths and accomplishments, and middle molecules, in which it is focusing on the establishment of new technology. In therapeutic antibodies, we have demonstrated our drug discovery capabilities by creating many innovative medicines and developing proprietary technologies. Now, we are taking these capabilities further.

Innovation of therapeutic antibodies will require an evolution in technologies such as antibody engineering, biology and platforms. "Biology" refers to deep understanding of pathology and the investigation of target molecules and modes of action. "Platforms" are the research infrastructure that we have systematically established. We have clear competitive advantages in platforms in particular, including a high-throughput system for obtaining candidate antibodies; COSMO,[3] a system that enables optimization of candidate antibody molecules ten times faster than was possible just a few years ago; and a deimmunization platform.[4] These platforms allow us to rapidly and efficiently actualize and evaluate drug discovery ideas that utilize our proprietary technologies.

Our antibody engineering technologies have steadily changed and advanced since we began working on creation of humanized antibodies in 1990. In contrast to previous technologies for improving properties such as pharmacological activity and pharmacokinetics, our initiatives in recent years have involved technologies that significantly change our overall approach to drug discovery through unique modes of action and cell specificity, and are expanding the possibilities for using therapeutic antibodies in medicine.

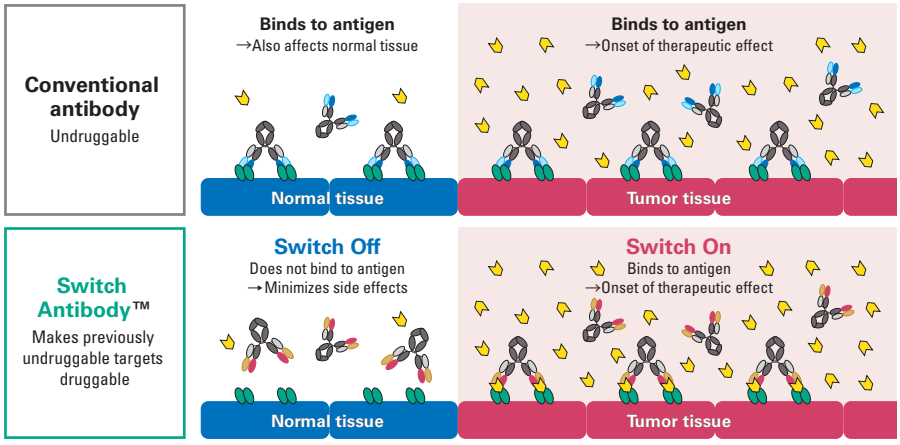
3. Acronym of COmprehensive Substitution for Multidimensional Optimization
4. A research platform technology to evaluate the immunogenicity of proteins containing antibodies in order to minimize the risk of anti-drug antibody production in the clinical setting.

Applications of New Antibody Engineering Technologies

1) Expanding the Scope of Drug Discovery

Chugai's novel antibody engineering technologies open up two promising directions in drug discovery. One direction makes it possible to approach new targets that were previously undruggable with the Recycling antibody, bispecific antibodies and other existing technologies.

Switch Antibody™



: Switch molecule. Expressed in high concentrations in tumor tissue.

Projects Utilizing New Antibody Engineering Technologies

	Discovery	Preclinical	Clinical		Launched
Recycling antibody® Sweeping antibody® Others	2	1	• satralizumab • SKY59 (crovalimab) • GYM329/RG6237	• nemolizumab • AMY109	
Bispecific antibodies (1st, 2nd and 3rd generation)	7		• ERY974	• NXT007	• Hemlibra
Switch antibody™	6	1			
Antibodies applying other new technologies	2	1			

Our Sweeping antibody is a recycling antibody engineering technology that has been further engineered to eliminate, or sweep, target antigens from plasma. By combining the Sweeping antibody with technologies including TwoB-Ig, which selectively increases binding to an Fc receptor called FcγRIIb, we successfully moved in-house project GYM329 into clinical development in 2018.

A noteworthy new technology that we announced in 2019 is the Switch antibody (small molecule-dependent antigen binding). One of the remaining challenges in the development of antibody drugs is on-target toxicity, in which toxicity increases in normal tissue when the antibody binds to the target molecule. Severe toxicity has been observed in projects by many pharmaceutical companies, in some cases resulting in the cancellation of development. Chugai's Switch antibody is a technology that solves this problem. By focusing on a small molecule (the switch molecule) called adenosine triphosphate (ATP), which is present at high extracellular concentrations in tumors, the Switch antibody is designed to "switch on," or bind to the target antigen, only in a tumor microenvironment, where the concentration of extracellular ATP is high, but to "switch off," or not bind to the antigen, in normal tissue, where the concentration of extracellular ATP is low. As a result, target molecules that have been undruggable due to the increase in toxicity can be made druggable, greatly extending the boundaries of drug discovery. We are currently conducting discovery projects utilizing this technology. One project is scheduled to enter clinical development in 2020 and six more are in the discovery stage.

2) Creating Novel Modes of Action

The other promising direction that we want to explore with new antibody engineering technologies is the creation of novel modes of action. By combining technologies such as the next-generation bispecific antibody and the Switch antibody, we will further broaden the possibilities for innovative drug discovery, with our sights set on curing or completely managing diseases.

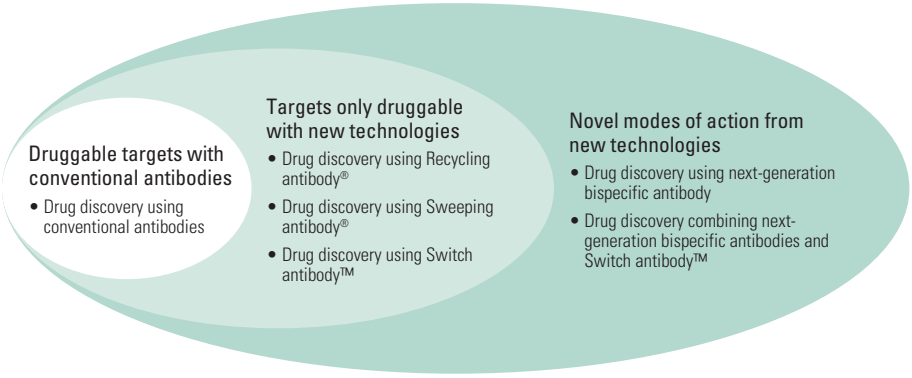
The first-generation bispecific antibody engineering technology used in Hemlibra has common light chains, but the second-generation technology uses different light chains to make more diverse antibody designs possible. The third-generation technology enables antibodies to not only bind to two types of antigens, but also to control the form of bonding with two different antigens. Moreover, while our Switch antibody switches on or off in response to ATP concentration, it can also be engineered to do the same for changes in concentration of other small molecules in specific environments. This will make it possible to target not only cancer, but a wide range of other diseases, and to actualize innovative drug discovery ideas.

When these drug discovery approaches become possible, coming up with ideas will be even more important. In addition to further developing its technologies, Chugai is working to accelerate generation of new ideas through a focus on biology research, TACTICS, and other initiatives. We believe that these initiatives will be essential for maximizing the use of our antibody discovery technologies, for which the possibilities are broadening further.

For details on new antibody technologies, refer to the Information Meeting on Antibody Engineering Technologies (webcast) held on December 9, 2019.

https://www.chugai-pharm.co.jp/english/ir/reports_downloads/presentations.html#sec_85

Application of Antibody Engineering Technologies



The Potential of Antibody Engineering – a Researcher's View

No technology can keep its competitive advantage for very long, no matter how great it is. Technologies must constantly evolve, and that requires utilizing and linking our stock of technologies and expertise. For example, realizing the Switch antibody technology was only possible because we had independently developed the Recycling antibody technology (pH-dependent antigen binding).

Such innovation cannot be achieved without overcoming numerous difficulties, but we are able to do so because we always have the patients in mind. In the creation of Hemlibra, our discovery research was driven by our strong belief that this drug would offer significant value to people with hemophilia and to their families, and that we absolutely had to make it available. Later on, the letters we received from people who had used Hemlibra made us very happy because they confirmed again that our aspirations during research had become a reality.

The purpose of our drug discovery research is to provide medicines that offer true value to patients and society. New antibody engineering technologies can also be expected to lead to the creation of drugs for diseases for which there are currently no treatments, and may lead to new biological discoveries and the innovation of treatment methods. We are striving to be a top innovator in the healthcare industry that contributes to patients and society not only through the innovative medicines we create, but also through the advancement of technology and life science.

Zenjiro Sampei
Head of Discovery Biologics Group 3, Discovery Biologics Dept.

FOCUS 2
Digital Transformation

Chugai's Digital Transformation Goal

New scientific methods that make use of technologies such as AI as well as real-world data (RWD) and evidence are emerging as a result of rapid advances in IT and digital technology. Moreover, amid growing measures to restrain healthcare costs, there is increasing need for pharmaceutical products with true value for patients.

To become a top innovator in the healthcare industry, Chugai is accelerating innovative drug discovery and uncovering opportunities to advance PHC by combining its existing strengths with advanced digital technology. One advantage we have is our ability to generate synergy with Roche through our access to the resources of the Roche Group, a leader in applying digital technology.

Under IBI 21, acceleration of our digital strategy is included in Strategy 3. We aim to further advance PHC and optimize the entire pharmaceutical value chain by concentrating resources for a digital transformation clearly distinct from earlier digitalization efforts. In October 2019, we established the Digital Strategy Department to oversee the digitalization measures of each department. We also formulated Chugai Digital Vision 2030 and a roadmap to achieve it.

CHUGAI DIGITAL

Logo that embodies the Digital Vision

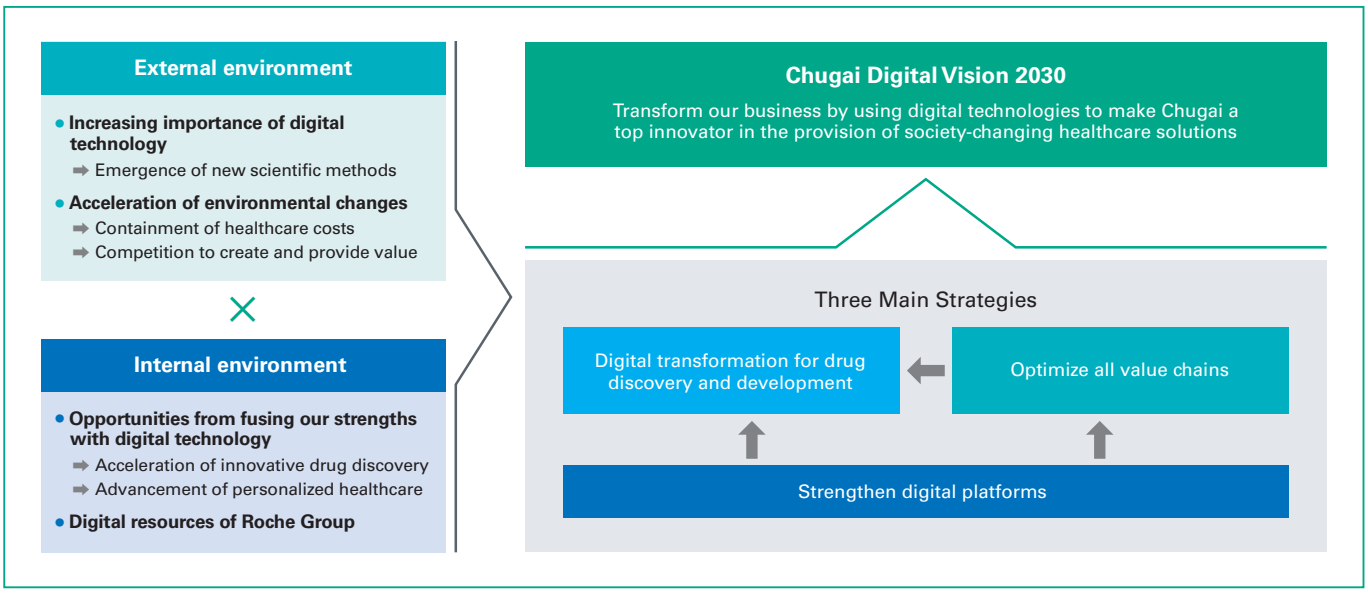
Three Main Strategies

To strengthen our digital platforms, we will develop both hardware and software solutions. We aim to establish world-class IT platforms through the integration of internal data and creation of a data analysis platform in cooperation with Roche. Additionally, we will establish and operate a Digital Innovation Lab to support employees in generating new ideas and taking on challenges, and will identify, acquire and develop the digital talent we need.

To optimize all value chains, we will use digital technology to dramatically boost the efficiency of each department and function, in particular production and marketing processes. Through comprehensive analysis of customer data, we will also commence development of new solutions to enhance the customer experience.

To create innovative drugs by leveraging digital technology, we will improve our capabilities in AI, RWD and digital biomarkers (dBMs) to achieve digital transformation for Drug Discovery and Development (DxD3) in a way that only Chugai can, with the aim of achieving true PHC. Using AI and other cutting-edge technologies, we will work to transform drug discovery, improve the development success rate, and promote labor-saving and automation of various tasks. We will also collaborate with top-tier partners such as Preferred Networks, Inc. In addition, we will develop dBMs to refine and improve outcome indicators from the patient's perspective, and provide support for treatment decisions through the use of wearable devices to monitor disease and health status. Other initiatives planned include renewal of our clinical development strategy and enhancement of evidence in clinical practice based on dBM and RWD.

Chugai Digital Vision 2030



A Strategy and Roadmap for Risks and Opportunities 10 Years from Now

Digital transformation (Dx) means using digital technology to transform products, services and the business model based on the needs of customers and society, as well as transforming business processes and the corporate culture to establish a competitive advantage. The wave of digital disruption that began sweeping through industries such as communications and finance several years ago has now reached the world of pharmaceuticals. Drug development involves multiple processes and takes many years. The cost of researching, developing and bringing to market a single drug has increased roughly 2.5 times over the last decade. The potential to achieve a high success rate in less time at a lower cost by applying AI and other digital technologies to enable high-speed analysis of various data in the drug development process is already being explored. We thought about how society and our industry will have changed 10 years from now, in 2030, and the risks and opportunities those changes will present. Based on that, we created Chugai Digital Vision 2030 to describe what Chugai should be in the future, as well as a digital strategy and roadmap to achieve this vision.

Satoko Shisai
Vice President
Head of Digital & IT Supervisory Div.

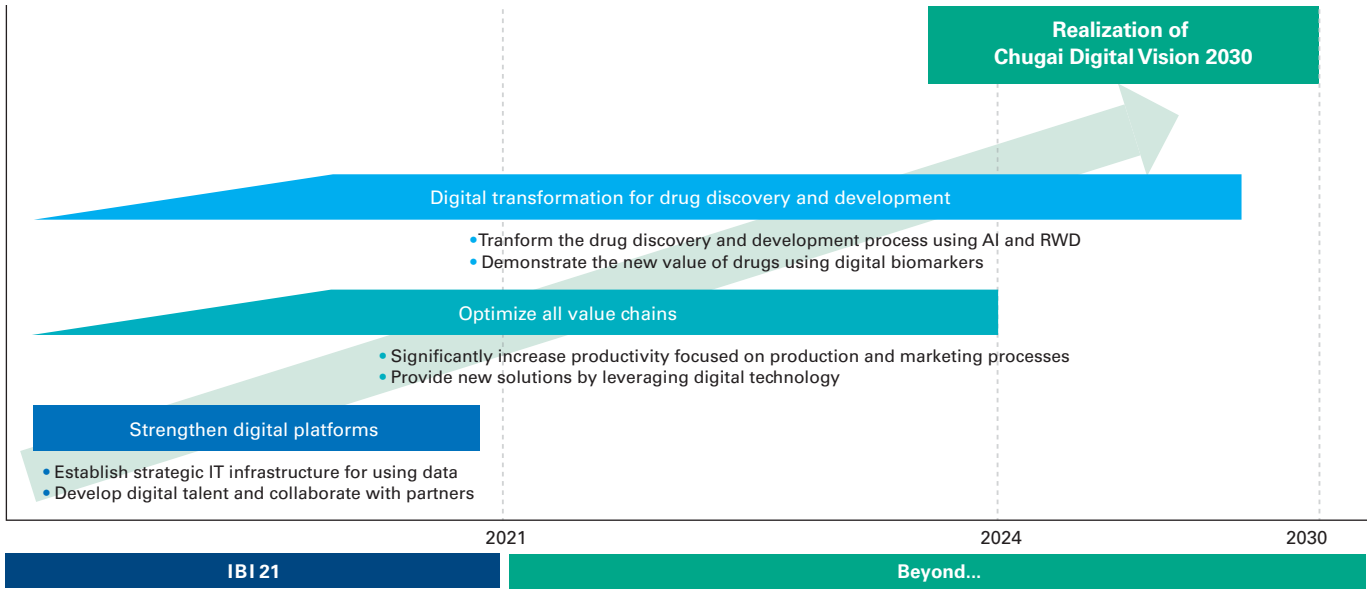
A Digital Strategy That Reflects Chugai's Unique Characteristics

This digital strategy reflects some of Chugai's unique characteristics. First and foremost, its vision and priority areas are aligned with Chugai's Envisioned Future and management strategies. It will accelerate and enhance the implementation of our IBI 21 strategies of Value Creation, Value Delivery and Promote Advances in PHC. It will also help us to achieve our goal of becoming a top innovator in the healthcare industry.

Next, as for implementation, we will focus on innovation by fusing business and IT. The Digital Strategy Department was launched in 2019 as a team of 23 people from eight different departments. Members were selected not only for their IT skills but also their understanding of business based on their diverse careers, which facilitates smooth communication with other departments. In addition, each business department has appointed a Digital Leader who works with the Digital Strategy Department by sharing and executing digital projects. As a result, unified efforts are being made to help enhance the value of each business department and upgrade the Company's operations.

The third characteristic of the digital strategy is our plan to transform the technology that supports our digitalization, as well as the culture of the Company. Rather than carrying out siloed digital initiatives in each department, we will foster a culture in which employees from different parts of Chugai are encouraged to exchange ideas and share examples, leading to the creation of new cross-departmental projects. Based on the strong support of the CEO, we have held workshops for management from the department manager level and up, as well as events at the Company-wide level to promote "Chugai Digital." We will also make use of the Digital Innovation Lab to generate digital projects based on new ideas of employees, with the aim of fostering a culture suggested by taking on new challenges without fear of failure, even when there is uncertainty. In addition, continuously publicizing "Chugai Digital" externally will lead to creation of new value in collaboration with outside partners and digital talent.

Roadmap to 2030



Message from the CFO

We are currently enjoying growth momentum. Nonetheless, we will remain vigilant and forge ahead with further structural reforms and innovation. We will also keep the balance of economic and social value in mind in our dialogue with stakeholders.

Toshiaki Itagaki

Executive Vice President & CFO
In charge of Finance & Accounting, Corporate Communications, Purchasing, Digital Strategy and IT Solution

The Global Expansion of Chugai Products is Driving Our Growth Momentum

Mid-term business plan IBI 21 got off to a strong start in 2019, as results exceeded expectations. Chugai made significant upward revisions to its financial forecasts during the year, yet still outperformed the revised figures with revenues of ¥686.2 billion (up 18.4 percent year-on-year), Core operating profit of ¥224.9 billion (up 72.6 percent) and a ratio of operating profit to revenues of 32.8 percent. It was our third consecutive year of record revenues and profit.

We expect revenues and profit growth to continue in 2020. Our targets are revenues of ¥740.0 billion (an increase of 7.8 percent year-on-year), Core operating profit of ¥275.0 billion (up 22.3 percent) and a ratio of operating profit to revenues of 37.2 percent. In addition, we have raised the IBI 21 target for Core EPS CAGR,[1] our financial KPI, from the high single digits (7-9 percent range) to around 30 percent. As with IBI 18, the previous mid-term business plan, we will make IBI 21 another three years of high growth.

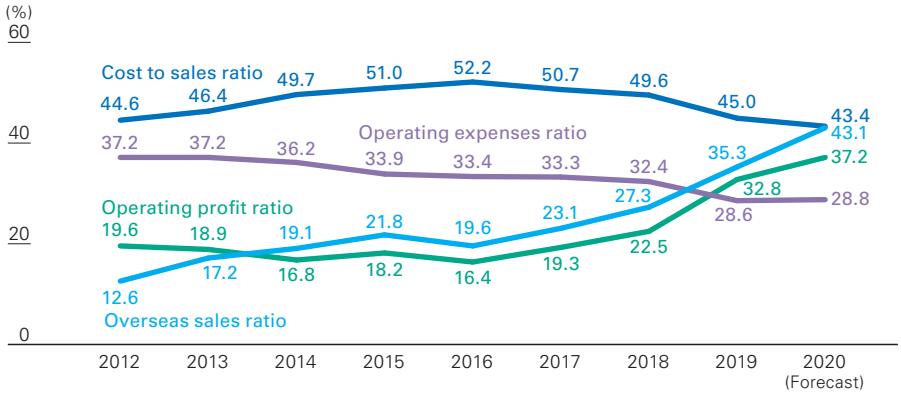
Chugai's growth momentum over the past few years has been driven by the global expansion of innovative products from in-house research. Our business outside Japan consists of our own sales through overseas affiliates plus export business through Roche's network, the latter being particularly strong. Actemra, Alecensa and Hemlibra are all manufactured and exported by Chugai and sold by Roche worldwide (except in Japan, Taiwan and South Korea). The ratio of overseas revenues to total revenues has surged in seven years to 35.3 percent from 12.6 percent. Contributions to profit by export business have also increased dramatically. The cost to sales ratio for our products is lower than that for in-licensed products. Therefore, as our product sales expand worldwide, they account for a larger proportion of profit, thus increasing our gross profit margin. Royalties and other income that we receive based on Roche's sales go directly into operating profit. For that reason, the creation and global expansion of innovative medicines from in-house research are vital to our sustainable growth and a high-profit business structure.

1. Core earnings per share compound annual growth rate

Defending Value Creation Capabilities in a Tough Domestic Market

Our business in Japan, on the other hand, will be facing headwinds for some time to come. In 2020, growth products Perjeta, Actemra and Hemlibra are subject to repricing based on market expansion. Avastin and Xeloda, which have been domestic revenue drivers, will lose premium pricing status, leading to

Earnings Structure



* Cost to sales ratio is the comparison of product sales to total sales.
Overseas sales ratio, operating expenses ratio and operating profit ratio are comparisons to revenues.

a substantial cut in the prices for both products. In addition, the launch of biosimilars and generics will bring fierce competition to mainstay products Avastin, Herceptin, Rituxan, Xeloda, Edirol and Mircera. In these challenging conditions, we are projecting negative growth of 5.9 percent for domestic revenues in 2020. In 2021 and beyond, drug price revisions will be implemented annually, and other healthcare cost-containment measures may be implemented and strengthened, and the market itself is expected to shrink.

In terms of size, Japan accounts for no more than about seven percent of the global market. Increasing the proportion of revenues from overseas is necessary for Chugai as it seeks to be a top innovator in the healthcare industry. Nevertheless, Japan is where our research, development, production, marketing and all other supply chains are located, and its importance as a business area will not change.

Even in an age of increasing uncertainty marked by the evolution of drug discovery modalities, the advancement of digital technology, the entry of competitors from other industries, and restrictions on drug detailing and sales promotion, Chugai will remain focused on innovation. This is because solving social issues with innovation is our mission, and without innovation we cannot grow. The networks we have built with academia, medical institutions and healthcare professionals, startup companies, suppliers and others will be instrumental in creating and delivering innovative medicines with world-class quality. We will maintain and strengthen this foundation.

Concentration and Selection Are the Key to Structural Reform

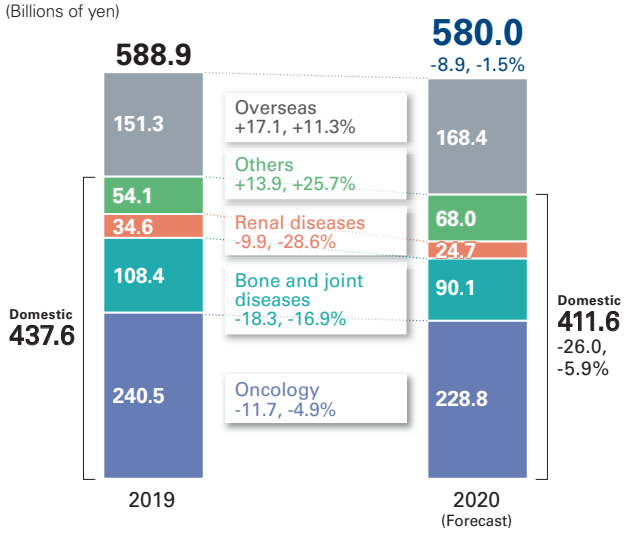
Since the alliance with Roche began, Chugai has continued business process re-engineering (BPR) and other cost optimization initiatives. Although profitability has increased to a certain extent, there is still room for improvement in productivity and efficiency.

We cannot afford to be complacent about our current growth momentum. We have made fundamental structural reform one of the growth strategies in IBI 21 to further establish a solid cash generation cycle. Our basic policy for structural reform is concentration and selection. We will upgrade core functions by concentrating resources in innovation and improve business efficiency in ways such as using shared services and business process outsourcing (BPO) for selected non-core businesses and functions.

Specific activities in 2019 are summarized in the chart on the next page. As a move toward "concentration," we decided to establish the new Chugai Life Science Park Yokohama and close the Fuji Gotemba and Kamakura Research Laboratories. Other initiatives included the start of construction on a new manufacturing facility for active pharmaceutical ingredients (APIs) for small and middle molecule drugs, the launch of the FMI business, and in-licensing of an oncolytic viral immunotherapy. We also began improving our business foundation to support growth by establishing the

2020 Sales Forecast

(Billions of yen)



Change in Sales of Main Products

	Sales Forecast	Year-on-Year Change (Billions of yen/%)
Overseas		
Hemlibra	23.9	+20.3 (+563.9%)
Alecensa	39.0	-6.3 (-13.9%)
Others		
Hemlibra	42.1	+16.9 (+67.1%)
Foundation Medicine	4.5	+4.1 (11 times)
Tamiflu (ordinary)	3.4	-4.0 (-54.1%)
Renal diseases		
Mircera	15.4	-6.8 (-30.6%)
Bone and joint diseases		
Edirol	26.1	-10.6 (-28.9%)
Oncology		
Tecentriq	44.6	+24.0 (+116.5%)
Kadcyla	11.7	+2.7 (+30.0%)
Perjeta	28.8	-1.9 (-6.2%)
Xeloda	3.1	-4.9 (-61.3%)
Rituxan	6.3	-5.6 (-47.1%)
Herceptin	19.2	-7.5 (-28.1%)
Avastin	73.3	-22.3 (-23.3%)

Digital & IT Supervisory Division to lead Company-wide digital and IT strategies. Initiatives for "selection" included the transfer of long-term listed products (off-patent branded drugs) and the sale of all shares in C&C Research Laboratories, the sale of cross-held stock, the decision to outsource logistics and packaging operations, the implementation of an early retirement incentive program, the introduction of robotic process automation for back-office tasks, and the integration of expense and payment systems.

Going forward, we will also focus on strengthening our digital infrastructure and on initiatives for utilizing and applying AI, ICT and real-world data. While proactively pursuing collaboration with academia and startups for drug discovery that combines biology and technology, we will also consolidate redundant functions that overlap our corporate organization, divisions and subsidiaries.

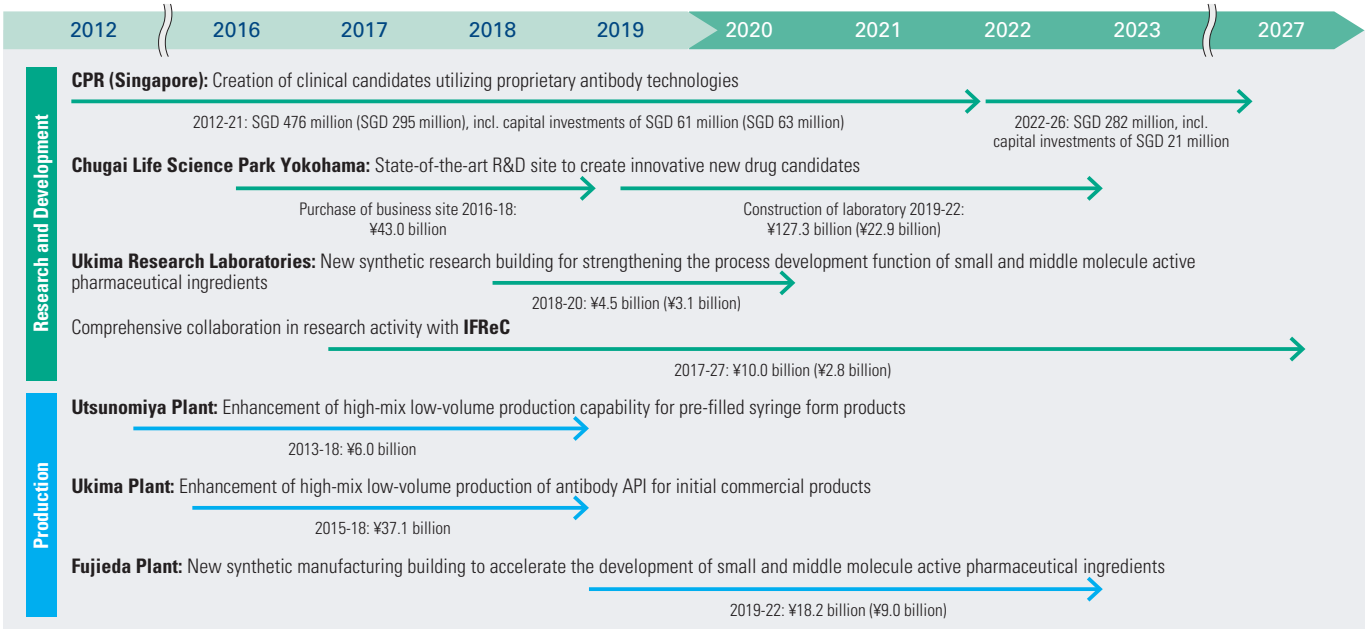
Balancing Investment for Value Creation and Shareholder Returns

Chugai believes that the establishment of middle molecule technologies to complement its small molecule and antibody technologies will lead to drug discovery innovation, and has therefore been conducting related research and development for more than a decade. With a middle molecule candidate about to move into clinical trials, we have started construction of a synthetic research building and manufacturing facility for middle molecule APIs and other compounds. In addition, investment in Chugai Life Science Park Yokohama has begun in earnest, comprehensive collaboration with Osaka University Immunology Frontier Research Center (IFReC) has entered the joint research stage, and we have decided to continue investing in Chugai Pharmabody Research in Singapore. We are also proactively investing in efficiency, productivity and other improvements across the supply chain with AI use in drug discovery, digitalization and utilization of digital information, and use of ICT. Furthermore, if opportunities arise, we will allocate

Main Fundamental Structural Reforms in 2019

Concentration Upgrading of innovation and core functions	• Entered into exclusive licensing agreement for Telomelysin and capital tie-up agreement with Oncolys BioPharma Inc. (Announced April 8) • Construction of new manufacturing facility for APIs at Fujieda Plant (Announced April 24) • Decided to construct Chugai Life Science Park Yokohama and close Fuji Gotemba Research Laboratories and Kamakura Research Laboratories (Announced May 21) • Launched genomic mutation analysis program and began providing testing services (June 3) • Comprehensive alliance with Preferred Networks, Inc. extended for two years (September 1) • Established Digital & IT Supervisory Div. to lead integration of Company-wide digital and IT strategy (October 1) • Established Marketing & Sales Planning Dept. and made Business Development Dept. and Intellectual Property Dept. corporate organizations (October 1)
Selection Increase of efficiency through business concentration and outsourcing	• Introduction of Concur Expense as expense management system (January 1) • Business transfer of UlcerImin to Fuji Chemical Industries Co., Ltd. by September 30, 2019 (Announced April 1) • 172 people retired at end of June under early retirement incentive program • Full outsourcing of logistics operations to Mitsubishi Logistics starting in January 2021 (Announced June 14) • Introduced and began using robotic process automation for Company-wide back-office tasks • Transferred rights for Oxarol Ointment and Oxarol Lotion to Maruho Co., Ltd. (Completed December 1) • Transferred shares of C&C Research Laboratories in Korea to JW Pharmaceutical Corporation (Completed by December 31, 2019)

Current Status/Plan for Major Investments



( ): Cumulative amount as of December 31, 2019

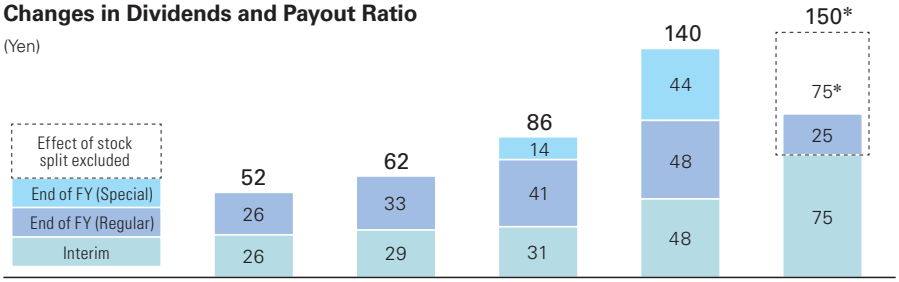
funds to drug discovery technologies and modalities, in-licensing of development projects to supplement our pipeline, and cooperation and capital alliances with startup companies.

Innovation in the age of VUCA[2] will require greater diversity in human capital, technologies, information and funding. Amid remarkable advances in life science and digital technology, creating new business value will require a strong financial footing that enables flexible and focused strategic investments.

After considering factors including the variability of earnings growth and the strength of our financial base going forward, we changed our target Core EPS payout ratio to 45 percent on average from 50 percent on average. This will better position us to maintain stable dividends.

2. VUCA: Acronym for volatility, uncertainty, complexity and ambiguity

Changes in Dividends and Payout Ratio



		2016	2017	2018	2019 End of FY: Plan	2020 Forecast
Core payout ratio	5-year average	49.2%	48.4%	48.6%	47.4%	45.0%
	Single FY	50.7%	44.7%	48.7%	45.8%	41.0%

* Three-for-one split of ordinary shares planned for July 1, 2020. Amount shown excludes effect of the stock split.

Managing Efficiency with KPIs That Fit Our Business Model

We use Core EPS CAGR as one of our financial KPIs in the mid-term business plan. The intention behind this can be explained in terms of our expanded formula for return on equity (ROE). Chugai specializes in biopharmaceuticals, which have long production lead times, and we have to keep safety stocks because many of our products have a large market share. Consequently, our ability to increase the asset turnover ratio is limited. Moreover, to maintain management independence in our alliance with Roche, we must keep Roche's shareholding ratio within a certain range, so our ability to use share buybacks to increase financial leverage is also limited. Therefore, the key to raising ROE is to increase the profit margin in our core business. For that reason, we use Core EPS CAGR as a mid-term financial KPI to show sustainable growth of the margin in clear terms from the viewpoint of shareholders.

We are also mindful of the cost of capital. When developing medium- to long-term business plans, we set out our growth strategy by factoring in the equity spread to clarify the gap between targets and current conditions. In assessing the business feasibility of investments and development projects, the concept of cost of capital is built into our internal decision-making processes and mechanisms in ways such as calculating present value by discounting at the weighted average cost of capital (WACC).[3]

In addition, in 2019 we began using ROIC[4] as a long-term financial KPI. In the pharmaceutical business, new drugs are brought to market at a success rate of one in tens of thousands, despite large investments over long periods of time. For that reason, we believe that it is necessary to use material accounting to manage with long-term investment efficiency in mind, and not be swayed by short-sighted thinking about earnings.

Core ROIC in 2019 was 31.9 percent, which is well above WACC, a return on investment that shareholders and other capital providers expect. As such, we judge that management is maintaining high capital efficiency.

3. The most common method of calculating cost of capital, WACC is the weighted average of the cost of borrowing money and the cost of raising funds through equity.
4. ROIC indicates how efficiently a company uses capital invested for business activities (invested capital) to generate profit.

Dialogue from Financial and Non-Financial Perspectives

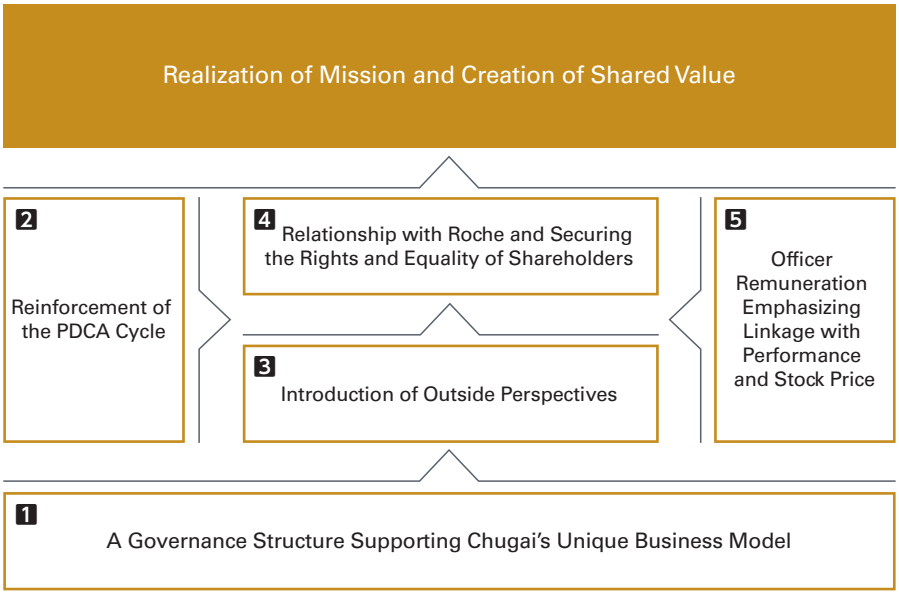
Chugai has been using various media to carry out timely and appropriate disclosure about its Envisioned Future, strategies and specific initiatives, including ESG, and their progress. We have also been focusing on balanced dialogue.

In 2019, these efforts included visits from investors, media briefings, individual interviews and briefings for more than 350 domestic and overseas investors and analysts, and CEO roundtable conferences. We held a first-ever ESG meeting for analysts and investors, and introduced Chugai's new technologies at a presentation on antibody engineering technologies. Other activities included an online briefing for individual investors and our participation in joint investor briefings and conferences. Overall, we had more opportunities for dialogue than ever before.

Our market capitalization as of December 31, 2019 exceeded ¥5 trillion, growing 60 percent from the beginning of the year, and ranked 14th among companies on the First Section of the Tokyo Stock Exchange (ranked 10th at ¥6.6 trillion as of February 29, 2020). We see this as evidence that our shareholders and other stakeholders understand and support our initiatives, including not only the economic value we provide but also the social value of our ESG activities. This has given us confidence, but at the same time, a strong sense of responsibility to live up to expectations.

Chugai's business partner, Roche, is also the Company's largest shareholder. Under these circumstances, we recognize the importance of fair and open communication with minority shareholders. We will continue to engage with shareholders in balanced dialogue, with transparency and fairness in mind, and look forward to receiving honest opinions and feedback.

Enhancement of Corporate Governance



Chugai's Corporate Governance

Chugai's Mission is to dedicate itself to adding value by creating and delivering innovative products and services for the medical community and human health around the world. Under this Mission, Chugai aims to achieve the advanced and sustainable patient-centric healthcare set forth in its Envisioned Future through the creation of shared value with its various stakeholders.

To create shared value, Chugai considers it important to establish and evolve its unique system for corporate governance, which is an integral part of management.

Based on the above, Chugai has identified five priority issues for corporate governance.

① **Board of Directors:** Makes decisions on management issues of primary importance, receives quarterly reports on the state of business execution as well as reports on key decisions made at the Executive Committee, and conducts oversight.
- Chair: Executive Director
- Composition: 9 members (3 executive directors, 6 non-executive directors (including 3 independent outside directors))
- Convened: 9 times in 2019

② **Executive Committee:** Makes decisions on Company-wide management strategy and important matters concerning business execution. Corporate management committees (⑨) have also been established under the Executive Committee.
- Composition: 12 members (2 directors, 10 executive officers (excluding directors))
- Convened: 32 times in 2019

③ **Appointment Committee:** As an advisory body to the Board of Directors, deliberates on the selection of director candidates and succession plans for or dismissal of executive directors, including the CEO. Members from inside the Company are appointed by the Board of Directors from among the representative directors and persons with experience as representative directors. Members from outside the Company are appointed by the Board of Directors from among the non-executive directors and persons with experience as non-executive directors.
- Chair: Independent outside director
- Composition: 4 members (1 executive director, 3 non-executive directors (including 2 independent outside directors))
- Convened: 3 times in 2019

④ **Compensation Committee:** As an advisory body to the Board of Directors, deliberates on remuneration policy and the remuneration of individual directors. It consists solely of members from outside the Company, appointed by the Board of Directors from among the non-executive directors, including outside directors, and persons with experience as non-executive directors.
- Chair: Non-executive director
- Composition: 3 members (3 non-executive directors (including 1 independent outside director))
- Convened: 2 times in 2019

⑤ **Audit & Supervisory Board Member Audits:** Chugai is a company with an Audit & Supervisory Board. Chugai's Audit & Supervisory Board members conduct audits of management decision-making and business execution independently from business operations. Audit & Supervisory Board members express their opinions in real time from the standpoint of appropriate corporate governance in a variety of situations including at meetings of the Board of Directors, the Executive Committee (full-time Audit & Supervisory Board members only) and the Audit & Supervisory Board.
- Composition: 5 members (2 full-time members, 3 outside members (all 3 of whom are independent Audit & Supervisory Board members))
- Convened: 11 times (including 1 extraordinary meeting) in 2019

⑥ **Internal Audits:** The Audit Department, with a staff that includes certified internal auditors and certified fraud examiners, conducts audits of the status of business execution of the Chugai Group, including subsidiaries, from various standpoints, such as the effectiveness, efficiency and compliance of business activities; reports and makes recommendations to the Executive Committee; and reports to the Audit & Supervisory Board. In addition, Audit Department staff serve as Audit & Supervisory Board members at subsidiaries.

⑦ **Accounting Audits:** KPMG AZSA LLC handles accounting audits and internal control audits.

⑧ **Cooperative Auditing:** Audit & Supervisory Board members, the Audit Department and the Accounting Auditor cooperate closely by regularly exchanging information to improve the effectiveness of their respective audits. Audit & Supervisory Board members and the Accounting Auditor confirm each other's audit plans and hold regular meetings to exchange opinions on matters including the results of quarterly audit reports. In addition, they coordinate with Audit & Supervisory Board members at subsidiaries on quarterly reports, fiscal year-end reports and other matters. The Office of Audit & Supervisory Board Members ensures the independence and enhances the auditing functions of Audit & Supervisory Board members.

⑨ **Corporate Management Committees:** The Corporate Communications Committee makes decisions and oversees promotion of activities regarding information disclosure and dialogue with stakeholders; the Risk Management Committee oversees risk management and promotes activities to identify and measure major risks; the EHS Committee works to integrate management of environment and occupational health and safety issues by making decisions, formulating strategies and overseeing the activities of each department; and the Compliance Committee reinforces the PDCA cycle for compliance activities and monitors the status and implementation of countermeasures for particular items. Collectively referred to as the corporate management committees.

1 A Governance Structure Supporting Chugai's Unique Business Model—a prerequisite for all that follows. It is essential for value creation. Chugai has a highly unique business model. Under the strategic alliance with Roche, one of the world's largest pharmaceutical manufacturers, Chugai is a member of the Roche Group, but at the same time maintains managerial autonomy and independence as a separate listed company. Chugai pursues management that fulfills the mandate of many stakeholders appropriately and fairly. Director composition and monitoring mechanisms are also based on this mindset. Furthermore, demonstrating the true value of this unique business model to generate innovation is a key requirement of management.

2 Reinforcement of the PDCA Cycle—a core responsibility of management. Chugai constantly implements the PDCA cycle to continuously examine and improve corporate governance in order to increase corporate value.

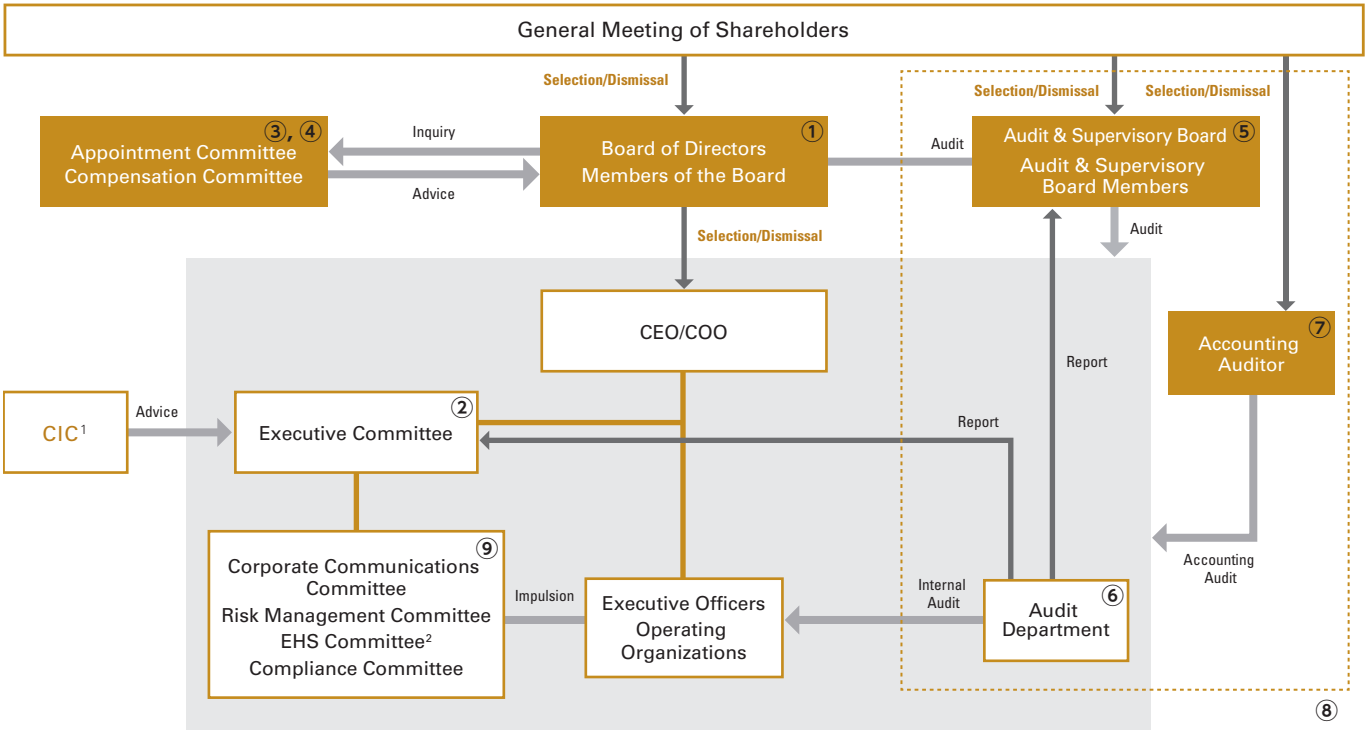
3 Introduction of Outside Perspectives—important for ensuring a stakeholder viewpoint and objectivity in order to create shared value with stakeholders under this unique business model. **4** Relationship with Roche and Securing the Rights and Equality of Shareholders—a priority issue for properly ensuring the interests of minority shareholders as well as Roche, the majority shareholder. **5** Officer Remuneration Emphasizing Linkage with Performance and Stock Price—indispensable for improvement and evolution with regard to the first four issues. The following pages explain Chugai's corporate governance in terms of these priority issues.

Chugai continuously verifies and reviews the status of compliance with each principle of the Tokyo Stock Exchange's Corporate Governance Code in accordance with the revision of June 2018. The following item has not been implemented, the reason for which is also disclosed on the Company's website and elsewhere.

Principle 4-10-1: Establishment of independent advisory committees. Chugai's Compensation Committee consists solely of non-executive directors, including one or more independent outside directors. Therefore, Chugai believes that the current mechanism enables transparent and objective deliberation on compensation.

Corporate Governance
https://www.chugai-pharm.co.jp/english/profile/governance/

Chugai's Corporate Governance System (As of April 1, 2020)



1. Chugai International Council (CIC): Chugai established the CIC as an advisory body composed of Japanese, American and European industry leaders and professionals in various sectors to respond accurately to changes in the global business environment and conduct business in an appropriate manner, and to provide advice to further enhance decision-making.
2. Environment, Health and Safety Committee. Promotes EHS activities for the Chugai Group.

1 A Governance Structure Supporting Chugai's Unique Business Model

In order to promote Chugai's unique business model while ensuring its effectiveness, we separate management decision-making (Board of Directors) and business execution (Executive Committee and others), thereby expediting business execution and clarifying executive responsibility. The Chief Executive Officer (CEO) has ultimate responsibility for making decisions on Company-wide management strategies and the Chief Operating Officer (COO) has ultimate responsibility for making decisions on important matters concerning business execution.

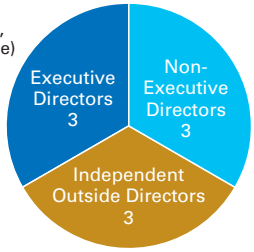
Composition of the Board of Directors

To demonstrate the true value of its unique business model, Chugai's Board of Directors comprises three types of directors: executive directors, independent outside directors, and non-executive directors. The balance of experience among directors of each type enables effective corporate governance that ensures management autonomy as an independent publicly listed company within the Roche Group, and helps to increase corporate value.

Executive directors are responsible for business execution and supervision, report on and explain business execution matters and hold discussions on management. They execute the strategies decided in Board of Directors meetings. Currently, three executive directors are representative directors. Independent outside directors are appointed based on their knowledge and expertise as outside corporate executives or as medical, academic and other professionals. Their role is to provide advice concerning management, exercise supervisory functions and participate in discussions and decision-making at Board of Directors meetings from an objective, outside perspective. Other non-executive directors are appointed from the management team of the Roche Group. They provide an objective, expert perspective from a standpoint that is independent from business execution, offer recommendations and advice regarding strategies and management, and participate in discussions at Board of Directors meetings.

Composition of the Board of Directors in 2020

- Tatsuro Kosaka
  Representative Director, Chairman & CEO
  (Chairman of the Board of Directors, Member of Appointment Committee)
- Motoo Ueno
  Representative Director, Deputy Chairman
- Dr. Osamu Okuda
  Representative Director, President & COO



- Dr. Christoph Franz
  Chairman of the Board of Directors of Roche Holding Ltd.
  (Member of Compensation Committee)
- William N. Anderson
  CEO of Roche Pharmaceuticals
  (Chairman of Compensation Committee, Member of Appointment Committee)
- Dr. James H. Sabry
  Global Head of Roche Pharma Partnering

- Masayuki Oku
  Outside Director
  (Chairman of Appointment Committee, Member of Compensation Committee)
  Outside Director of Komatsu Ltd.
  Outside Director of Rengo Co., Ltd.
  Outside Director of The Royal Hotel, Ltd.
  Outside Auditor of Nankai Electric Railway Co., Ltd.
  Non-Executive Director of The Bank of East Asia (China)
- Yoichiro Ichimaru
  Outside Director
  (Member of Appointment Committee)
  Senior Advisor of Aioi Nissay Dowa Insurance Co., Ltd.
  Outside Director of Seino Holdings Co., Ltd.
- Dr. Mariko Y Momoi
  Outside Director
  Futabakai Social Welfare Corporation Professor Emeritus of Jichi Medical University
  Visiting Professor of School of Medicine, Shinshu University
  Regent of Tokyo Medical University (part-time)

Principal Matters Deliberated by the Board of Directors

Matters Concerning the General Meeting of Shareholders	• Calling of the General Meeting of Shareholders and determination of the agenda items • Approval of the Business Report, financial statements and other documents • Selection of director and Audit & Supervisory Board member candidates
Matters Concerning Directors and Audit & Supervisory Board Members	• Selection and dismissal of representative directors and executive directors • Directors' remuneration and bonuses • Selection and dismissal of executive officers and advisors
Matters Concerning Stock	• Payment of interim dividends
Matters Concerning Management in General	• Formulation of plans and policies, and reports on their progress • Discussion of new business plans, alliances and other matters • Discussion of decision-making structure and organizations • Matters concerning finance and assets
Other Matters	• Approval and reporting of competing transactions • Approval and reporting of conflict of interest transactions • Reporting on internal control, risk management and IR activities • Implementation and reporting of evaluation of the effectiveness of the Board of Directors • Status of voting on proposals at the General Meeting of Shareholders • Verification of cross shareholdings

Results and Progress in 2019

In 2019, two non-executive directors retired and two new non-executive directors were appointed (William N. Anderson and Dr. James H. Sabry; both from the Roche Group). One full-time Audit & Supervisory Board member retired and a new full-time member was appointed, and one independent outside Audit & Supervisory Board member was newly appointed. Dr. Yuko Maeda, who was newly appointed as an independent outside Audit & Supervisory Board member, has extensive experience and knowledge in areas including utilization of intellectual property and industry-academia collaboration, and Chugai determined that she is qualified to be an Audit & Supervisory Board member for the promotion of Chugai's strategies going forward. As a result, she was appointed as Chugai's first female Audit & Supervisory Board member.

At the General Meeting of Shareholders held on March 30, 2020, proposals were approved for the retirement and appointment of new members for one executive director, one independent outside director and one independent outside Audit & Supervisory Board member (Osamu Okuda, Mariko Y Momoi and Kenichi Masuda were newly appointed). Mariko Y Momoi, who was newly appointed as director, has extensive experience and knowledge as a physician and university professor, as well as organizational management experience, including at universities and hospitals. Consequently, Chugai has determined that she is qualified to appropriately provide advice and oversight on the Company's management. Kenichi Masuda is a registered attorney with extensive experience and knowledge as an expert in corporate law, and Chugai determined that he is qualified to appropriately perform his duties as an Outside Audit & Supervisory Board member.

Message from Retiring Director Osamu Nagayama

Osamu Nagayama

Senior Advisor,
Honorary Chairman

Former Representative
Director & Chairman

As I retire from the position of Representative Director, which I have held since 1989, I would like to express my sincere thanks to Chugai's shareholders, investors, and other stakeholders for their support.

With the conviction that enhancing new drug discovery capabilities and globalizing the Company are crucial to contributing to patients around the world, Chugai's management has been focusing on establishing a drug discovery technology platform that continuously generates innovation and strengthening its management platform to be able to withstand global competition. The highlight was the formation of the strategic alliance with Roche. Compared with 2002, when the alliance started, Chugai has achieved four-fold growth in revenues and eight-fold growth in operating income as of December 31, 2019, and contributed to healthcare through patient prescriptions for Chugai's drugs in more than 100 countries worldwide.

In 2012, Deputy Chairman Motoo Ueno, President Tatsuro Kosaka and I formed a three-person management structure. In 2018, Mr. Kosaka became President and CEO, and as of 2020 this troika consists of Mr. Kosaka in his new position as Chairman and CEO, Deputy Chairman Ueno, and newly appointed President and COO Dr. Osamu Okuda. During this time, Chugai has aggressively conducted initiatives to contribute to future growth, including enhancing its therapeutic antibody engineering technologies, reinforcing its drug discovery platform for the new modality of middle molecule drugs, and commencing construction of Chugai Life Science Park Yokohama. I believe that the succession plan we developed over several years, centered on discussions by the Appointment Committee, has functioned effectively and that we have created a governance system for sustainable growth. In addition, since entering into the strategic alliance as a member of the Roche Group that is also listed on the Tokyo Stock Exchange, we have firmly established a stance that emphasizes fairness to all our shareholders by consistently giving full consideration to the interests of minority shareholders.

Nevertheless, the operating environment of the medical and pharmaceutical industry is severe, with the trend toward reductions in drug prices worldwide, intensifying global competition in drug creation and rapidly rising costs. With greater changes expected in this environment from the disruptive technologies of AI and the Internet of Things, we are entering an era where the common practices and conventions of old no longer apply. The very structure of the industry is also likely to change. Under these circumstances, we must continue to create shared value with society to contribute to its sustainable development in the course of our growth. Even amid uncertain conditions, I am sure that Chugai will continue to create value under a management system capable of speedy decision-making.

Actually, I believe Chugai is an innovative company that has been highly responsive to change, including its commitment to drug discovery of first-in-class products and its proactive efforts for industry-academia cooperation. Looking back over our history, we have made decisions that laid the foundation for the Chugai of today, including those made in times of difficulty, such as business structure reforms that achieved a shift to the prescription drug business, and our pioneering focus on biopharmaceuticals. The entire Company has worked together to take on unprecedented challenges that have included large-scale investment in therapeutic antibody drug discovery, ensuring the success of the strategic alliance with Roche and taking the initiative to build a new scheme for industry-academia cooperation with the Osaka University Immunology Frontier Research Center (IFReC) from the basic research stage.

Even in a rapidly changing operating environment, I expect Chugai to continue to contribute to patients and society as an innovation-driven healthcare industry leader.

I hope that you will continue to look forward to great things from Chugai.

In addition, we have examined and reviewed support for a series of external international initiatives. In February 2020, we announced our support for the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). Decisions on matters relating to climate change are overseen and deliberated by the EHS Committee, with final decisions made by the Executive Committee.

Change in Representative Directors in 2020

At a meeting held after the close of the General Meeting of Shareholders on March 30, 2020, the Board of Directors approved a change in representative directors. Former President Tatsuro Kosaka was appointed Representative Director and Chairman, retaining the concurrent position of CEO, and former Executive Vice President Osamu Okuda was appointed Representative Director, President and COO. Regarding the change, the Appointment Committee (chaired by an outside director) had been discussing a succession plan for a smooth generational change of the management team. Osamu Nagayama, who has led Chugai for many years, retired from the Board of Directors and was appointed Senior Advisor, Honorary Chairman under a newly established special advisory system.

Since Mr. Kosaka was appointed CEO in March 2018, Chugai has been building a system for cooperation to continuously generate innovation. At the same time, the operating environment for healthcare has changed significantly, with stricter policies to contain healthcare costs in Japan and overseas, the emergence of new technologies in the life science and digital fields, and other factors, necessitating speedier decision-making in all aspects of management. As a result of this personnel change, the CEO will handle important issues related to Company-wide management strategies, and the COO will handle individual policy issues regarding the execution of business, thereby resulting in faster, more precise decision-making for the entire Company.

2 Reinforcement of the PDCA Cycle (Items Revised in 2019)

Based on the belief that constantly implementing the PDCA cycle to improve corporate governance is essential, Chugai has focused on evaluation of the effectiveness of the Board of Directors and improvement activities based on evaluation results since 2015.

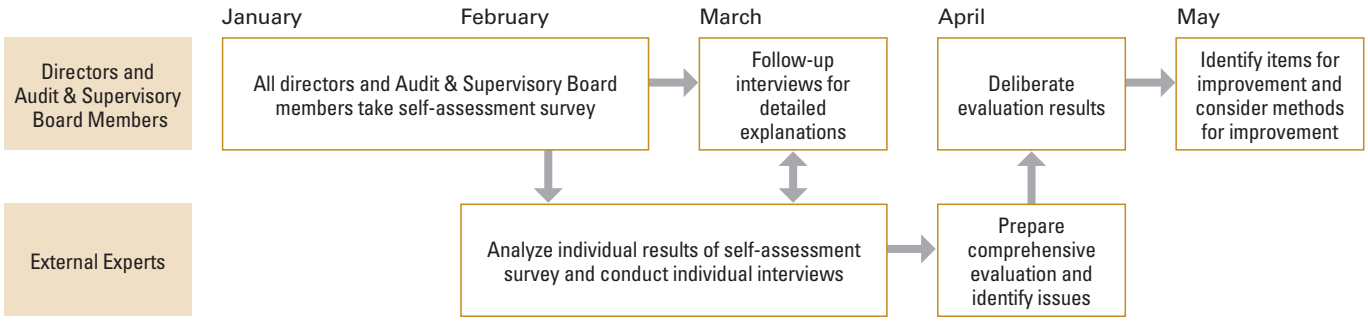
As its process for evaluating effectiveness up to 2018, Chugai conducted a self-assessment survey in January every year for directors and Audit & Supervisory Board members who were in office during the applicable period, and discussed the results after receiving reports from the Secretariat for the Board of Directors. Based on the advice of external experts, the Secretariat for the Board of Directors prepared the survey, collected the directors' responses and reported the results to the Board of Directors after having them aggregated and analyzed by the external experts.

Results and Progress in 2019

Ensuring greater diversity of the Board of Directors and providing more information to outside directors and outside Audit & Supervisory Board members were identified as items for improvement from an analysis of 2018 results. In response, in 2019 we examined how to ensure diversity and endeavored to provide information in ways such as holding briefings on business in forums other than Board of Directors meetings, and holding Board of Directors meetings and site tours at business sites the Board had not previously visited.

Starting with the 2019 effectiveness evaluation, to further enhance outside perspectives and objectivity, we have changed from the former aggregation, evaluation and analysis by external experts based on self-assessment to the method shown below. Under this method, external experts act as third-party evaluators to analyze the grounds for self-assessment, the rationality of the logic leading to the results of self-assessments and other matters, then conduct individual interviews for a comprehensive evaluation, and report issues and effective countermeasures to the Board of Directors.

Process for Evaluating the Effectiveness of the Board of Directors



Status of Improvements Identified through Evaluation of the Effectiveness of the Board of Directors

	Main Items for Improvement	Main New Initiatives Implemented after Analysis and Evaluation
2016	• Review structure of self-evaluation survey and answer options • Assiduously provide materials for Board of Directors meetings at least four business days prior to the event • Enhance content of reports provided to Board of Directors and make materials easily understood	• Began providing information on industry environment trends and other information to outside directors in a CEO message at the beginning of the Board of Directors meetings • Provided Board of Directors meeting schedule for the coming year at an early date • Implemented factory tours
2017	• Change the procedure for providing materials to outside officers • Enhance topics for reports to the Board of Directors	• Held lectures (information on trends of general shareholders meetings) by external experts (attorneys)
2018	• Conduct prior and additional explanations on agenda items with complex content such as governance and legal matters	• Issued the Chugai IR Activities Report to outside officers (every quarter) • Provided a glossary of technical terms, abbreviations and the like to outside officers
2019	• Ensure greater diversity of the Board of Directors • Provide more information to outside directors and outside Audit & Supervisory Board members	• Deliberation by the Appointment Committee • Convened a Board of Directors meeting and conducted a tour at the Fujieda Plant • Held briefings on departmental operations

Masayuki Oku

Independent Outside Director
Outside Director of Komatsu Ltd.
Outside Director of Rengo Co., Ltd.
Outside Director of The Royal Hotel, Ltd.
Outside Auditor of Nankai Electric Railway Co., Ltd.
Non-Executive Director of The Bank of East Asia (China)

Enhancing the Effectiveness of Governance
(Message from an Outside Director)

Chugai is a company with a "parent-child listing" arrangement (a publicly listed subsidiary of a publicly listed parent), with Roche owning about 60 percent of Chugai's shares. The key points in this arrangement with Roche are how to protect the rights of minority shareholders and how to continue finding meaning in a relationship of this kind. The unique, win-win business model has worked effectively so far, but continuing to increase corporate value by developing the model in a rapidly changing environment will not be easy.

In governance, we must take these characteristics and challenges into account. We outside directors in particular must act as spokespersons for minority shareholders by supervising management while supporting and encouraging value creation by executive directors. Speaking in generalizations and requesting rationales for decisions are not enough. As outside directors, we must deploy our collective experience to prepare the way for value creation.

To establish Chugai's unique style of governance, the Board of Directors focuses on enhancing its effectiveness. For example, my suggestions in effectiveness assessments have been adopted immediately, including starting off meetings with a CEO message in which information such as trends in the industry environment and strategic direction is shared with outside directors, and conducting factory tours to give outside directors a better sense of frontline operations. Information is shared early with directors, and board meetings have become forums for discussion and debate rather than simply reporting and voting. Also, successor development is being systematically carried out, as illustrated by the recent appointment of the new president.

One remaining issue to address is diversity. Promotion of women in the workplace is an area where Chugai clearly lags behind companies at the global level. In addition to appointing female outside directors and Audit & Supervisory Board members, it is important to increase the number of women in all executive positions. This may take time, but Chugai firmly believes diversity accelerates innovation, so I am confident that it will make greater efforts in this area.

3 Introduction of Outside Perspectives

To reflect diverse stakeholder viewpoints in business decisions, Chugai actively takes measures to obtain outside perspectives under the basic management policy of creating shared value. These measures include nominating outside directors and outside Audit & Supervisory Board members, enhancing support for outside officers, and establishing a council made up of domestic and overseas specialists.

Chugai International Council (CIC)

To respond accurately to changes in the global business environment and conduct international business in an appropriate manner, Chugai works to further enhance decision-making by operating the Chugai International Council (CIC), which is composed of Japanese and international professionals from various sectors. Of the current 10 council members, including the CIC Chair, one is a woman and one is Japanese.

Support System for Outside Directors and Outside Audit & Supervisory Board Members

Secretarial Department staff provide support for outside directors. Managers including the Head of the Corporate Planning Department provide, as needed, reports on major changes in the operating environment and advance explanation of particular items. The Office of Audit & Supervisory Board Members is responsible for supporting the activities of Audit & Supervisory Board members in ways such as conveying internal information and providing materials for board meetings in advance.

In addition, Chugai invigorates the deliberations of the Board of Directors by preparing materials containing adequate information relevant to agenda items and distributing them to outside directors and outside Audit & Supervisory Board members well in advance of meetings. Chugai also provides additional information required by outside directors and outside Audit & Supervisory Board members and

Chugai International Council Composition

CIC Chair

- Henry L. Nordhoff (U.S.)
  Former Chairman of the Board, Gen-Probe, Inc.

CIC Members

- Virginia Bottomley (U.K.)
  Former Health Secretary of the U.K.
- William M. Burns (U.K.)
  Former Chief Executive Officer of the Pharmaceuticals Division, F. Hoffmann-La Roche Ltd
- Andrew von Eschenbach (U.S.)
  Former Commissioner of the U.S. Food and Drug Administration
- Victor Halberstadt (Netherlands)
  Professor, Leiden University
- Andre Hoffmann (Switzerland)
  Vice Chairman, Roche Holding Ltd.
- Franz B. Humer (Switzerland)
  Former Chairman, Diageo plc
  Former Chairman, Roche Holding Ltd.
- Robert A. Ingram (U.S.)
  Former Vice Chairman of Pharmaceuticals, GlaxoSmithKline plc
- Arnold J. Levine (U.S.)
  Professor Emeritus at the Institute for Advanced Study, Princeton University
  Discoverer of the p53 cancer suppressor protein
- Sonosuke Kadonaga (Japan)
  President, Intrinsics

Director Roles and Expertise in 2020

	Roles and Responsibilities	Name	Committees	Expertise of Non-Executive and Independent Outside Directors					Board of Directors Meeting Attendance in 2019
				Corporate Management	International Operations	Organizational Management	Medicine	Pharmaceuticals	
Executive Directors	Representative Director, Chairman & CEO Chairman of the Board of Directors	Tatsuro Kosaka	Chairman of the Board of Directors Appointment Committee						9 of 9
	Representative Director, Deputy Chairman In charge of Sustainability Dept., Audit Dept.	Motoo Ueno	Board of Directors						9 of 9
	Representative Director, President & COO	Dr. Osamu Okuda	Board of Directors						—
Independent Outside Directors	Director	Masayuki Oku	Board of Directors Chairman of Appointment Committee Compensation Committee	●	●	●			9 of 9
	Director	Yoichiro Ichimaru	Board of Directors Appointment Committee	●	●	●			9 of 9
	Director	Mariko Momoi	Board of Directors			●	●		—
Non-Executive Directors	Director	Dr. Christoph Franz	Board of Directors Compensation Committee	●	●	●		●	9 of 9
	Director	William N. Anderson	Board of Directors Appointment Committee Chairman of Compensation Committee	●	●	●		●	7 of 7
	Director	Dr. James H. Sabry	Board of Directors	●	●	●		●	6 of 7

takes advantage of opportunities to provide advance explanation.

Results and Progress in 2019

At its meeting in November 2019, the CIC's agenda included discussion of topics such as medium- to long-term global megatrends that merit close attention, Chugai's business opportunities and risks, and changes in medicine resulting from advances in digital technology, as well as a review of mid-term business plan IBI 21.

In addition, Chugai adopted the creation of shared value as its basic management policy in 2019. Consequently, with the involvement of executive directors and key executive officers, Chugai has been holding discussions on strengthening sustainable platforms with the Chugai Sustainability Advisory Committee, which consists of external experts, and on issues including corporate governance and support and design of scenarios for external international initiatives with external specialist consultants.

4 Relationship with Roche and Securing the Rights and Equality of Shareholders

Roche, the parent company of Chugai, holds 59.89 percent of Chugai's outstanding shares based on the strategic alliance agreement between the two companies. Roche and Chugai have agreed to cooperate in maintaining the listing of Chugai's common stock on the First Section of the Tokyo Stock Exchange.[3]

The aim of this alliance is to establish a new business model that differs from conventional corporate acquisitions and joint ventures. Although Roche Holding Ltd. includes Chugai in its consolidated accounts, Chugai functions as an independent listed company and makes all of its own management decisions based on the principle of self-governance. Chugai believes that autonomy and diversity are key to generating innovation, that maintaining its independent management brings diversity to the Roche Group, and that the pharmaceuticals it creates as a result contribute to all stakeholders, including patients and minority shareholders. Chugai recognizes that the various benefits from being listed on the First Section of the Tokyo Stock Exchange – such as its solid credit rating, flexible fund procurement, name recognition and social presence – are supported by the understanding of shareholders other than Roche, i.e., minority shareholders and

Dr. Severin Schwan
Roche Group CEO

Chugai and Roche are well positioned in an intensely competitive environment to maximize value creation for the benefit of all stakeholders.

It is exciting to see the important medical advances we are bringing to millions of patients with difficult to treat diseases in Japan and globally through the strategic alliance between Chugai and Roche. We have a truly win-win partnership that successfully leverages our respective strengths. The relationship is anchored firmly in a mutually beneficial business model. Although Roche is the majority shareholder, Chugai maintains its Japanese culture and identity and is managed autonomously, yet closely coordinated with Roche. This approach fosters self-reliance and an entrepreneurial spirit at Chugai that drives innovation in research and drug discovery. Roche's global organization delivers Chugai's breakthrough medicines such as Actemra, Alecensa, and Hemlibra to patients around the world, whilst Chugai brings Roche's medicines to Japanese patients.

Today, disruptive technology, coupled with advances in life sciences, are altering the way we work and search for innovative solutions, and competition grows more intense every year. I am confident, however, that our focus on science and innovation, combined with the strengths of our strategic alliance will enable Chugai and the Roche Group to become faster and more agile in maximizing value creation for the benefit of patients globally and ultimately for all our stakeholders, including minority shareholders.

The appointment of Tatsuro Kosaka as Chairman & CEO and Osamu Okuda as President & COO places the transition to a new generation of strong leaders to further build on Chugai's outstanding record of achievements. Together we will continue to create and deliver breakthrough innovations that bring new hope to millions of patients worldwide.

investors who are potential shareholders. That is why in its business dealings with the Roche Group, Chugai conducts all transactions fairly using third-party prices to protect the interests of minority shareholders, and is working to gain their trust.

Chugai believes that securing substantially equal treatment of shareholders is very important. We therefore emphasize giving due consideration to minority and foreign shareholders and to maintaining an environment that allows them to exercise their rights. Therefore, recognizing that business plans are a commitment to shareholders, Chugai promotes the disclosure of a variety of information and constructive dialogue with shareholders and investors. Directors and executive officers make every reasonable effort to meet requests for interviews from shareholders and investors.

Results and Progress in 2019

Following the announcement that Chugai will place greater emphasis on dialogue with stakeholders under IBI 21, we held an ESG meeting for investors for the first time in 2019 and increased opportunities for dialogue involving directors and executive officers.

▶ See "Communication with Shareholders, Investors and Other Stakeholders" on page 68.

Restrictions on Roche's Shareholding

Period	Maximum Shareholding
Oct. 1, 2002 – Sep. 30, 2007	50.1%
Oct. 1, 2007 – Sep. 30, 2012	59.9%
Oct. 1, 2012 and thereafter	Cooperate in maintaining Chugai's listing

3. The Tokyo Stock Exchange requires delisting if the ratio of tradeable shares to listed shares is less than 5 percent.

5 Officer Remuneration That Emphasizes Linkage with Performance and Stock Price

Chugai has designed its remuneration plan for directors and Audit & Supervisory Board members to attract outstanding people and appropriately motivate them in order to continuously increase the Chugai Group's corporate value.

As part of this plan, we target market-competitive levels of remuneration. Executive director remuneration is determined by benchmarking levels against a group of major Japanese corporations and other domestic pharmaceutical companies. Specifically, the Board of Directors decides remuneration levels annually after deliberation by the Compensation Committee based on the results of a survey by an external expert organization and other factors.

In order to further clarify the link between remuneration and the Company's business performance and shareholder value, and to raise directors' ambition and motivate them to improve performance, executive director remuneration consists of bonuses paid according to performance and other factors in each fiscal year as a short-term incentive and restricted stock compensation linked to medium- and long-term performance (tenure-based and performance-based) as a long-term incentive, in addition to fixed regular compensation. Remuneration of non-executive directors, including outside directors, and Audit & Supervisory Board members consists solely of fixed regular compensation. The guideline for the composition of CEO remuneration is 35 percent regular compensation, 30 percent bonuses and 35 percent restricted stock compensation, and the composition for other executive directors is determined in consideration of duties and other factors.

https://www.chugai-pharm.co.jp/english/ir/share/agm/files/200227eChugai_109thAGM_Convo.pdf#page=21

Bonuses, which are a short-term incentive, are determined by multiplying the standard amount set for each position by an evaluation coefficient corresponding to the degree of achievement of Company and individual performance targets in the previous fiscal year. For restricted stock compensation granted as a long-term incentive, 50 percent is tenure-based restricted stock with a transfer restriction period of three to five years, and 50 percent is performance-based restricted stock. The number of shares to be granted is determined by dividing the standard amount set for each position by the closing price of the Company's shares on the day before the resolution for their allotment by the Board of Directors. The transfer restriction shall be removed at the expiration of the transfer restriction period for the shares granted, provided that the recipient has held the position of director of the Company continuously during the transfer

System for Remuneration of Directors and Audit & Supervisory Board Members

Type of Remuneration			Eligible Officers: Executive Directors	Eligible Officers: Non-executive Directors (including Outside Directors)	Eligible Officers: Audit & Supervisory Board Members	Payment Criteria	Payment Method
Fixed Regular Compensation	Regular Compensation		●	●	●	Paid according to position and other factors	Monthly (Cash)
Performance-based Remuneration	Bonuses		●	—	—	Paid according to performance in each fiscal year	Yearly (Cash)
	Long-term Incentive (Stock-based Compensation)	Tenure-based Restricted Stock	●	—	—	Paid according to fixed length of service	Yearly (Common stock)
		Performance-based Restricted Stock	●	—	—	Paid according to performance over fixed period in addition to above	Yearly (Common stock)

restriction period. For performance-based restricted stock, the number of shares for which the transfer restriction shall be removed is additionally based on the result of a comparison between the total shareholder returns of domestic pharmaceutical companies and total shareholder returns of the Company.

Officer remuneration is determined by resolution of the Board of Directors for directors and following deliberation by the Audit & Supervisory Board members for Audit & Supervisory Board members, both within the total amounts approved at the General Meeting of Shareholders. The Compensation Committee, which consists of three or more external members appointed by the Board of Directors, including at least one independent outside director, deliberates on remuneration of individual directors to ensure the transparency and objectivity of the determination process.

Criteria for Performance-Based Remuneration and the Method to Determine Its Amount

Type of Remuneration		Indicators and Evaluation Methods
Bonuses		• Comprehensive evaluation is based on degree of achievement of factors including Core operating profit, revenues, R&D performance and Company-wide tasks in the previous fiscal year • After deliberation by the Compensation Committee, the amount paid is determined by the Board of Directors within a range of 0% to 200% of the standard amount
Restricted Stock Compensation	Tenure-Based	• Continuous service during the transfer restriction period
	Performance-Based	• Determination of the number of shares for which transfer restrictions are to be removed is based on the result of a comparison between the total shareholder returns of domestic pharmaceutical companies and total shareholder returns of the Company, in addition to the condition of continuous service • Evaluation period for total shareholder returns is three fiscal years • Removal of transfer restrictions is within a range of 0% to 100% of allotted shares

Results in 2019: Amount of Remuneration Paid to Directors and Audit & Supervisory Board Members

Position	Total Remuneration, etc. (Millions of yen)	Total Amount by Type of Remuneration, etc. (Millions of yen)				Number of Eligible Officers
		Regular Remuneration	Bonuses	Restricted Stock Compensation		
				Tenure-Based	Performance-Based	
Directors (Excluding Outside Directors)	552	254	136	86	76	3
Outside Directors	43	43	—	—	—	3
Total	596	433		162		6
Audit & Supervisory Board Members (Excluding Outside Audit & Supervisory Board Members)	63	63	—	—	—	3
Outside Audit & Supervisory Board Members	33	33	—	—	—	3
Total	96	96		—		6

1. Amounts are rounded to the nearest million yen.
2. The table above includes one Audit & Supervisory Board Member who retired during 2019, and two directors and one Audit & Supervisory Board member who retired at the conclusion of the Ordinary General Meeting of Shareholders on March 30, 2020.
3. The amounts of "restricted stock compensation (tenure-based and performance-based)" shown in the table above are the amounts that were posted as expenses for the fiscal year under review as each respective restricted stock compensation.
4. In addition to the above total remuneration, the following is provided as retirement benefits for directors from the time of inauguration to the termination of the retirement benefits system as follows.
Retired director (internal): One person, ¥498 million

Results in 2019: Amount of Remuneration Paid to Representative Directors

Name	Total Consolidated Remuneration, etc. by Type (Millions of yen)				Consolidated Remuneration Total (Millions of yen)
	Regular Remuneration	Bonuses	Restricted Stock Compensation		
			Tenure-Based	Performance-Based	
Osamu Nagayama	126	37	17	31	211
Motoo Ueno	58	30	26	19	132
Tatsuro Kosaka	71	69	43	26	209

1. Amounts are rounded to the nearest million yen.
2. Other than the representative directors in the table above, no director or Audit & Supervisory Board member received total remuneration of more than ¥100 million.
3. Osamu Nagayama retired at the conclusion of the Annual General Meeting of Shareholders on March 30, 2020, and has been paid ¥498 million as retirement benefits.

Risk Management

Chugai views risk management as a priority issue pertaining to the Company's core operations and strives to promote the evolution of risk management on a day-to-day basis. For its risk management system, Chugai has established Risk Management Regulations based on its Risk Management Policy to prevent the materialization of risks that could affect the Company's business activities, as well as to ensure prompt and appropriate handling of any problems that arise. We have also

established the Risk Management Committee, which is a corporate management committee chaired by a representative director, as well as division risk management committees in each division and at subsidiaries in Japan and overseas. The Risk Management Committee monitors and evaluates risk management at each division with a Company-wide perspective, identifies risks that may have a material impact on management as Group-wide risk issues, and submits progress reports on Company- wide measures to the Executive Committee. Division risk management committees create and quantitatively evaluate risk maps that identify the risks in the respective divisions. To address priority risks, the division risk management committees draw up annual response plans for priority risks and submit quarterly reports on the progress of the plans to the Risk Management Committee.

▶ See "Business Risks" on page 124.

To effectively comprehend and analyze Group-wide risk information, Chugai developed an original risk management system and began implementing it globally in 2019. Using the database for centralized management, divisions can record their risk maps and annual risk response plans. This enables us to analyze risks for the Group as a whole, and monitor countermeasures at each division.

Chugai and Compliance

Rooted in its belief that corporate ethics take priority over profit, Chugai places paramount importance on respect for life, and strives for fair and transparent corporate activities based on high ethical standards, along with sincere scientific initiatives.

Chugai strictly complies with laws, regulations and voluntary industry standards and proactively takes part in the compliance activities of various associations and organizations. Chugai has also established its own guidelines for transparency, helping to ensure a high level of ethics, morality and transparency in its various business activities including collaboration with medical institutions and other parties and cooperation with patient groups.

In response to the external environment and the diversification of our business activities, we consolidated oversight functions for compliance promotion for the whole Chugai Group, including overseas subsidiaries, and established the Compliance Committee as a corporate management committee, thereby creating a compliance system linked more directly to management. At the same time, we established compliance oversight functions (Sustainability Department, Quality & Regulatory Compliance Unit) to monitor, lead and support compliance of the Chugai Group, including overseas subsidiaries. We conduct monitoring surveys every six months and improvement activities for all organizations, and enhance compliance education through training programs. In addition, each division appoints a Compliance Manager and Compliance Officer who work to ensure thorough legal compliance in the workplace.

The internal and external consultation desks have been established to receive inquiries and reports from Chugai Group employees concerning laws, Company rules, the Chugai Group Code of Conduct and other related matters.

Chugai's Transparency Guidelines
* https://www.chugai-pharm.co.jp/english/sustainability/transparency/

Communication with Shareholders, Investors and Other Stakeholders

To receive fair valuation in capital markets, Chugai has a policy of conducting timely, appropriate and fair disclosure of information to shareholders and investors in accordance with laws and regulations. As one aspect of ensuring transparency, we provide easy access to the information we disclose by making it available in Japanese and English. To engage more proactively in discussions with our shareholders and investors, in 2019 we conducted briefings on ESG and R&D, topics of great interest to investors. We also give quarterly briefings on financial results and hold conference calls and investor meetings. We provide production site tours and briefings for individual shareholders and investors; senior management conducts visits to overseas institutional investors; and the CEO holds informal discussions with investors and analysts as an opportunity to speak directly in small groups.

Moreover, we emphasize proactive and straightforward communication of information in order to gain the support and trust of a wide range of stakeholders. Chugai takes an active approach to media relations through press releases, various types of information meetings and informal discussions with management. We also use our website and a variety of other tools to promote understanding among the general public of the broad range of activities through which our businesses contribute to healthcare, the environment, human rights, society, human resource development and other areas.

Main Initiatives and Progress in 2019

- Media and IR information events: 25
- Meetings held with security analysts and institutional investors worldwide: 376 analysts and investors
- Briefings for individual investors and shareholders: 8
- Attendees at the General Meeting of Shareholders: 387
- Second Prize, Nikkei Annual Report Awards 2019
- Prize for Excellence in Integrated Reporting, 7th WICI Japan Award for Excellence in Integrated Reporting
- 3rd place, Pharmaceuticals Category, 2019 Awards for Excellence in Corporate Disclosure, The Securities Analysts Association of Japan
- 2nd place, Best IR Programs. (sell-side), The 2019 All-Japan Executive Team Rankings, *Institutional Investor magazine*
- Renewed Sustainability website

Message from an Outside Audit & Supervisory Board Member

Dr. Yuko Maeda

Outside Audit & Supervisory Board Member
Director, CellBank Corp.
Auditor (Part-time), Japan Agency for Marine-Earth Science and Technology

Auditing the Risks Involved in Improving Corporate Value over the Medium to Long Term

I was appointed as an independent outside Audit & Supervisory Board member in March 2019. I am very honored to take up this position at Chugai, an industry leader. Now that diversity in management teams is being emphasized, the fact that I am a woman was perhaps a major factor in my selection. However, in order meet the expectations of shareholders, investors and other stakeholders, I must perform audits that contribute to raising Chugai's corporate value. As two other outside members with extensive skills and experience in law and accounting are charged with the responsibility of auditing those areas, as a person with a background in the field of technology I believe my duty is to leverage my own experience to help strengthen Chugai's corporate governance.

I have worked in research and new business startup roles at a manufacturing company, accumulated experience in supervising sustainability and conducted management as an executive officer. My other positions have included director of the technology transfer center at a national medical university, as well as establishing and operating a network for collaboration between industry and academia. At present, I serve as an Auditor (part-time) at the non-profit Japan Agency for Marine-Earth Science and Technology (JAMSTEC), a position equivalent to Audit & Supervisory Board member at a private-sector company. I conduct audits with an awareness of the significance of the agency's existence for the citizens of Japan, who are its stakeholders.

In light of my experience in the fields of research and management, I view my role as, simply put, to audit the business risks involved in achieving sustainable improvement in corporate value. I will work to closely examine these risks and express my opinions to the executive members.

Emphasis on Social Value, Human Resource Management and Drug Discovery

Specifically, my audits currently focus on three main points that are issues for Chugai.

The first is social value. At JAMSTEC, I conduct audits with a focus on the value of the agency's existence to society. As an industry leader, Chugai should also continue to create value for society while collaborating with other organizations and companies. Audits taking into account Chugai's responsibilities to patients, healthcare, society and other parties are essential.

The second is human resource management. Generating results at a higher level is not easy for a leading company that sets its own targets rather than following in others' footsteps, and to that end, its organizational culture and human resource strategy are extremely important. I am emphasizing audits from the standpoint of whether workplaces allow employees to take charge of their own growth, maintain good physical and mental health and have a sense of fulfillment.

The third is drug discovery. To maintain its win-win relationship with Roche, Chugai must continuously create innovative drugs. Applying my experience in research, I intend to closely examine the risks Chugai faces in generating ongoing innovation, including in areas such as resource allocation and speed sensitivity.

As an outside Audit & Supervisory Board member, I intend to proactively visit workplaces and concentrate on auditing that fully utilizes my technical background to help Chugai achieve sustainable improvement in corporate value.

Board of Directors, Audit & Supervisory Board and Executive Committee Members (As of April 1, 2020)

Representative Directors

Tatsuro Kosaka
Representative Director, Chairman & CEO
Outside Director of Asahi Group Holdings, Ltd.

Executive Director

(Shares of the Company owned: 46,430 shares)

1976 Joined the Company
1995 Deputy President of Chugai Pharma Europe Ltd. (U.K.)
2000 General Manager of Business Strategy Planning Office
2002 Vice President, General Manager of Corporate Planning Dept.
2004 Senior Vice President, General Manager of Corporate Planning Dept.
2005 Senior Vice President, Deputy Managing Director of Sales & Marketing Group
Senior Vice President, Head of Strategic Marketing Unit
2008 Senior Vice President, Head of Lifecycle Management & Marketing Unit
2010 Director, Executive Vice President
2012 Representative Director, President & COO
2016 Outside Director of Asahi Group Holdings, Ltd. (to present)
2018 Representative Director, President & CEO (to present)
2020 Representative Director, Chairman & CEO (to present)

Motoo Ueno
Representative Director, Deputy Chairman
In charge of Sustainability Dept., Audit Dept.

Executive Director

(Shares of the Company owned: 817,174 shares)

1984 Joined the Company
1991 General Manager of London Representative Office
1993 Director
1994 Director, General Manager of Medical Information Div.
1995 Director, General Manager of Clinical Research & Development Division
1996 Director, Deputy General Manager of Research & Development Division
1997 Director, Senior Vice President
1998 Senior Vice President
2000 Director, Senior Vice President
2002 Director, Deputy President
2003 Director, Deputy President, Vice President
2004 Representative Director, Deputy President
2006 Representative Director, President of Chugai Pharma Manufacturing Co., Ltd.
2012 Representative Director, Deputy Chairman (to present)

Dr. Osamu Okuda
Representative Director, President & COO

Executive Director

(Shares of the Company owned: 9,883 shares)

1987 Joined the Company
2008 Department Manager of Lifecycle Management Dept. II
2009 Department Manager and Lifecycle Leader of Lifecycle Management Dept. II
2011 President of Roche Products (Ireland) Limited
2013 General Manager of Oncology Unit, Marketing & Sales Div. of the Company
2014 Executive Officer, General Manager of Oncology Unit, Marketing & Sales Div. of the Company
2015 Executive Officer, General Manager of Corporate Planning Dept. of the Company
2017 Executive Vice President, General Manager of Corporate Planning Dept. of the Company
2018 Executive Vice President, Co-Head of Project & Lifecycle Management Unit
2020 Representative Director, President & COO (to present)

Non-Executive Directors

Audit & Supervisory Board Members

Non-Executive Directors

1 Masayuki Oku

Outside Director of Komatsu Ltd.
Outside Director of Rengo Co., Ltd.
Outside Director of The Royal Hotel, Ltd.
Outside Auditor of Nankai Electric Railway Co., Ltd.
Non-Executive Director of The Bank of East Asia (China)

Outside **Independent**

1968 Joined The Sumitomo Bank, Ltd. ("SB")
1994 Director of SB
1998 Managing Director of SB
1999 Managing Director and Managing Executive Officer of SB
2001 Senior Managing Director and Senior Managing Executive Officer of SB
Senior Managing Director and Senior Managing Executive Officer of Sumitomo Mitsui Banking Corporation ("SMBC")
2002 Senior Managing Director of Sumitomo Mitsui Financial Group, Inc. ("SMFG")
2003 Deputy President and Executive Officer of SMBC
2005 Chairman of SMFG
President and Chief Executive Officer of SMBC
2015 Director of the Company (to present)
2017 Director of SMFG
Honorary Advisor of SMFG (to present)
2019 Outside Director of Rengo Co., Ltd. (to present)
Outside Director of The Royal Hotel, Ltd. (to present)

2 Yoichiro Ichimaru

Senior Advisor of Aioi Nissay Dowa Insurance Co., Ltd.
Outside Director of Seino Holdings Co., Ltd.

Outside **Independent**

1971 Joined Toyota Motor Sales Co., Ltd.
2001 Member of the Board of Directors of Toyota Motor Corporation ("TMC")
2003 Managing Executive Officer of TMC
2005 Senior Managing Director of TMC
2009 Representative Director, Executive Vice President of TMC
Corporate Auditor of Aioi Insurance Co., Ltd.
2010 Corporate Auditor of Aioi Nissay Dowa Insurance Co., Ltd.
2011 Senior Corporate Auditor of TMC
2015 Executive Advisor of TMC
Representative Director, Chairman of Aioi Nissay Dowa Insurance Co., Ltd.
2017 Director of the Company (to present)
Senior Advisor of Aioi Nissay Dowa Insurance Co., Ltd. (to present)
2019 Outside Director of Seino Holdings Co., Ltd. (to present)

3 Dr. MarikoY Momoi

Chief Medical Officer of Ryoumou Seishi Ryogoen, Kiryu Ryoiku Futabakai Social Welfare Corporation
Professor Emeritus of Jichi Medical University
Visiting Professor of School of Medicine, Shinshu University
Regent of Tokyo Medical University (part-time)

Outside **Independent**

1994 Head of Department of Pediatrics, Jichi Medical University
2006 Director of Jichi Children's Medical Center Tochigi
2010 Dean of School of Medicine, Jichi Medical University
2012 Visiting Professor of School of Medicine, Shinshu University (to present)
2013 Professor Emeritus of Jichi Medical University (to present)
Vice President of International University of Health and Welfare
2014 Director of Japanese Medical Specialty Board (part-time)
2015 Vice President of International University of Health and Welfare and Head of IUHW Hospital
2017 Chief Medical Officer of Ryoumou Seishi Ryogoen, Kiryu Ryoiku Futabakai Social Welfare Corporation (to present)
2018 Regent of Tokyo Medical University (part-time) (to present)
2020 Director of the Company (to present)

4 Dr. Christoph Franz

Chairman of the Board of Directors of Roche Holding Ltd.
Member of the Board of Directors of Zurich Insurance Group Ltd. (Switzerland)
Member of the Board of Directors of Stadler Rail (Switzerland)

1990 Joined Deutsche Lufthansa AG
1994 Member of the Executive Board and CEO of Passenger Transport Division of Deutsche Bahn AG
2004 CEO of Swiss International Air Lines AG
2009 Deputy Chairman of the Executive Board of Deutsche Lufthansa AG
2011 Chairman of the Executive Board and CEO of Deutsche Lufthansa AG
2014 Chairman of the Board of Directors of Roche Holding Ltd. (to present)
2017 Director of the Company (to present)

5 William N. Anderson

CEO of Roche Pharmaceuticals and Member of the Roche Corporate Executive Committee

1997 Joined Biogen Idec
1999 Managing Director, United Kingdom and Ireland of Biogen Idec
2001 Vice President of Finance, Business Planning of Biogen Idec
2004 Vice President and General Manager of Neurology Business Unit of Biogen Idec
2006 Senior Vice President of Immunology & Ophthalmology Business Unit of Genentech
2010 Senior Vice President of BioOncology Business Unit of Genentech
2013 Head of Global Product Strategy, Chief Marketing Officer of Roche
2017 CEO of Genentech
2019 CEO of Roche Pharmaceuticals and Member of the Roche Corporate Executive Committee (to present)
Director of the Company (to present)

6 Dr. James H. Sabry

Global Head of Roche Pharma Partnering and Member of the Roche Enlarged Corporate Executive Committee

1997 Co-founder, President and CEO of Cytokinetics
2008 President and CEO of Arete Therapeutics
2010 Global Head and Vice President of Genentech Partnering
2013 Global Head and Senior Vice President of Genentech Partnering
2018 Global Head of Roche Pharma Partnering and Member of the Roche Enlarged Corporate Executive Committee (to present)
2019 Director of the Company (to present)

Audit & Supervisory Board Members

7 Mamoru Togashi (Full-time)

(Shares of the Company owned: 1,841 shares)

1982 Joined the Company
2004 President, CBS Co., Ltd.
2006 General Manager of Corporate Communications Dept.
2009 General Manager of Human Resources Management Dept.
2010 Vice President, General Manager of Human Resources Supervisory Div. and General Manager of Human Resources Management Dept.
2017 Audit & Supervisory Board Member (to present)

8 Atsushi Sato (Full-time)

(Shares of the Company owned: 907 shares)

1981 Joined the Company
2009 General Manager of Risk Management & Compliance Dept.
2011 General Manager of Corporate Social Responsibility Dept.
2015 General Manager of Corporate Social Responsibility Dept. and General Affairs Dept.
General Manager of Corporate Social Responsibility Dept.
2016 Associate Vice President, General Manager of Corporate Social Responsibility Dept.
2019 Associate Vice President
Audit & Supervisory Board Member (to present)

9 Takaaki Nimura

Representative of Nimura Certified Public Accountant Office

Outside **Independent**

1974 Joined Arthur Young & Co., Tokyo Office
1980 Seconded to Asahi & Co., Osaka Office
1983 Seconded to Arthur Young & Co., Los Angeles Office
1989 Partner, Asahi Shinwa & Co.
1993 Joined Showa Ota & Co.
1997 Senior Partner, Showa Ota & Co.
2008 Executive Board Member, Ernst & Young ShinNihon LLC
2010 Established Nimura Certified Public Accountant Office
2012 Outside Director, Sony Corporation
2016 Outside Audit & Supervisory Board Member of the Company (to present)

10 Dr. Yuko Maeda

Director of CellBank Corp.
Auditor (Part-time) for Japan Agency for Marine-Earth Science and Technology

Outside **Independent**

1984 Joined Bridgestone Corporation
1998 CFO of BTR Power Systems Japan
2001 (Concurrent) Vice President of Tokyo University of Agriculture and Technology TLO Co., Ltd.
2003 Director, Technology Transfer Center of Tokyo Medical and Dental University
2009 Project Coordinator of Innovation Initiative Network Japan
(Concurrent) Visiting Professor of Tokyo Medical and Dental University
2011 (Concurrent) Specially Appointed Professor of Kyoto Prefectural University of Medicine
2013 Executive Officer of Bridgestone Corporation
2014 (Concurrent) Auditor of Japan Agency for Marine-Earth Science and Technology (to present)
2017 Director of CellBank Corp. (to present)
2019 Outside Audit & Supervisory Board Member of the Company (to present)

11 Kenichi Masuda

Partner of Anderson Mōri & Tomotsune
Outside Director of Bridgestone Corporation
Outside Corporate Auditor of LIFENET INSURANCE COMPANY
Outside Audit & Supervisory Board Member of Mercuria Investment Co.,Ltd.
Visiting Professor of School of Law, The University of Tokyo

Outside **Independent**

1988 Registered as an attorney-at-law (Daini Tokyo Bar Association)
Joined Anderson Mōri & Tomotsune
1993 Registered as an attorney-at-law in the state of New York
1997 Partner of Anderson Mōri & Tomotsune (to present)
2007 Outside Corporate Auditor of LIFENET INSURANCE COMPANY (to present)
2010 Part-time Lecturer at School of Law, The University of Tokyo
2011 Outside Corporate Auditor of Bridgestone Corporation
2016 Outside Director of Bridgestone Corporation (to present)
2016 Outside Audit & Supervisory Board Member of Mercuria Investment Co., Ltd. (to present)
2019 Visiting Professor of School of Law, The University of Tokyo (to present)
2020 Outside Audit & Supervisory Board Member of the Company (to present)

Independent Independent officer pursuant to Article 436-2 of the regulations of Tokyo Stock Exchange, Inc.

Note: Non-executive directors and outside Audit & Supervisory Board members do not own Company shares.

Members of the Executive Committee and Enlarged Executive Committee Not on the Board of Directors (As of April 1, 2020)

1 Shinya Unno

Deputy President
Supervisory responsibility for Human Resources Management, Human Capital Development, Legal, Intellectual Property, General Affairs
In charge of General Affairs Dept.

EC * EEC **

1999 Joined the Company
2005 General Manager of Corporate Planning Dept.
2006 Vice President and General Manager of Corporate Planning Dept.
2007 Vice President and Deputy General Manager of Sales Div.
2010 Senior Vice President, General Manager of Corporate Planning Supervisory Div. and General Manager of Corporate Planning Dept.
2015 Senior Vice President, in charge of General Affairs and Secretarial Dept.
2017 Executive Vice President and General Manager of Human Resources Supervisory Div., in charge of General Affairs Dept. and Secretarial Dept.
2020 Deputy President
Supervisory responsibility for Human Resources Management, Human Capital Development, Legal, Intellectual Property, and General Affairs
In charge of General Affairs Dept. (to present)

2 Dr. Hisafumi Okabe

Executive Vice President
Supervisory responsibility for Research and Translational Research and Head of Translational Research Div.

EC EEC

1991 Joined Nippon Roche K.K.
2002 Joined the Company; Department Manager of Pharmaceutical Research Dept.
2007 Director, Forerunner Pharma Research Co., Ltd.
2009 Vice President and General Manager of Research Div. Head, C&C Research Laboratories (Korea)
2012 Director and COO, Chugai Pharmabody Research Pte. Ltd. (Singapore) (to present)
2016 Senior Vice President and General Manager of Research Div.
2018 Executive Vice President and Head of Translational Research Div. (to present)

3 Toshiaki Itagaki

Executive Vice President & CFO
Supervisory responsibility for Finance & Accounting, Corporate Communications, Purchasing, Digital Strategy, and IT Solution

EC EEC

1983 Joined the Company
2007 General Manager of Finance & Accounting Dept.
2010 Department Manager of Planning & Research Dept.
2012 Department Manager of Marketing & Sales Planning Dept.
2015 Vice President, General Manager of Finance & Accounting Dept.
2018 Executive Vice President & CFO, General Manager of Finance Supervisory Div., General Manager of IT Supervisory Div. and General Manager of Finance & Accounting Dept.
2020 Executive Vice President & CFO
Supervisory responsibility for Finance & Accounting, Corporate Communication, Purchasing, Digital Strategy, and IT Solution (to present)

4 Junichi Ebihara

Senior Vice President
Head of Legal Dept. and Intellectual Property Dept.

EEC

2014 Joined the Company; Senior Corporate Advisor
Vice President and General Manager of Legal Dept.
2017 Senior Vice President and General Manager of Legal Dept.
2019 Head of Legal Dept. and Intellectual Property Dept. (to present)

5 Dr. Yoshiaki Ohashi

Senior Vice President
Head of Quality & Regulatory Compliance Unit and Head of Drug Safety Div.

EEC

1988 Joined the Company
2004 Department Manager, Quality & Regulatory Compliance Dept.
2009 Department Manager, Drug Safety Coordination Dept.
2011 Global PV Head (to present), Pharmacovigilance Manager
2013 General Manager of Drug Safety Div.
2015 Vice President, Head of Quality & Regulatory Compliance Unit, Head of Drug Safety Div. and Pharmaceutical Officer (to present)
2018 Senior Vice President, Head of Quality & Regulatory Compliance Unit and Head of Drug Safety Div. (to present)

6 Tetsuya Yamaguchi

Senior Vice President
Head of Corporate Planning Dept. and Head of Foundation Medicine Unit

EEC

2004 Joined the Company
2008 Department Manager of Planning & Research Dept.
2010 Roche Dee Why Australia
2011 Department Manager of Life Cycle Management Dept.-2
2012 Department Manager of Business Development Dept.
2016 Vice President, General Manager of Business Development Dept.
2020 Executive Vice President, Head of Corporate Planning Dept. and Head of Foundation Medicine Unit (to present)

7 Dr. Minoru Watanabe

Vice President
Head of Project & Lifecycle Management Unit

EEC

2007 Joined the Company
2011 Lifecycle Leader (Avastin) of Oncology Lifecycle Management Dept.
2012 Department Manager of Oncology Lifecycle Management Dept.
2015 Department Manager of R&D Portfolio Management Dept.
2017 General Manager of Research Div.
2018 Vice President, General Manager, Head of Corporate Planning Dept. and Foundation Medicine Unit
2020 Vice President and Head of Project & Lifecycle Management Unit (to present)

8 Dr. Hiroshi Murata

Vice President
Head of Pharmaceutical Technology Div.

EEC

1986 Joined the Company
2008 Department Manager of CMC Regulatory Affairs Dept.
2011 Department Manager of CMC Development Dept.
2012 Manager of Fujieda Plant, Chugai Pharma Manufacturing Co., Ltd.
2016 General Manager of Pharmaceutical Technology Div.
2018 Vice President and Head of Pharmaceutical Technology Div. (to present)

9 Shinji Hidaka

Vice President
Head of Marketing & Sales Div.

EEC

1987 Joined Nippon Roche K.K.
2009 Department Manager of Oncology Marketing & Sales Promotion
2011 Head of Oncology Unit
2013 Associate Vice President and Head of Primary Unit
2014 Vice President and Head of Primary Unit
2017 Vice President and Deputy General Manager of Marketing & Sales Div. (Marketing & Sales Promotion)
2018 Vice President and General Manager of Medical Affairs Div.
2020 Vice President and Head of Marketing & Sales Div. (to present)

* Executive Committee
** Enlarged Executive Committee

Chugai in Action

Overview of Activities in 2019

* 1: Value Creation 2: Value Delivery 3: Promote Advances in PHC 4: Strengthen Human Capital and Conduct Fundamental Structural Reform 5: Strengthen Sustainable Platforms

Category	Main initiatives	Connection with IBI 21 strategies*				
		1	2	3	4	5
Research	• Continuously generating first-in-class[1] and best-in-class[2] drugs	●				●
	• Creating molecular targeted drugs that contribute to personalized healthcare (PHC)	●	●	●		●
	• Strengthening innovative proprietary research technologies and creating innovative antibodies	●				●
	• Providing support and education for researchers from Asia				●	
	• Maintaining high animal welfare standards in accordance with international guidelines					●
Development	• Improving clinical development of drugs to address unmet medical need[3]	●		●	●	●
	• Identifying latent medical need and achieving early PoC[4]	●			●	
	• Increasing productivity and speed of global clinical development for early market launches	●		●	●	●
	• Conducting simultaneous development and regulatory filing of drug therapies and diagnostics that contribute to PHC	●		●	●	●
	• Strengthening lifecycle management to maximize product value	●		●	●	●
	• Obtaining early approval for projects in-licensed from Roche	●			●	
Pharmaceutical Technology and Production	• Providing a stable supply of high-quality drugs and investigational drugs	●	●			●
	• Enhancing the system for faster global launches and simultaneous development of multiple products	●	●			
	• Achieving early PoC by raising the level of CMC[5] development	●			●	
	• Raising the level of competitive advantages from late-stage development to initial commercial production (including investigation of next-generation industrial technologies)					●
	• Achieving world-class quality control systems and continuously raising their level	●				●
Marketing	• Contributing to advances in medicine as Japan's leading therapeutic antibody company		●			
	• Promoting standards of care and proper use of medicines in oncology		●	●		
	• Promoting PHC for optimal treatment options		●	●		
	• Supporting the resolution of medical issues in mainstay product areas and regions		●			
	• Consideration of patient-centric therapeutic approach		●			
Medical Affairs	• Building a consistent global medical affairs promotion system with proper independence of roles		●			
	• Strengthening systems for healthcare compliance and governance of contract-based post-marketing studies		●			
	• Generating evidence and promoting scientific communication activities		●			
	• Expanding and upgrading global medical information functions		●			

1. An original drug that is highly novel and useful, and will significantly change the therapeutic system
2. A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target
3. Medical need that is not adequately met due to a lack of effective treatments
4. PoC is confirmation that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.
5. Chemistry, Manufacturing and Controls: Control functions from development of manufacturing processes to drug quality and manufacturing

	Main performance indicators in 2019
	• Generated multiple drug discovery projects from candidate compounds that originated from the Collaboration Promotion Laboratory at IFReC • Created development candidates using proprietary antibody engineering technologies • Created development candidates using proprietary middle molecule technologies • Started construction of Chugai Life Science Park Yokohama
	• Conducted development of NXT007 and obtained early approval for Rozlytrek • Provided insights for promoting utilization of data, including real-world data (RWD), and maximizing product value • Further improved processes by carrying out operational consolidation and analysis of clinical operations, systems and processes, as well as management of contract research organizations and vendors, etc. that are common among projects
	• Invested in facilities for faster launches and simultaneous development of multiple antibodies and small molecule drugs (started operation of new antibody API manufacturing facility (UK3) at Ukima Plant, began manufacturing Actemra subcutaneous injection using a tray filler at Utsunomiya Plant, and started construction of new manufacturing facility for APIs for small and middle molecule drugs at Fujieda Plant) • Received FDA pre-approval inspection for satralizumab • Received pre-approval inspection and approval for Hemlibra in countries around the world • Strengthened global supply chain management • Enhanced next-generation core technologies for API and formulation manufacture • Strengthened development ability by reducing costs from the early stage onward and planning and implementing a formulation strategy • Conducted structural reform of production functions to enhance competitiveness and improve operational efficiency
	• Conducted support activities for patient-centric regional healthcare and multidisciplinary team care, including promotion of disease awareness in cooperation with the government • Provided an information-sharing support tool to facilitate smooth communication between patients and their healthcare professionals • Enhanced communication of safety information through use of post-marketing surveillance and adverse reaction databases and cooperation with Safety Experts • Enhanced marketing functions in accordance with regional healthcare conditions • Education for MRs with a high level of expertise
	• Generated clinical evidence by conducting industry-initiated clinical studies and supporting investigator-initiated clinical studies • Generated non-clinical evidence by conducting basic research to shed light on modes of action of drugs, etc. • Improved business efficiency through introduction of MI chat, a chatbot for product information inquiries • Promoted global-level medical activities in cooperation with Roche and overseas subsidiaries • Implemented and supported construction of data utilization system for database research, etc. • Established appropriate governance and compliance system in response to Guidelines for Prescription Drug Marketing Information Provision and other regulations

* 1: Value Creation 2: Value Delivery 3: Promote Advances in PHC 4: Strengthen Human Capital and Conduct Fundamental Structural Reform 5: Strengthen Sustainable Platforms

Category	Main initiatives	Connection with IBI 21 strategies*				
		1	2	3	4	5
Drug Safety	• Strengthening pharmacovigilance system to meet the world's strictest standards and most comprehensive global regulations					●
	• Providing solutions to patients and healthcare professionals using drug safety information		●			
	• Preparing and implementing risk management plans (RMPs)		●			●
Quality and Regulatory Compliance	• Strengthening global quality governance					●
	• Establishing system to provide product quality solutions from customer's perspective		●			
	• Establishing global quality and regulatory intelligence management system for post-marketing products and late-stage development projects		●			
	• Establishing and conducting new quality and regulatory compliance scheme in response to new business developments (medical devices, regenerative medicine, etc.)		●	●		
	• Establishing quality and regulatory compliance framework and governance for data use		●	●		●
Intellectual Property	• Protecting and effectively using rights for broadly applicable innovative technologies		●	●	●	●
	• Filing high-quality patent applications and effectively allocating resources	●	●	●	●	●
	• Aggressively filing patent applications outside Japan with a view to global co-development	●	●	●	●	●

Highlights of 2019

Products and Development Projects

March	• Hemlibra obtained approval for additional indication (severe hemophilia A without inhibitors; Europe) • Rituxan obtained approval for additional indication (CD20-positive chronic lymphocytic leukemia; Japan) (Zenyaku Kogyo Co., Ltd.) • Actemra intravenous infusion obtained approval for additional indication (cytokine release syndrome; Japan) • Risdiplam received orphan drug designation (spinal muscular atrophy; Japan)
May	• Actemra intravenous infusion obtained approval for additional indication (adult Still's disease; Japan)
June	• FoundationOne CDx Cancer Genomic Profile launched and testing services on consignment started • Rozlytrek obtained approval (*NTRK* fusion gene positive advanced/recurrent solid tumors; Japan) • FoundationOne CDx Cancer Genomic Profile obtained approval as a companion diagnostic for Rozlytrek
August	• Tecentriq obtained approval for additional indication (extensive-stage small cell lung cancer; Japan)
September	• Rozlytrek launched (Japan) • Satralizumab received orphan drug designation (neuromyelitis optica and neuromyelitis optica spectrum disorder; Japan) • Tecentriq obtained approval for additional indication (PD-L1-positive triple-negative breast cancer (TNBC)) and additional formulation (840 mg) • FoundationOne CDx Cancer Genomic Profile obtained approval for expanded use as a companion diagnostic for Lynparza
October	• Telomelysin (OBP-301) receives Sakigake Designation • Hemlibra obtained approval (hemophilia A without inhibitors; Taiwan)
November	• Hemlibra launched (hemophilia A with inhibitors; Taiwan) • Polatuzumab vedotin received orphan drug designation (diffuse large B-cell lymphoma; Japan) • Tecentriq Intravenous Infusion 840 mg (launched in Japan)
December	• Nemolizumab received breakthrough therapy designation (pruritus associated with prurigo nodularis; U.S.) (Galderma S.A.)

	Main performance indicators in 2019
	• Increased capacity for generating and providing drug safety information using advanced technologies such as epidemiology and information technology, and enhanced the activities of Safety Experts, a specialist position for handling drug safety information • Established global-level safety functions to prepare for business expansion in Asia • Led the industry by conducting activities to raise awareness regarding the use of the risk management plan (RMPs) among healthcare providers
	• Strengthened quality systems and handled overseas inspections by EMA, FDA, etc. (for all GxP) • Complied fully with the Guidelines for Prescription Drug Marketing Information Provision • Established system to provide product quality solutions through coordination among the Marketing & Sales Division, Pharmaceutical Technology Division and Quality & Regulatory Compliance Unit • Strengthened cooperative schemes including with out-licensees, partners and overseas bases • Dealt with quality management system and new modalities (regenerative medicine, gene therapy, etc.) for genomic mutation analysis program FoundationOne CDx Cancer Genomic Profile • Established a digital compliance system for handling human-derived data
	• Market defense in lawsuits with manufacturers of similar products with the equivalent effect or developers and manufacturers of biosimilars • Operated a system for monitoring other companies' patents • Strengthened cooperation with the Research Division, Pharmaceutical Technology Division and IFReC using IP liaisons as a hub • Strengthened cooperation with IP functions of Roche and Genentech Inc. and with internal and external stakeholders

Management

January	• Transferred rights for Oxarol Ointment 25μg/g, Oxarol Lotion 25μg/g and Marduox Ointment to Maruho Co., Ltd. • Announced new Mission Statement and new mid-term business plan IBI 21, aiming to grow together with society by creating and delivering innovative drugs and services
March	• Entered into business partnership agreement with Miraca Holdings Inc. for FoundationOne CDx Cancer Genomic Profile
April	• Transferred UlcerImin business to Fuji Chemical Industries Co., Ltd. • Entered into exclusive licensing and capital tie-up agreements with Oncolys BioPharma Inc. for Telomelysin (OBP-301) oncolytic viral immunotherapy • Implemented early retirement incentive program • Decided to construct a new manufacturing facility for APIs for small and middle molecule drugs at the Fujieda Plant
May	• Decided to establish Chugai Life Science Park Yokohama and to relocate research laboratories
June	• Entered into service agreement for logistics operations with Mitsubishi Logistics Corporation
November	• Agreed with JW Pharmaceutical Corporation to make their joint venture in Korea, C&C Research Laboratories, a wholly owned subsidiary of JW Pharmaceutical
December	• Announced change in representative directors

Stakeholders

January	• Started operation of MI chat (Medical Information ChatBot), an automated conversation program that uses AI to respond to product information inquiries from healthcare professionals
February	• Chugai was one of four recipients, including Osaka University, of the Minister of Education, Culture, Sports, Science and Technology Award at the 1st Japan Open Innovation Prize for "University–Industry Co-creation from the Basic Research Stage –Collaboration between Organizations–" • Joined the World Federation of Hemophilia Humanitarian Aid Program, together with Roche • Received the President's Award of the Japan Techno-Economics Society for the creation of anti-IL-6 receptor antibody Actemra, at the 7th Technology Management and Innovation Awards
March	• Selected as a grant recipient by the Global Health Innovative Technology Fund (GHIT Fund) for a joint research project with the Agency for Science, Technology and Research, Singapore (A*STAR) for an anti-dengue virus antibody
July	• Maintained listings on all ESG indices selected by Government Pension Investment Fund
September	• Selected as an index component of the Dow Jones Sustainability Asia Pacific Index for the fifth time and the second consecutive year • Donated para-transit vehicles to welfare services • Announced Chugai Group Non-Smoking Declaration • Began providing a treatment support tool using a private medical care SNS for rheumatoid arthritis, lupus nephritis, and chronic kidney disease
December	• Rating and Investment Information, Inc. (R&I) raised Chugai's issuer rating from "AA–" to "AA"

Research

Key Points of IBI 21
(2019-2021)

- Development of leading drug discovery technologies and continuous additions to pipeline
- Creation and promotion of innovative projects through the deepening of biological research into human diseases
- Expansion of opportunities to acquire new candidate compounds using external network

• Proprietary drug discovery technology, particularly in biotechnology • Efficient collaboration with the Roche Group, including infrastructure sharing	S (Strengths)	W (Weaknesses)	• Infrastructure for recruiting researchers is incomplete • Lack of resources for biotechnology research
• Progress in new modalities, including middle molecule drugs • Mounting social expectations for drug discovery and healthcare as a growth industry	O (Opportunities)	T (Threats)	• Increasing difficulty and escalating cost of new drug development worldwide, and intensifying competition • Potential paradigm shift due to disruptive technologies, etc.

Performance in 2019

14
In-house projects in the development pipeline
(As of January 31, 2020)

55
Publications in academic papers and presentations at scientific conferences regarding Chugai's innovative proprietary antibody engineering technologies
(2015-2019)

88
Publications in academic papers regarding Chugai's research findings
(2015-2019)

14.9%
R&D expenditures to revenues ratio
(2019)

Functions

Chugai began conducting research and development of biopharmaceuticals more than 30 years ago, and the former Nippon Roche had also established world-class technology for the discovery of chemically synthesized agents. Over the years, we have cultivated knowledge and gained experience through our advanced initiatives while also incorporating outside technologies. As a result, we have continuously evolved our capabilities, and have built a technology platform that we can flexibly and appropriately apply to drug discovery.

We are using this platform to generate a steady stream of innovative new drugs with first-in-class or best-in-class potential to address unmet medical need. In addition to developing antibody engineering technologies ahead of other companies, Chugai has industry-leading research and technological capabilities backed by small and middle molecule[1] technologies, the world-class research infrastructure of the Roche Group and a powerful external network with academia and other parties. Through presentations of research findings at scientific conferences and other means, these strengths lead to benefits for the medical community around the world as we leverage them in the creation of in-house projects.

1. Molecules with a molecular weight between 500 and 2,000. Middle molecules are expected to be capable of inhibiting protein–protein interaction (PPI) in intercellular molecules, which is difficult to achieve with antibodies and small molecules.

Business Model

One of Chugai's strategic advantages that enables it to continuously create innovative drugs is its ability to concentrate resources on innovative research. Efficient development in Japan of projects in-licensed from Roche provides a stable revenue base while we conduct global development of projects from our own research in collaboration with Roche. This enables us to concentrate personnel and funds on groundbreaking in-house projects, leading to the creation of a steady stream of innovative drugs. Another of our strengths is access to Roche's global research infrastructure. The ability to share Roche's global research resources and infrastructure, including a rich, high-quality compound library for use in high-throughput screening,[2] is a significant plus for Chugai in terms of cost, efficiency and other factors, and has dramatically increased our research productivity.

In addition, by concentrating on the development of next-generation antibody engineering technologies and the creation of new therapeutic antibodies, Chugai Pharmabody Research (CPR), which we established in Singapore in 2012, is working to continuously create innovative therapeutic antibody drugs and to accelerate the speed of drug discovery.

2. A technology for conducting evaluations at a high speed with robots or other means to select chemical compounds that show activity for drug creation targets from a library consisting of a vast number of compound types with various structures

Allocation of Resources

In allocating research resources, we prioritize each project based on the following criteria:
(1) The project's potential for development as a novel medicine that can be clearly differentiated
(2) Whether it has a scientific basis for addressing unmet medical need
(3) Whether it will enable PHC

At decision points during research, we focus first and foremost on patient need in the belief that creating medicines truly needed by patients and healthcare providers will lead to Chugai's medium-to-long-term growth.

Bioethics and Animal Welfare

To ensure that research using human-derived samples is carried out appropriately, Chugai has established Ethical Guidelines for Research That Uses Human-Derived Samples and a Research Ethics Committee. More than half of the members of this committee are from outside the Company, enabling fair evaluations from a pluralistic frame of reference.

Moreover, when handling laboratory animals used in research, Chugai acts in accordance with the Guidelines for the Care and Use of Laboratory Animals it has established to respect their lives from the standpoint of animal welfare, and to minimize pain, keeping in mind the scientific conditions.

Chugai's measures, which are based on the principles of the 3Rs (Replacement, Reduction and Refinement), were positively evaluated by AAALAC International,[3] a global third-party

evaluation organization, and the Company has maintained full accreditation since 2007.

3. The Association for Assessment and Accreditation of Laboratory Animal Care International, a private non-profit organization that promotes the humane treatment of animals in scientific research through voluntary inspection and accreditation programs. More than 900 facilities in 39 countries have obtained AAALAC accreditation.

Main Initiatives and Progress

Promotion of Unique Biological Discoveries

Created based on a novel concept, Hemlibra is the product of innovation achieved by uniquely combining Chugai's extensive understanding of the biology of diseases and its antibody engineering technologies. To continuously generate such innovations and to reinforce and pass down an organizational culture that produces breakthrough medicines with clear value for healthcare, in 2019 we adopted a scheme to allocate 20% or more of approximately half of our researchers' workloads to the creation, testing and verification of new ideas as a cross-departmental activity of the Research Division.

Collaboration with Our External Network

In April 2017, the Collaboration Promotion Laboratory began operating under our comprehensive agreement with Osaka University Immunology Frontier Research Center (IFReC) to conduct ongoing assessment and introduction of new candidate compounds from its cutting-edge immunology research.

Immunity is involved not only in diseases of the immune system itself, but also in cancer and various other diseases, and immune-mediated therapies are now becoming mainstream cancer treatments. Combining the global top-class research in immunology at IFReC and Chugai's expertise in drug discovery research, accumulated through its proprietary technologies, is expected to result in the creation of innovative new drugs.

We are also looking to innovate the drug discovery process itself, including for next-generation PHC, by applying the highly advanced genomic analysis techniques and other capabilities of Foundation Medicine Inc. (FMI),[4] which joined the Roche Group in 2015.

Research at Satellite Labs

Research at satellite labs has also yielded solid results, leading to the successful establishment of stable cell lines of colon cancer stem cells in October 2012 and the identification of new molecular targets at Chugai's wholly-owned subsidiary, Forerunner Pharma Research Co., Ltd. Furthermore, CPR is making steady progress in the discovery of new therapeutic antibodies and the creation of new development candidates to follow GYM329 and SKY59, which have already entered clinical development.

Evolution of Drug Discovery Modalities

In the pharmaceutical industry, modality refers to the material classification of drugs such as therapeutic antibodies or therapeutic nucleic acids. Until around 1990, small molecule drugs were virtually the only modality available, but modality options are now increasing. Chugai is currently focusing on establishing middle molecules as a third modality in addition to biologics and small molecules, in which it is already strong. Middle molecules are a valuable method for reaching intracellular targets that are difficult to approach using antibodies and small molecules, and we are proactively promoting the establishment of a hit-to-lead compound generation technology platform as we work toward the creation of development projects.

Enhancing Our Intelligence Functions

Rapid scientific and technological advances, especially in life science, digital technology and information and communications technology (ICT), are bringing dramatic changes to society, including the pharmaceutical industry. Chugai's response to emerging issues in the healthcare business is mainly the responsibility of the Science and Technology Intelligence (STI) Department, which was established in April 2017 as an intelligence unit.

Healthcare in the future is expected to center on PHC, which provides optimal solutions tailored to individual patient needs, and will need to provide comprehensive value in a sustainable form that encompasses prevention and prognosis in addition to diagnosis and treatment, which are the focus of the current model. We aim to contribute to higher-quality healthcare with solutions that lead to new value, and a critical part of that effort is formulating strategies for disruptive innovation,[5] which will be essential for realizing such solutions.

STI's mission is to find signs of change and to create strategies for bringing it about. In the three areas of life science, digital ICT, and advanced PHC, STI not only collects and analyzes information, but also works to establish conditions for initiating disruptive innovation.

In July 2018, Chugai entered into a comprehensive partnership agreement with Preferred Networks, Inc. (PFN), a global leader in AI technology. We are currently conducting multiple cooperative projects with the aim of creating innovative drugs and new value through the application of PFN's cutting-edge deep learning technology and Chugai's expertise, technologies and data.

4. FMI was established in Massachusetts, U.S.A. in 2010. In 2015, Roche took a majority stake, and then acquired the remaining outstanding shares in 2018 to make FMI a wholly-owned subsidiary. Chugai established the FMI business as a specialized unit in October 2018 to carry out commercialization and product value maximization of FMI's Comprehensive Genomic Profiling Service in Japan.

5. Innovation that disrupts the order of existing business and causes drastic changes in the industry structure

Progress of Development Projects in 2019

(February 1, 2019 – January 31, 2020)

	Number of Projects	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration/ Formulations, Expanded Use
Approved	13	1	6	6
Filed	8	3	3	2
Started or moved to phase III	6	2	4	0
Started or moved to phase II	1	1	0	0
Started phase I	5	5	0	0
Development suspended	5	3	2	—

Comparison of Drug Discovery Modalities

	Small Molecules	Middle Molecules	Biologics
Molecular weight	Below 500	500 - 2,000	10,000 and above
Target specificity	Fair	High	High
Intracellular targets	Wide range	Numerous	Limited
PPI[6] inhibition	Fair	Good	Good
Administration route	Oral/Injection	Oral/Injection	Injection
Manufacturing method	Organic synthesis	Organic synthesis	Cell culture

6. PPI: Protein–Protein Interaction

Development

Key Points of IBI 21
(2019-2021)

- Establishment of development methods for Chugai products with new modalities and mechanisms of action
- Further acceleration of development through use of data assets
- Maximization of product value based on VBHC[1]

1. Value-based healthcare

• Comprehensive development track record (total no. of clinical trials: 115[2]) • High development success rate of innovative in-house products (FPI[3]: 1 project; breakthrough therapy designation (BTD)[4]: 1)[2] • Global collaboration with Roche (global studies: over 58%; joint development projects: 33)[5]	S (Strengths)	W (Weaknesses)	• Evolution of quality and speed at a top global level in early development • Constant and cross-functional operation of the process for proof of value • Infrastructure development and acquisition of human resources for utilization of real world-data (RWD), data assets, and cutting-edge technologies
• Increasing expectations for development of innovative drugs using proprietary technology • Advances in development of PHC using large-scale data such as genetic information • Greater flexibility and diversification in the application filing process	O (Opportunities)	T (Threats)	• Intensified global competition in new drug development and escalating development costs • Potential paradigm shift due to disruptive technologies, etc. • Decline in competitive advantage of in-house products due to the emergence of new modalities

2. January-December 2019 3. First patient in 4. A system introduced in July 2012 by the U.S. Food and Drug Administration aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms 5. As of December 31, 2019

Performance in 2019

49
Pipeline projects
(As of January 31, 2020)

23
New products launched and new indications
(2015–2019)

40
Projects being co-developed with Roche Group
(As of January 31, 2020)

18
Projects in-licensed from Roche
(2015–2019)

Functions

Chugai has established a lifecycle management[6] system for project-level integrated management of each of its functions, and cooperates with numerous medical institutions and clinical research centers. In this way, we implement clinical trials distinguished by exceptional speed, efficiency and scientific rigor.

Specifically, in clinical development, we draw up clinical development plans based on the latest scientific findings and invite medical institutions to conduct clinical trials. In pharmaceutical technology and production, we examine commercial production that will turn candidate compounds into pharmaceutical products and manufacture investigational drugs for clinical trials. In drug safety, we ensure a high level of safety in clinical trials by gaining an understanding and beginning assessments of each drug's safety profile from the early stages.

Through our alliance with the Roche Group, we are implementing multiple global development projects (global studies) and strengthening the process that enables simultaneous development of drugs and companion diagnostics intended for PHC. Through these global initiatives, we are creating best practices in development and filing for approval, which we believe contribute to the advancement of the industry.

6. The various measures taken to maximize the potential value of a drug, including shortening development time, expanding sales, extending the product's life, and conducting appropriate cost control. Competitiveness can be strengthened further by using earnings from sales of established drugs to strategically reinvest in new drug development, marketing or other areas.

Enhancement of Functions and Organizational Change

In October 2019, Chugai reorganized the functions of the Translational Research (TR) Division, which acts as a bridge between preclinical and early clinical development. The new Early Clinical Development Department was established to consolidate planning and promotion functions for early clinical development of projects originating at Chugai in order to improve operational efficiency and strengthen early clinical development skills. This is expected to give more impetus to integrated development of in-house products from the research stage to the early clinical development stage. For overseas development of projects from in-house research, overseas subsidiaries Chugai Pharma USA, Chugai Pharma Europe, Chugai Pharma Science (Beijing) and Chugai Pharma Taiwan conduct high-quality clinical trials in close cooperation with medical institutions in each country.

We also accelerate global development by sharing knowledge and platforms for clinical development with the Roche Group. Moreover, we utilize FMI and others to generate evidence from the clinical development stage that will lead to PHC.

Moreover, the Clinical Development Division has assigned a clinical solutions supervisor to carry out integrated management and execution of shared work among projects for all clinical studies, and to take the lead for further process improvement, optimal vendor strategies and other matters.

Main Initiatives and Progress

A Well-Stocked Pipeline

In 2019, all projects made steady progress. Chugai filed for regulatory approval for eight projects, and obtained approval for one project. Chugai's pipeline grew even richer, with eight new projects (in-house or in-licensed from Roche) advancing to the clinical phase.

Speedy Global Development

Chugai has been working to speed up global development by following a development model with a high probability of success and by making efforts to prove the value of in-house projects from the early stages of development. As a result, Alecensa took just seven years from concept to launch, and Hemlibra, for which we filed for approval simultaneously in Japan, the United States and Europe, obtained approval in less than five years from initiation of clinical development, far ahead of our initial plan. Hemlibra is dramatically transforming treatment strategies for hemophilia and achieving unprecedented results.

Moreover, after nemolizumab (CIM331) received BTD and satralizumab (SA237) obtained positive results in global studies under Chugai's management, in 2019 we completed filings in Japan, the United States and Europe in collaboration with Roche.

Pharmaceutical Technology and Production

Key Points of IBI 21
(2019-2021)

- Acquisition of PoC with world-class speed
- Realization of a production system with a strong competitive advantage from the pre-launch stage
- Structural reform of the commercial production system

• Advanced therapeutic antibody production technology and state-of-the-art equipment • Proven track record of global inspections and applications (Hemlibra, Alecensa, and satralizumab) • Timely identification and response to requests from regulatory authorities that can be shared with the Roche Group	**S** (Strengths)	**W** (Weaknesses) • Creation of an efficient production system utilizing external resources in accordance with rapid changes in demand
• Fast-track review system to support early approval of innovative new drugs • Initiation of a system for pharmaceutical quality management • Increase in product supply volumes as a result of expansion of the Asian (Chinese) market	**O** (Opportunities)	**T** (Threats) • Progress in global control over drug costs, loss of premium pricing status for new drug creation on mainstay products amid drastic reform of NHI drug prices, and cost reductions in response to the emergence of generic drugs and the increased need for greater productivity

Performance in 2019

Began operations of facilities that can handle multiple antibody development projects simultaneously

Upgraded world-class system for pharmaceutical quality management

62
Research papers and other publications from the Pharmaceutical Technology Division (2015-2019)

Functions

Our pharmaceutical technology and production functions play a wide range of roles in the pharmaceutical value chain – from turning drug candidates into products to stably supplying them. These candidates may be compounds created in our laboratories or projects in-licensed from Roche or elsewhere.

Product creation includes research on production methods for active pharmaceutical ingredients (APIs), formulation and packaging design, production of investigational APIs, and collection and analysis of production data. Among these activities, we have most recently been taking positive steps to build and patent a new technology platform that will give us a distinct advantage in commercial production of innovative medicines such as next-generation antibodies and middle molecules.

Through stable supply of our products, we maintain the trust of patients and healthcare professionals – a responsibility central to Chugai's existence as a pharmaceutical manufacturer. That is why we need to build and maintain a robust supply chain with production bases (including contract manufacturing organizations) around the world.

Chugai has competencies at Japan's top level, including bioproduction technology and the ability to accommodate inspections. We will leverage our strengths as a member of the Roche Group to become a top innovator in our pharmaceutical technology and production operations.

Main Initiatives and Progress

Improving Flexibility and Speed

In its pharmaceutical technology and production operations, Chugai is aiming for simultaneous development of multiple products for the quickest launches possible.

Specifically, at the Ukima Plant, we have achieved a significant increase in capacity utilization by employing plastic single-use bioreactors. For development candidates that apply next-generation antibody engineering technologies, we have started operation of UK3, a new antibody API facility capable of high-mix, low-volume production from late-stage development to initial commercial products. At the Utsunomiya Plant, we have increased production flexibility by installing tray fillers that can handle filling of liquid medicines without making line changes or modifications, regardless of the syringe type.

At the Fujieda Plant, we will introduce an API manufacturing facility for investigational drugs for middle molecules, which are a next-generation modality, with the aim of starting operations in 2022.

Evolving Supply Chain Management

To minimize risks related to the supply and price of raw materials, we promote the globalization of our suppliers of raw materials and intermediate products in tandem with the globalization and establishment of two production bases for each finished product.

Our subsidiary Chugai Distribution Co., Ltd. handles distribution of pharmaceuticals in Japan. The company's computerized inventory management and inspection ensure stable and safe distribution, and the staff conducts ongoing process innovation in packaging.

Thorough Quality Assurance

Quality assurance functions have diversified in recent years in response to the increasing complexity of supplying products and accelerated development with the introduction of the fast-track review system to support the early launch of innovative new drugs.

In view of these trends, Chugai is working to further strengthen GMP* management oversight to promote more rigorous and high-level quality assurance. As part of these efforts, Chugai promotes the building and operation of a world-class system for pharmaceutical quality management.

* Good Manufacturing Practice: Standards for pharmaceutical production management and quality control

Biological API Production: Our Facility Portfolio

Plant	Target	Bioreactors	Features	Products
Utsunomiya	Commercial production (Large-scale)	10,000 L x 8 (UT1, UT2: Stainless steel tanks)	• Competitive low-cost production • Dedicated facilities	Actemra
Ukima	Commercial production/ Production of investigational APIs (Medium-scale)	6,000 L x 6 (UK3: Stainless steel tanks)	• Emphasis on flexibility • Can handle high-mix, low-volume production	Future development projects
Ukima	Commercial production/ Production of investigational APIs (Small-scale)	2,000 L x 4 (UK1, UK2: Single-use plastic bags)	• Improved capacity utilization through the application of single-use bioreactor technology	Hemlibra and future development projects

Close-Up 1 Standout Initiatives under IBI 21

Advancing Middle Molecule Drugs to the Clinical Phase

In relation to our goal of starting clinical development of middle molecule drugs during the term of IBI 21, particular challenges lie ahead in production of investigational APIs and clinical trial design as well as drug discovery. Given our aim of achieving a high level of convenience as well as efficacy and safety, our middle molecule drugs have highly specific structures and physicochemical properties. The manufacturing process is more complicated than for the small molecule drugs we have produced in the past, and we must overcome the hurdle of mass production. Moreover, demonstrating new concepts in molecular therapeutic effect also entails the establishment of a clinical prediction system for human subjects, which is extremely difficult, as well as appropriate methods for setting and evaluating biomarkers. Despite facing difficulties that we have not encountered before, various departments are cooperating from the earliest stages as we work to establish this next-generation modality of middle molecule drugs, so that we can deliver innovative medicines to patients as quickly as possible.

Satoshi Tanida
Discovery Technology Dept.,
Research Div.

Mikiko Nakamura
Clinical Pharmacology Dept.,
Translational Research Div.

Akie Honma
API Process Development Dept.,
Pharmaceutical Technology Div.

Stepping Up Initiatives and Future Outlook at Chugai Pharmabody Research

When Chugai Pharmabody Research (CPR) was first established in Singapore in 2012, its role was to concentrate on creating new antibodies. Having produced results in line with this objective, its functions have expanded since 2017. A compact organization with diverse human resources, CPR possesses all drug discovery research functions from antibody production to drug metabolism and pharmacokinetics, pharmacological evaluation, and development of new technologies. CPR and the Research Division are now leveraging their individual strengths and expertise to collaborate on joint projects, technology development and discussions of new ideas.

Stepping up initiatives at CPR will expedite Chugai's drug discovery and help to demonstrate that diversity is the wellspring of innovation. We will generate further synergies to create innovative drugs with value for patients.

Priyanka Chichili
Protein Production Unit,
Chugai Pharmabody Research Pte. Ltd.

Hitoshi Katada
Discovery Biologics Dept.,
Research Div.

Takaaki Noguchi
Discovery Pharmacology Dept.,
Research Div.

Realizing Sustainable Supply Chain Management

Establishing robust supply chain management that enables us to work together with suppliers to address sustainability issues is essential for stably delivering high-quality drugs to patients and helping to resolve global social issues.

In 2019, in addition to creating a comprehensive system for evaluating suppliers and starting supplier due diligence based on this policy, we established a model for cooperation between the Pharmaceutical Technology Division and the Sustainability Department. However, despite a high level of awareness of sustainability, only a limited number of suppliers have codified and established sustainability in their policies and systems, and we have the sense that the differing languages, cultures, and customs in the global supply chain make it difficult to ascertain actual labor conditions. This initiative will take time, but we will carry it out steadily and emphatically while defining our priorities.

Shinobu Aizawa
Supply Chain Management Dept.,
Pharmaceutical Technology Div.

Koichi Kawahara
Business Ethics Group,
Sustainability Dept.

Marketing

Key Points of IBI 21
(2019-2021)

- Maximization of the value of growth drivers (innovative drugs and services)
- Enhancement of consulting activities to select the best treatment using innovative products according to each patient's condition
- Provision of solutions through cooperation with diverse specialized human resources and incorporation of digital technology

• Leading presence in specialty areas, such as biopharmaceuticals and PHC • A system for providing advanced solutions based on regional and customer characteristics, multidisciplinary team care and drug safety activities utilizing a database of adverse events, etc.	S (Strengths)	W (Weaknesses) • Response to an increase in competing products and new entrants • Response to the emergence of biosimilars[1] and generic drugs[2]
• Further increase in unmet medical need[3] as a result of the aging population as well as rare and refractory diseases • Increase in therapeutic opportunities due to early detection and promotion of testing • Progress in personalized and advanced healthcare, including genetic diagnosis	O (Opportunities)	T (Threats) • Progress in global control over drug costs, and the shrinking domestic market amid drastic reform of NHI drug prices • Loss of premium pricing status for new drug creation on mainstay products and the emergence of generic drugs • Tighter regulations on promotional activities due to higher ethical and transparency standards

1. Follow-on products to biopharmaceuticals whose patent term has expired, made by manufacturers other than the manufacturer that developed the antecedent biopharmaceutical
2. Drugs approved after the expiry of the patents for original drugs with the same active ingredients and efficacy
3. Medical need that is not adequately met due to a lack of effective treatments

Performance in 2019

23.9%[4]
Share of sales in the Japanese therapeutic antibody market

16.4%[4]
Share of sales in the Japanese oncology market

1[5]
Satisfaction ranking based on healthcare professionals' assessments
(Oncology; hospitals with 100 or more beds)

1[6]
Adequacy ranking for provision of safety information based on healthcare professionals' assessments
(Hospitals with 100 or more beds)

4. Copyright © 2020 IQVIA. Source: JPM 2019. Reprinted with permission. The scope of the market is defined by Chugai.
5. Source: INTAGE Healthcare Inc., CS Survey of Oncology, 2019. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
6. Source: INTAGE Healthcare Inc., 2019 questionnaire about safety information needs.

Functions

The need for new therapeutic agents to deal with cancers or rare or refractory diseases that lack effective treatments (unmet medical need) is high, and more sophisticated and individualized medical procedures such as cancer immunotherapy and genomic testing are attracting attention. Chugai is pursuing initiatives to meet unmet medical need based on its extensive lineup of first-in-class and best-in-class drugs and new diagnostic technologies.

As medicine becomes more sophisticated and individualized, healthcare professionals will be expected to promptly provide high-quality information. Chugai takes three approaches to this process, which it refers to as "consulting."

For patients

We conduct patient-centric consulting that gives the highest priority to patients, including proposing the optimal drug treatment according to each patient's condition, providing relevant information on proper use and safety, and follow-up activities.

For regional healthcare

We provide liaison services for regional healthcare with the aim of solving medical issues according to local area characteristics. We conduct consulting that improves patients' access to treatment by supporting regional healthcare coordination among healthcare professionals and medical institutions as well as collaboration among local governments, public entities, and other industries.

For stakeholders

Multidisciplinary team care has advanced in recent years, with various specialist healthcare professionals working in collaboration to carry out treatment according to each patient's condition. We conduct consulting to support our diverse stakeholders, while multidisciplinary teams follow up on treatment through proper management of adverse events.

Because consulting activities necessarily require extensive communication with relevant parties, our MRs play a key role. In addition to MRs, we also have a system for providing solutions that meet medical need through participation in cross-functional teams by members of the Marketing & Sales, Medical Affairs and Drug Safety divisions, who have high-level expertise.

We are also innovating business processes using the latest digital technologies such as artificial intelligence and the Internet of Things to build a system that can provide more efficient and effective solutions based on higher-quality consulting.

Main Initiatives and Progress

Oncology

In 2019, sales in the oncology area in Japan increased 6.6 percent year on year to ¥240.5 billion. The contribution from new products included ¥20.6 billion from rapid market penetration of Tecentriq, an anti-PD-L1 monoclonal antibody launched in 2018 and used primarily for lung cancer, and ¥3.6 billion from Gazyva, a treatment for CD20-positive follicular lymphoma launched in 2018 to which we actively promoted a switch from Rituxan. In addition, market uptake substantially exceeded expectations for Perjeta, which obtained approval for the additional indication of HER2-positive early breast cancer in 2018, and sales increased ¥14.6 billion (90.7 percent) to ¥30.7 billion, contributing significantly to results.

In addition, amid the emergence of various new drugs in each area and their changing position in treatment, we were able to minimize the impact of the launches of biosimilars for Herceptin and Rituxan by maintaining sales volume for mainstay drug Avastin and growing sales of new and existing products. Meanwhile, overseas sales of Alecensa, including exports to Roche, continued to be firm due to its widespread use in first-line treatment, increasing ¥15.8 billion (53.6 percent) to ¥45.3 billion.

In 2020, despite the expected impact on Avastin from the loss of premium pricing status and from biosimilars, we aim for further growth in the oncology area led by Tecentriq, which obtained approval in 2019 as a first-line treatment for small cell lung cancer and triple-negative breast cancer, as well as from market uptake of Gazyva, Kadcyla, Alecensa and other products.

Bone and Joint Diseases

In 2019, sales in the bone and joint diseases area in Japan increased ¥7.9 billion (7.9 percent), year on year to ¥108.4 billion. Growth was driven by Actemra, a first-line biologic for the treatment of rheumatoid arthritis (RA) that is growing based on an additional indication for a rare disease, Edirol, which has been recognized as a base treatment for osteoporosis, and Bonviva, which is available in an oral formulation in addition to the intravenous formulation. Sales of Actemra outside Japan including exports to Roche increased ¥7.7 billion (9.6 percent), to ¥88.3 billion due to firm global sales by Roche.

In 2020, although there will be negative factors in Japan including the expected launch of a generic of Edirol, we foresee growth in sales of Actemra outside Japan, mainly due to further uptake of the subcutaneous formulation for RA and sales for giant cell arteritis, which became an additional indication in 2017.

Renal Diseases

Sales in the renal diseases area in Japan in 2019 decreased ¥1.7 billion (4.7 percent), year on year to ¥34.6 billion. Mircera, which only needs to be administered once every four weeks, has established a reputation in the pre-dialysis segment for convenience and long duration of action, and prescriptions are increasing. However, sales decreased slightly due to competition from biosimilars and other therapeutic agents in the dialysis field and as a result of the NHI drug price revision. Sales of Oxarol decreased partly due to the impact of generics.

In 2020, we aim to maintain and improve the market presence of Mircera and Oxarol in the pre-dialysis and dialysis stages through ongoing provision of information and patient-centric activities rooted in our high level of expertise in the area of renal diseases.

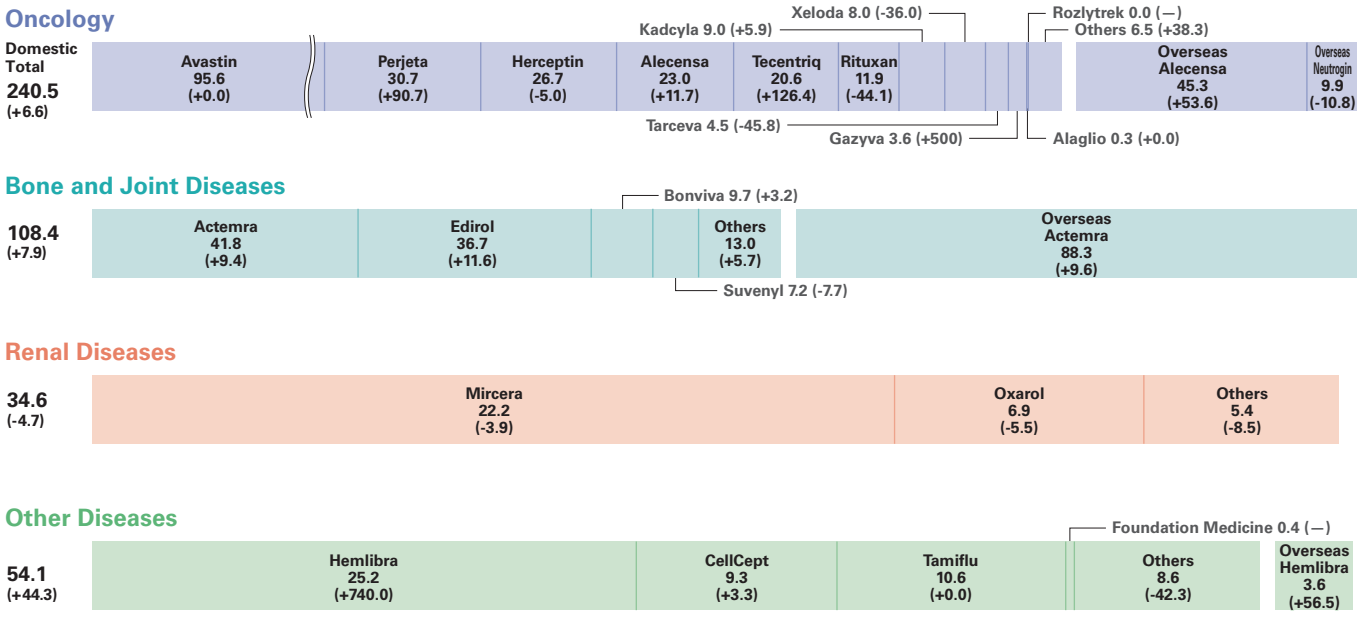
Other Diseases

Hemlibra is a bispecific antibody created using Chugai's proprietary antibody engineering technologies. It obtained approval and was launched in May 2018 for routine prophylaxis in people with congenital hemophilia A with blood coagulation factor VIII inhibitors. In December 2018, Hemlibra also obtained approval for an additional indication for people with hemophilia A without factor VIII inhibitors, enabling administration regardless of the presence of such inhibitors. The approval also allowed dosing intervals of two weeks or four weeks in addition to once-weekly administration, enabling treatment options according to the needs of people with hemophilia A and their healthcare professionals. Because Hemlibra's product characteristics are different from those of conventional coagulation factor agents, we focused on providing information on clinical results demonstrating its high level of efficacy in reducing the frequency of bleeding episodes, and sales in Japan totaled ¥25.2 billion in 2019. In 2020, by focusing on collecting and providing safety information on people who are already using Hemlibra as well as continuing our activities to promote its proper use among people with and without factor VIII inhibitors, we anticipate further uptake of Hemlibra as a treatment for congenital hemophilia A.

In the influenza segment, where Chugai plays an important role as a provider of Tamiflu, we focus on providing information on the product's safety and effectiveness, including prevention of the disease, based on extensive clinical data accumulated over a long period. Sales of Tamiflu, including sales for government stockpiles, were ¥10.6 billion.

Sales of CellCept, an immunosuppressant, increased ¥0.3 billion (3.3 percent), to ¥9.3 billion in 2019 due to the effect of an increase in kidney transplants and an increase in use in treating lupus nephritis, a refractory disease. Despite expectations of a decrease in sales, we will continue to maintain a presence in the transplant segment in 2020 and expect further uptake for lupus nephritis.

2019 Product Sales by Therapeutic Area (Billions of yen)



Note: Figures in parentheses are year-on-year percentage changes.

Medical Affairs

Key Points of IBI 21
(2019-2021)

- Acceleration and advancement of evidence generation to realize patient-centric healthcare
- Promotion of innovative medical affairs by strengthening collaboration with stakeholders and actively introducing new technologies

S (Strengths) • Extensive track record in generating evidence • Global collaboration with Roche and overseas subsidiaries	**W (Weaknesses)** • Systematic development of clinical research infrastructure
O (Opportunities) • Improved quality of clinical research in association with the promulgation of the Clinical Trials Act • Increase in opportunities to use internal and external databases following the promulgation of the Next-Generation Medical Infrastructure Act • Unmet medical need appearing with the advancement of medical care • Greater awareness due to the announcement of the JPMA's Consensus Statement on Medical Affairs Activities and Consensus Statement on Medical Science Liaison Activities	**T (Threats)** • Increase in clinical research costs in association with the promulgation of the Clinical Trials Act • Potential paradigm shift due to disruptive technologies or other factors • Greater complexity of medical systems in association with the development of many new drugs, the implementation of genetic testing, etc.

Performance in 2019

37
Contract-based post-marketing studies
(2019)

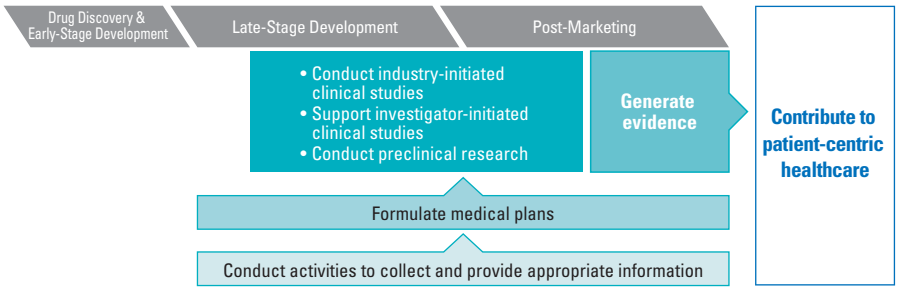
155
Staff with GCP Passport (Japan Society of Clinical Trials and Research certification)
(As of January 31, 2020)

29
Number of joint preclinical studies
(2019)

Functions

In addition to creating a steady flow of innovative drugs, Chugai recognizes the importance of ensuring that the value of its products is delivered accurately to patients, which will lead to better treatment. In support of this objective, we have been focusing on generating evidence on efficacy and safety in the clinical setting and on the modes of action of drugs through non-clinical studies (basic research), as well as on supplying appropriate information on the evidence generated from clinical and non-clinical studies to healthcare providers. We have also been working to establish a global support system for post-marketing studies. We are one of the first companies to operate a scheme for contract-based post-marketing studies to guarantee the independence and transparency of research, and have established a research support structure that conforms to the GCP[1] guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to raise the quality and reliability of research. We also established an implementation and support system for post-marketing studies under the Clinical Trials Act that was promulgated in Japan in April 2018, and we are supporting the implementation of multiple clinical trials under this act. In addition, we conducted database research based on the Next-Generation Medical Infrastructure Act, which was promulgated in May 2018. In 2017, Chugai acquired third-party accreditation[2] for its medical science liaison (MSL) certification program from the Japanese Association of Pharmaceutical Medicine, and we maintain global-level compliance standards, including transparency in funding and appropriate separation of marketing and medical affairs.[3] At the same time, we are working to further enhance our internal systems to help raise the quality and scientific level of clinical and preclinical (basic) research and to deal with changes in our operating environment. Furthermore, in response to the Consensus Statement on Medical Affairs Activities and the Consensus Statement on Medical Science Liaison Activities (announced by the Japan Pharmaceutical Manufacturers Association (JPMA) in April 2019), and the Guidelines for Prescription Drug Marketing Information Provision (promulgated by the Ministry of Health, Labour and Welfare in April 2019), we have established an appropriate governance and compliance system for conducting high-quality medical activities.

Main Medical Affairs Activities



Main Initiatives and Progress

Enhancing Intelligence Functions and Measures for PHC

In January 2019, we started operation of MI chat, an interactive program that uses AI to respond to inquiries from healthcare professionals. This program improves convenience such as reducing the time spent searching for information. We will continue to work on innovation, including the use of new digital technologies, to provide new solutions.

Future changes in the healthcare environment are expected to include progress in establishing preventive and treatment methods based on the elucidation of pathological conditions caused by diseases, genetics and other factors as well as the establishment of healthcare that takes environmental and lifestyle differences into consideration. We will respond promptly to this changing environment by enhancing our intelligence functions, such as using ICT and other means to obtain medical information and gain insights from its analysis. We also intend to provide more suitable healthcare through the generation of new evidence with higher scientific value and other activities that provide solutions. Through these measures, we will contribute to the development of patient-centric medical research and advanced healthcare.

1. Good Clinical Practice: Standards for conducting pharmaceutical clinical trials
2. Composed of evaluation criteria (a total of 222 items in 42 categories) from the three perspectives of independence from promotional activities (compliance system), medical and scientific expertise, and the training system. In the accreditation examination, mail-in and on-site surveys of the evaluation criteria are conducted to evaluate whether the MSL certification program at the applicant company is being properly implemented.
3. Activities that contribute to healthcare from a scientific standpoint

Drug Safety

Key Points of IBI 21
(2019-2021)

- Maximization of the value of growth drivers through a commitment to promoting appropriate use
- Provision of new value based on insights garnered from customer needs
- Strengthening of systems for evaluating drug safety from the early stage of clinical trials

• Industry-leading achievements (introduction of the database tool and establishment of Safety Experts, etc.) • Solid partnership with the Drug Safety Division of Roche Group • A track record of industry activities in areas utilizing epidemiological and medical data	**S** (Strengths)
• Response to the constant shortage of high-quality human resources	**W** (Weaknesses)
• Rising need for safety information to effectively launch innovative new drugs • Possible automation of some business operations and solutions due to disruptive technologies • Deepening PHC and growing demand for provision of safety information	**O** (Opportunities)
• Strengthening of global pharmacovigilance (PV) regulations in Europe, Asia and other regions • Dramatic increase in the volume of safety information • Fewer opportunities to convey drug safety information due to tighter regulations on visits to medical institutions	**T** (Threats)

Performance in 2019

185 thousand
Cases for which safety information was collected in clinical trials and post-marketing studies
(2019)

29
Lectures, papers and conference presentations on drug safety
(2019)

12 products
Enforcement of risk management through RMPs
(As of January 31, 2020)

Functions

In Japan and overseas, Chugai handles numerous biopharmaceuticals, molecular targeted therapies and other pharmaceuticals with innovative modes of action. To promote the appropriate use of these pharmaceuticals around the world and gain acceptance from patients and healthcare providers, Chugai establishes pharmacovigilance protocols with Roche and other partners and collects safety information on a global level. We consider expert safety evaluation and speedy decision-making to be essential for timely provision of safety information and implementation of measures to ensure safety. Consequently, Chugai has established an independent Drug Safety Division and a system directly linked to management. Through measures such as these, Chugai is building greater credibility, with the aim of providing truly valuable safety data and contributing to patients and healthcare worldwide.

Main Initiatives and Progress

Collecting and Managing Safety Information

Post-marketing surveillance, which includes all-case registration surveillance and database surveys, is conducted in (real world) clinical settings to collect safety information unobtainable in clinical trials. Data on safety collected from medical institutions through post-marketing surveillance are analyzed using diverse methods including epidemiology. Information on the results is provided to medical institutions and announced via scientific conferences, papers and other means.

Moreover, Chugai leads the industry in drug safety evaluation and safety measures through its wide-ranging and rigorous management methods, such as management of distribution and confirmation of conditions of use, for numerous anticancer agents, innovative new biopharmaceuticals and other drugs.

Leading the Industry in Risk Management Plans

Chugai has been ahead of its competitors in drawing up and applying risk management plans (RMPs), and discloses them on its website. Chugai considers RMPs to be part of its commitment to patients and healthcare professionals. In applying RMPs, we believe we need to strengthen our ability to analyze data from an epidemiological standpoint. To achieve this, a specialized internal group in charge of epidemiology functions is cooperating with specialized companies and others to help upgrade Japan's epidemiological database. We are also driving the industry in ways such as proactively working to formulate industry-wide recommendations and guidance for database research for proposal to regulatory authorities.

Communications on Safety

Chugai provides information on noteworthy adverse events to medical institutions and academic societies. We also distribute information leaflets for patients, post information on our website and present a variety of lectures. In particular, our ability to rapidly provide information according to patient characteristics through the post-marketing surveillance database tool (PMS DB tool) and safety information database tool (SAFETY DB tool) that we began operating in 2016 has won praise from healthcare professionals.[1] With these tools, which include domestic post-marketing safety data, we can respond in a timely manner to urgent needs for safety information. In 2018, we broadened our contribution through the rollout of a clinical trial database tool that presents safety information from clinical trials submitted for regulatory approval so that healthcare professionals can use new products with confidence immediately after their launch. In 2019, we added product information about new approvals and additional indications. We also use an app[2] that supports adherence to medication and helps to alleviate the anxiety of patients undergoing treatment by facilitating smooth communication between patients and healthcare professionals. In addition, our Safety Experts, who are professional safety staff, are at the core of ongoing efforts to provide safety consultations that meet the needs of healthcare providers and to build networks with local doctors and pharmacists. Through these initiatives we aim to offer safety measures that are closely attuned to patient needs.

1. Source: Online article by Nikkei Medical Publishing, Inc. on AGING Web "Chugai's Ideal Information Prescription: 'PMS and SAFETY Database Tools' Providing Necessary Information to Those Who Need It, When They Need It" (Japanese only)
   Part 1 (November 10, 2017) https://project.nikkeibp.co.jp/atcl21f/innovator/2017111001/
   Part 2 (November 17, 2017) https://project.nikkeibp.co.jp/atcl21f/innovator/2017111701/
2. A service developed by Chugai to support multidisciplinary team care in cancer treatment. The app is linked with MedicalCareSTATION, a completely private SNS developed exclusively for healthcare providers and operated by Embrace Co., Ltd., and promotes drug adherence and adverse event management.

Quality and Regulatory Compliance

Key Points of IBI 21
(2019-2021)

- Development of quality and regulatory compliance system for medical device program, regenerative medicine and other fields
- Establishment of quality and regulatory compliance and governance for use of digital technology in PHC strategy
- Enhancement of global quality assurance standards and quality and regulatory compliance framework

• Excellence in global inspections and quality assurance • Corporate culture and organizational climate in pursuit of compliance and quality	S (Strengths)	W (Weaknesses) • Response to expected cost performance demands and need for high-speed development • Global countermeasures against counterfeit pharmaceuticals
• Rising expectations on quality management through technology revolution • Advancement of pharmaceutical regulations and compliance for global standardization • Advancement in the use of digital technology	O (Opportunities)	T (Threats) • Need for enhanced quality compliance in complex business partnerships • Strict demands for ensuring data integrity and the quality of digital healthcare

Performance in 2019

8	**78**	**37**	**5,274**
Inspections by GMP regulatory authorities (2019)	GMP/GDP quality audits (2019)	GCP/GVP internal audits (2019)	Number of examinations of information and lecture materials (2019)

Functions

Protecting the rights of patients and clinical trial subjects and ensuring the reliability of data are serious responsibilities for the pharmaceutical industry. Chugai aims for product and service quality that resonates with all stakeholders under the slogan "Quality That Inspires." The Quality & Regulatory Compliance Unit is responsible for ascertaining trends in pharmaceutical regulations and ensuring the soundness of the quality management system spanning our business processes. It also ensures the reliability of data by confirming, improving and verifying the validity of these business processes through audits that cover the entire product lifecycle, as well as by introducing and operating a global IT system. Moreover, in leading cross-divisional activities for maintaining and improving quality, the unit aims to foster a self-sustaining quality mindset Company-wide and build a sturdier quality management system.

Main Initiatives and Progress

Compliance with Guidelines for Prescription Drug Marketing Information Provision

Chugai responds promptly to new regulatory requirements and has established a system to conduct appropriate activities in accordance with the Guidelines for Prescription Drug Marketing Information Provision (announced by the Ministry of Health, Labor and Welfare in September 2018, and came into partial effect in April 2019).

Establishing a Digital Compliance System for Human-Derived Data

In anticipation of trends in the regulatory environment, Chugai is taking the lead in the use of digital technology for compliance with the establishment of a digital compliance system data that handles genomic and other human-derived data.

Enhancing Measures for Data Integrity

In 2019, Chugai demonstrated a flexible response to recent changes in the regulatory environment by updating its Guidelines for Ensuring Regulatory Compliance and Quality Assurance in the Product Lifecycle (revised in November 2019, applicable from April 2020). The update, which is part of our efforts to strengthen global quality governance based on our Policy for Regulatory Compliance and Quality Assurance, codifies new quality requirements for data integrity, which is a topic of growing attention in regulatory inspections in Japan and overseas, establishing it as a quality requirement applicable to all GxP.

Fostering a Culture of Quality

Chugai has many procedures and rules to enhance quality and regulatory compliance, including the above, and continuously updates its quality and regulatory compliance systems and processes amid the ongoing issuance of new pharmaceutical regulations. Furthermore, we consider each employee's awareness of quality to be particularly important, and we hold Quality Meetings at each workplace (i.e. each division, overseas subsidiary, etc.) in Japan and overseas as forums to think about and discuss quality at our front lines.

In addition to complying with laws and regulations, we will endeavor to anticipate stakeholder expectations and demands to continue making improvements and reforms that deliver quality that inspires.

Digital Compliance System

Intellectual Property

Key Points of IBI 21
(2019-2021)

- Creation and use of a database of Chugai's competitors to search out opportunities for utilizing the Company's rights
- Utilization of antibody engineering technology patents through licensing and other means
- Formulation and execution of a scenario for combating biosimilars and generics

• Expanded and upgraded portfolio of technological patent applications • Progress in securing rights for products	**S** (Strengths)	**W** (Weaknesses) • Negative impact on the development of technological patent rights due to early applications for "Freedom to Operate" (FTO)* • Limited to capturing one-time opportunities for utilizing technological patents
• Increasing importance of protecting intellectual property based on the establishment of drug discovery technology infrastructure • Increase in opportunities to generate intellectual property due to progress in digital technology	**O** (Opportunities)	**T** (Threats) • Ensuring FTO in the intense, competitive R&D environment • Attacks by competitors on the Company's patent portfolio, including for biosimilar products

* The ability to conduct business without the possibility of infringing the rights of others

Performance in 2019

4,976
Number of patents held (including pending applications)
(As of December 31, 2019)

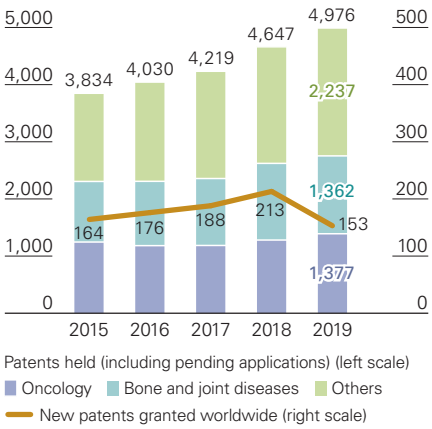
153
New patents granted worldwide
(2019)

Continued to provide value through resolution of disputes with manufacturers of generics and manufacturers of biosimilars

Functions

Chugai views its global intellectual property (IP) strategy as the foundation for creating innovative new drugs. By integrating it with our business and R&D strategies, we protect the competitive advantage of our products and ensure operational flexibility. We focus resources on and secure IP rights for high-priority R&D projects. At the same time, we actively work to secure rights outside Japan with a view to global co-development with the Roche Group. When we apply for patents for products, we include filings for lifecycle patents related to formulation, production method, diagnostic method and PHC in addition to those for the substance and use. We also work to establish rights globally for significant drug discovery technologies such as innovative antibody engineering technologies, and use those rights in planning and executing our IP strategy. Moreover, we are building our own database for patents related to antibody engineering technologies, which are becoming increasingly complex and sophisticated, and are using this database to plan IP strategies, including monitoring trends at other companies.

Number of Patents Held (Including Pending Applications) and New Patents Granted



Main Initiatives and Progress

Integration of IP and Research Strategies (Strategic Mix)

At Chugai, we view our antibody engineering technologies as a core drug discovery technology platform, and we are deploying research and development strategies both to cultivate basic technologies and to apply them to product development. Since 2018, we have been dispatching IP liaisons to the Fuji Gotemba Research Laboratories and Kamakura Research Laboratories to strengthen cooperation at the initial stage of research, and they are enhancing and promoting a strategic mix that builds a portfolio of our own technologies and development compounds in the white spaces (gaps) of technologies and rights. IP liaisons hold monthly meetings to review intellectual property with the Pharmaceutical Technology Division, which is also promoting the same strategic mix in manufacturing. In 2019, we dispatched an IP liaison to the Collaboration Promotion Laboratory at IFReC and began similar initiatives there.

Current Patent Portfolio

Supported by technological development, we have structured a well-balanced patent portfolio that reflects the diversity of products and development projects generated through Chugai's own R&D. Bone and joint diseases account for approximately 27 percent of patents by therapeutic area, oncology for approximately 28 percent, and other areas including chronic disorders, hematologic diseases, and drug discovery technology for approximately 45 percent. In 2019, Chugai acquired 153 patents in Japan, the United States, and major European countries, as well as other countries worldwide.

Maximizing Product Value in Response to Changes in the Competitive Environment

With the globalization of our portfolio of products developed in-house and the expansion of our portfolio of development projects and drug discovery and manufacturing technologies, our competitive environment is becoming increasingly intense. This requires more sophisticated IP activities to maximize the value of Chugai's intellectual property while respecting the effective rights of other parties. This in turn will help to maximize the value of our products, development projects and technologies.

We carry out IP activities in close cooperation with internal and external stakeholders including Roche, Genentech Inc. and other affiliated companies, outside attorneys, and our business and legal departments. In 2019, we had numerous successes in maximizing product value, including a ruling in favor of Chugai relating to Hemlibra at the Intellectual Property High Court and the implementation of a strategy for Herceptin to respond to other companies' biosimilars. Chugai will deepen cooperation in its intellectual property activities so that it can continue to provide value to society.

Close-Up 2 Standout Initiatives under IBI 21

Introducing a New Personnel System in Japan

With a view to achieving the five strategies of mid-term business plan IBI 21, we are introducing a new personnel system in April 2020. It is important that all employees understand and follow the new system, and the reasoning and purpose behind it. To that end, the Human Resources Management Department has been cooperating with HR Business Partner introduced in October 2019 to consider and implement measures for promoting the system's use. Following explanatory meetings for employees, we will hold discussions to identify issues and necessary measures at each division. To ensure the greater satisfaction of employees, we will also make enhancements to the personnel system intranet site, and consider and implement methods for operating and promoting the use of the system based on conditions at each division.

Yusuke Tokita
Human Resources Management Group, Human Resources Management Dept.

Masahito Kawasaki
Head of Marketing & Sales Human Resource Management Dept., Marketing & Sales Div.

Chizuko Tagawa
Human Resource Business Partner, Project & Lifecycle Management Unit

Contributing to Next-Generation PHC through Advances in Cancer Genomic Medicine

Although Japan is promoting cancer genomic medicine nationwide, many issues remain – few patients are able to undergo gene panel profiling, and the rate at which it leads to effective drug administration is currently low, at about 10 percent to 20 percent – and understanding and awareness of the significance of this domain have yet to become sufficiently widespread. Consequently, Chugai has been intensively disseminating information and holding study sessions for healthcare professionals to introduce two key products as an integral set: the cancer genomic profiling program FoundationOne CDx Cancer Genomic Profile and Rozlytrek, a tumor-agnostic therapy. We feel that these initiatives have begun to achieve a certain level of understanding. Through ongoing collaboration with various parties, we hope to help change cancer genomic medicine from "next-generation" to "standard" medicine.

Yusuke Yamashita
Precision Medicine Group, Foundation Medicine Business Dept., Foundation Medicine Unit

Yoshinari Kunihiro
FMI Planning Group, Foundation Medicine Business Dept., Foundation Medicine Unit

Ryouta Ishibe
Oncology Marketing & Sales Promotion Dept., Marketing & Sales Div.

Maximizing the Value of Hemlibra

Hemlibra is a drug with the potential to significantly change the lives of people with hemophilia A. To succeed, we must not only provide a product but also conduct activities to increase its value for patients. This entails consulting activities for healthcare professionals in close communication with patients and their families, safety measures and provision of information to minimize the risk of adverse effects such as thromboembolism and thrombotic microangiopathy, and collection of evidence regarding unresolved issues such as effectiveness for treating complications of hemophilia A and the activity level of patients. As we collect feedback throughout Japan from people who have taken Hemlibra and share that information internally, we are getting a stronger sense of the importance of this drug. The three divisions responsible for providing solutions – Marketing & Sales, Drug Safety and Medical Affairs – will continue working together to develop better drugs for people with hemophilia A.

Satoru Ito
Primary Lifecycle Management Dept., Project & Lifecycle Management Unit

Haruko Yamaguchi
Medical Science Dept., Medical Affairs Div.

Naoto Oiri
PV & Safety Science Dept., Drug Safety Div.

Human Resources

Key Points of IBI 21
(2019-2021)

- Assignment of the right people to the right positions and provision of growth opportunities through position management and talent management
- Promotion of talent management to quickly identify and develop leaders and highly competent specialists to accelerate strategy execution and innovation
- Maintenance and deepening of employee engagement, fostering of an organizational culture for the pursuit of innovation and accelerating the success of women

Performance in 2019

13.7%
Ratio of female managers[1,2]
(2019)

12.3%
Ratio of female managers[2]
(With subordinates)
(2019)

188
Number of employees posted through the Roche Human Resource Exchange Program
(2004–2019)

1. Number of female managers as a percentage of the total number of managers 2. Non-consolidated employee basis: Calculated based on Chugai Pharmaceutical (non-consolidated) employees, including employees assigned to affiliated companies and external companies.

Talent That Spearheads Innovation

Our people are our greatest asset in generating innovation to realize our Mission, and we therefore position human resource management as a key management theme.

Our Envisioned Future is to become a top innovator in the healthcare industry. Chugai will pursue this objective by building understanding and connection with the Mission Statement (corporate philosophy) among all employees. Furthermore, we will encourage employees to embody the Mission Statement while fulfilling their potential in accordance with their role.

Establishing an Organizational Culture That Generates Innovation

Chugai provides career development support over many years so that employees can excel in roles that reflect their expertise and ability, as well as their aptitude.

Since 2012, we have instituted various measures and systems, including introducing a talent management system, promoting diversity and revising our personnel systems. As a result of these initiatives, we have secured leaders capable of driving sustainable growth, assigned roles and growth opportunities according to each individual's ability and aptitude, and created an environment that supports the success of women.

At the same time, the pace of change in the business environment is escalating. Clarifying each employee's approach and responsibilities to improve quality and speed in strategy execution will be essential to realizing our management strategies and establishing a competitive advantage. In addition to these issues, an important theme is to support our employees in proactively taking on challenges to generate innovation and new added value.

We have determined the following human resource management priorities as measures for these objectives and themes. With these measures, we aim to establish an organizational culture in which employees support each other to continuously generate innovation.

1. Assignment of the right people to the right positions and provision of growth opportunities through position management and talent management.
2. Promotion of talent management to quickly identify and develop leaders and highly competent specialists to accelerate strategy execution and innovation.
3. Promotion of diversity and inclusion (D&I) to accelerate the success of women.

In addition, to promote organizational reforms linked to IBI 21, we switched to a new employee survey in 2018 to set more ambitious targets and identify issues more accurately. From 2020 onward, we will revise our personnel and remuneration systems to promote changes in attitude conducive to a corporate culture that embraces challenge.

Main Initiatives and Progress

Introducing a Balanced Personnel System That Assigns the Right People to the Right Positions to Reflect Roles and Results

The personnel system we are introducing in April 2020 will determine grades and wages based on the value of duties performed in each position, and assign the right people to the right positions. We have also designed it so that personnel can be assigned to management positions regardless of age, which will enable us to fast-track young employees. Moreover, setting and strictly implementing rules for assignment and dismissal will promote the rejuvenation of the organization.

Position profiles delineate the duties, performance responsibilities and human resource prerequisites required, as well as the criteria and processes for assignment

The All-Employee Survey

In 2018, Chugai conducted an all-employee survey to identify the organizational issues requiring reform in order to achieve its Envisioned Future and promote the strategies of IBI 21. The results showed that employee engagement was at a very high level, on par with strongly performing global companies, and suggested that establishing an environment where employees reach their potential would spur further innovation. Based on this, we are conducting initiatives on both tangible and intangible levels to resolve issues including implementing a framework to optimize Company-wide resources, introducing a personnel system that rewards employees who take on challenges and produce good results, establishing a system that allows employees to take the initiative in making their proposals a reality, and fostering personal commitment in the "patient-centric" approach that is part of Chugai's Envisioned Future and Core Values.

Question Categories	Employee engagement; environment for utilizing employees; strategy and direction; leadership; quality and customer orientation; respect for individuals; opportunities for growth; compensation and benefits; performance indicators; authority and discretion; resources; education and training; framework for collaboration; business processes and organizational structure; and innovation

and dismissal, and are made available to employees. Identifying all positions in the Company and the requirements for assuming those positions will facilitate self-directed career development and the ability to assume higher-level roles. We will also introduce a "challenge assignment" system that allows early selection for promotion, and expand our in-house job posting system to cover management positions.

Remuneration will be set at a level that is competitive according to the value of relevant duties, but we will also set indicators both for the performance required for a job (commitments) and for taking on challenges beyond that (targets). By doing so, we will improve satisfaction with evaluations and promote and support a spirit of challenge among employees.

Talent Management

Structuring Human Resource Development Plans with the Strong Commitment of Management

Chugai conducts talent management to identify and develop leaders and highly skilled specialists at an early stage in order to realize its corporate strategy and accelerate the creation of innovation.

Since 2012, Chugai has been promoting a talent management system for developing individuals based on visualization of human resources and their capabilities.

We are creating a talent pool of future management candidates in each department, discussing the selection of successor candidates for major positions in Japan and overseas as well as medium-to-long-term policies for cultivating successors, and formulating individual human resource development plans. To expedite the development of successor candidates, executive management and department managers discuss the plans, hold training and strategically allocate human resources to strengthen leadership.

In addition, we identify leadership and highly skilled specialist positions that are important for realizing our corporate strategy, and work to acquire and develop suitable candidates. To this end, we hold discussions among executive management and department managers, select human resources from inside and outside the Company, formulate and implement plans for their assignment, and monitor the status of their development.

Under IBI 21, we will review our training system to improve our ability to acquire, develop and deploy world-class human resources with the aim of identifying and training them more quickly. In addition to talent management, we will also use position management to assign the right people to the right positions throughout the Chugai Group.

Establishment and Enhancement of the Foundations of Human Resource Management

Promoting D&I and Work-Life Synergy to Improve Productivity

Chugai has positioned D&I as a material issue for the establishment and enhancement of the foundations of human resource management. We believe that D&I, which leads to the creation of a diverse workforce that works together with enthusiasm, is essential in order for employees to generate new value – in other words, diversity is necessary for generating innovation. As such, in 2010 we launched a working team led by the president, and in 2012 we established a dedicated organization that has since been conducting initiatives to promote diversity.

To promote gender diversity, we conduct annual training for prospective managers and leader candidates to help women plan and develop their careers. In 2019, we continued to conduct various measures to promote the success of women, including task management training for managers of employees using the short-time work system for childcare, in order to facilitate team members' career planning and growth while navigating life events. To promote the success of older employees and foreign employees in Japan, we are building awareness of their potential through training and other programs and creating environments including workplace systems to help them play active roles. Meanwhile, amid demands for more active participation by diverse human resources, we conducted e-learning on the topic of unconscious bias for managers, who play a key part in promoting D&I. We aim to enhance managers' practical workplace skills through this three-month program to help them recognize and control their own bias.

We also provide work arrangements and support systems so that all employees can benefit from work-life synergy that accommodates a variety of life events including childbirth, child care and nursing care. With respect to "work-style reform," which is currently a focal issue in Japan, studies and initiatives between labor and

Establishing Systems and Environments to Promote the Success of Diverse Employees

More flexible workplaces	• Telecommuting system (maximum 10 days per month; no maximum for "spot" telecommuting[3]) • Satellite office (pilot introduction) • Introduction of free address workspace (Head Office)
More flexible work schedules	• Flextime system (core time reduced to 11:30–13:30) • Discretionary work system (for researchers) • Paid leave system in units of half-days or hours
Support for work-life balance	• Support plan for living with spouse who is transferred (MRs) • Use of Company vehicles to take children to/from childcare • Consortium-managed childcare center (Head Office)
Support for career planning	• In-house job posting system • Leave for education and acquisition of qualifications • Volunteer leave system • Registration program for rehiring employees who left the Company due to marriage, spouse transfer, childcare or nursing care • Introduction of concierge for finding nursery care

3. Telecommuting for short periods before leaving home or after returning home (usable in units of 15 minutes)

Cooperation to Promote and Spread Group-Wide Personnel Strategies

To resolve medium-term management issues and achieve its business targets, the worldwide Chugai Group is fostering a culture of innovation and conducting talent management. In May 2019, personnel managers from overseas affiliates gathered in Japan to deepen their understanding of the Group-wide personnel strategies of IBI 21. Participants shared issues and success stories from each company on the theme of raising employee engagement as they formulated specific action plans for each company.

Workshop at the Global HR Forum

management are under way with the goals of improving the work environment to enable employees to fully demonstrate their capabilities and promoting innovation by organically combining diverse knowledge.

Promoting D&I and work-life synergy is all about supporting the autonomy and growth of individuals to help realize an organization that generates innovation, which in turn contributes significantly to improving organizational productivity and increasing corporate value over the medium to long term.

IBI 21 sets forth a target outcome of innovation stories generated by leveraging the strengths of D&I, and we have created a roadmap for expedited realization of our strategies. Based on respect for different values and ideas, we are working to address the following three issues to foster an inclusive organizational culture in which diverse human resources can succeed and pursue innovation.

1. Fostering an organizational culture that generates innovation and is accepting of failure
2. Improving engagement of diverse talent
3. Proactively appointing and deploying women and people from different cultures and backgrounds to take on business challenges

Non-Japanese employees engaged in follow-up training

For four years in a row since fiscal 2014, Chugai was selected as a Nadeshiko Brand for its exceptional record in promoting the success of women.

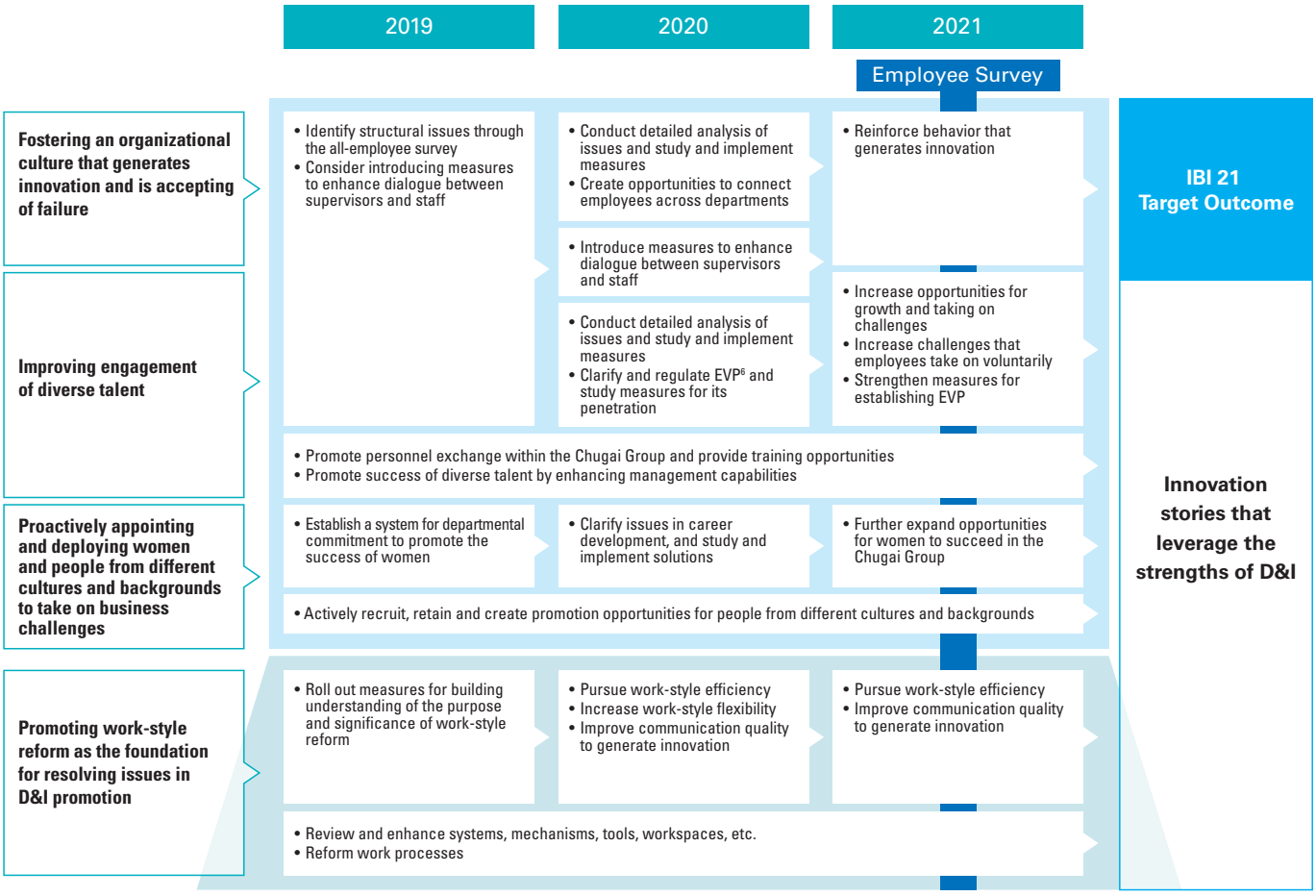
We are targeting a 16 percent or higher female manager ratio (non-consolidated employee basis) by the end of 2021, and will continue to focus on career planning and development measures for women.

Results of Work-Style Initiatives (Non-consolidated)

Rate of annual paid leave taken (average days taken) (April 2018 – March 2019 results)	61.2% (13.6 days)
Average overtime hours per month[4] (April 2018 – March 2019 results)	5.6 hours/ month
Percentage of male employees taking childcare leave (average days taken) (2019 results)	83.9% (14.7 days)
Percentage of employees using the telecommuting system[5] (2019 results)	50.1%

4. Excluding employees on a defacto or discretionary working hours system
5. Excluding MRs

D&I Roadmap for Promotion IBI 21



6. Employee Value Proposition: The value a company can provide to its employees

Human Rights

Key Points of IBI 21
(2019-2021)

- Continue to conduct human rights awareness training
- Conduct human rights due diligence, including for suppliers
- Cooperation with third-party organizations to execute measures for resolving social issues

Performance in 2019

Continued to conduct human rights awareness training	**8** Supplier evaluations conducted based on the PSCI Principles[1]	Continued to exchange opinions with third-party organizations

1. The Pharmaceutical Industry Principles for Responsible Supply Chain Management established by the Pharmaceutical Supply Chain Initiative (PSCI), a non-profit group of global pharmaceutical companies

Basic Approach

At Chugai, we declare our respect for human rights in the Chugai Group Code of Conduct, which is based on our shared Core Values. This is because we believe that a culture of respect for human rights is indispensable for a highly productive company where employees can work comfortably. It is also a cornerstone for a company to be recognized as a member of society and to earn trust. In respecting human rights, we aim to realize workplaces that prize diversity, where each person values his or her own feelings and accepts the values of others – allowing everyone to fully demonstrate his or her abilities, based on an organizational climate of appreciation for oneself and others. People in such a workplace can work creatively with enthusiasm and engagement, thus increasing their achievements. Moreover, helping build each employee's achievements will lead to improved productivity as an organization. We believe that the actions of individuals who raise their sensitivity to human rights and show respect for others in a workplace where human rights are respected in this way can also help to eliminate social discrimination and infringements of human rights in society in general through corporate activities and their private lives.

Today, companies are expected not only to conduct in-house initiatives regarding business and human rights, which have been increasing in importance as a social issue, but also to conduct business activities that respect human rights throughout the entire supply chain. With our deep involvement in people's lives and health as a member of the healthcare industry, we are promoting measures with a greater awareness of respect for human rights.

Chugai Group Human Rights Statement
https://www.chugai-pharm.co.jp/english/sustainability/humanrights/policy.html

Issues and Initiatives

Chugai has been conducting human rights initiatives for its employees in areas such as prohibition of workplace discrimination and harassment, respect for employee diversity, and safety and health. Furthermore, to conduct business activities in various regions of the world as a global company, we recognize the need to address human rights issues in our entire supply chain, including labor-related rights at stakeholders involved in our business activities. Based on the United Nations' Guiding Principles on Business and Human Rights (UNGPs), we formulated the Chugai Group Human Rights Statement and conducted employee training on corporate responsibility to respect human rights as set forth in the UNGPs. For supplier management, in addition to our conventional measures for stable supply and quality control, we have formulated guidelines based on the PSCI Principles for conducting human rights and environmental risk assessments and have started human rights due diligence.

Employee training

In October 2019, Chugai participated for the second year in the Business and Human Rights Conference in Tokyo sponsored by Caux Round Table Japan (the eighth yearly conference), and engaged in dialogue with individual experts from overseas. We received opinions and advice regarding procedures for and implementation of human rights due diligence for suppliers and methods of supplier management. We provided an explanation of the supplier management initiatives that Chugai has been conducting, and the experts evaluated those initiatives and expressed their expectations that we should incorporate and implement due diligence in our business activities based on the nature of approaches to human rights issues when conducting audits.

Based on the opinions received through this dialogue, we will also call on our business partners to comply with laws and social norms and respect human rights, as we conduct our human rights due diligence. Specifically, we will work with those partners in considering working conditions in ways including eliminating child labor and forced labor, prohibiting all forms of discrimination by race, gender or other attributes, respecting the dignity of individual employees and maintaining safety and health.

Roundtable dialogue

In addition, Chugai has established an Anti-Bribery Policy as part of the proper management of its corporate activities. As well as setting our own code of conduct, it prohibits our business partners from engaging in bribery of government officials, civil servants, corporate staff and other parties, whether corporations or individuals. We will continue our comprehensive efforts to prevent bribery.

We recognize Chugai's responsibility for respecting the human rights of all people involved in its business activities, and will work to fulfill that responsibility by ensuring that we do not infringe on the human rights of these people, and by responding appropriately with corrective action in the event of an infringement.

Environment, Health and Safety

Key Points of IBI 21
(2019-2021)

- Establishment of a global EHS promotion system
- Achievement of mid-term environmental goals and formulation of new mid- and long-term environmental goals
- Execution of priority items for health and productivity management and reassessment of evaluation indicators

Performance in 2019

-9.9%[1]
Energy consumption per employee compared with 2010
(2019)

91.6%[1]
Waste recycling ratio
(2019)

1.1%[1]
Final disposal ratio
(2019)

2020 健康経営優良法人 Health and productivity
(Large Enterprise Category)

1. Chugai Group in Japan

Functions

As an R&D-driven pharmaceutical company, Chugai is engaged in many specialized scientific activities. One aspect of those activities involves handling numerous antibodies and highly active pharmaceutical substances. We consider environmental protection and health and safety to be fundamental to the success of our business activities.

At the same time, the demands of society have grown more diverse and sophisticated. Integrated management of environment, health and safety is required worldwide because of the close connection between environmental protection and health and safety. Accordingly, in 2016, Chugai developed an integrated management system for EHS and has been implementing the PDCA cycle for ongoing improvement of its EHS promotion activities based on a consistent policy Company-wide, from top management to each facility.

To utilize the PDCA cycle effectively, we began safety risk assessments in 2014, and then following the integration of EHS management, we introduced EHS risk assessment in 2017 to eliminate EHS risks in the workplace. Since 2008, we have implemented a Group-wide assessment system to reduce the risk of occupational injuries from exposure to all substances handled, not only restricted substances.

EHS management extends throughout the value chain, from the procurement of raw materials to the manufacture of products and their supply to patients and healthcare professionals. Going forward, we intend to broaden our activities to cover the overall value chain in closer cooperation with customers and suppliers, partners and industry organizations.

As the effects of climate change become more severe year after year, stakeholders, including investors, have been calling for adequate disclosure of its impact on corporate business activities. To meet these stakeholder demands, Chugai is conducting a scenario analysis based on the framework outlined in the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD)[2] and will use it to address climate change risks and opportunities and further enhance disclosure of information.

2. Disclosure of climate-related information that has a financial impact on a company

TCFD
https://www.fsb-tcfd.org/

Main Initiatives and Progress

Promotion and Progress of Environmental Protection Activities

Chugai's aims encompass not only its own sustainable development but also environmental protection in local communities and globally. We have set priority items to be addressed as well as medium-to-long-term targets.

Chugai has designated climate change countermeasures, energy conservation, resource conservation and waste management, biodiversity protection, prevention of environmental pollution and improvement of environmental literacy as priority items. In 2010, we set four mid-term environmental goals focusing on management of energy consumption and waste from a medium-term perspective, with 2020 as the final year. We are implementing the PDCA cycle and conducting initiatives to meet these goals.

As measures to conserve energy, we are reducing energy consumption by introducing highly energy-efficient facilities, switching fuels, introducing eco-friendly cars, and conducting an energy conservation program in daily business activities while curbing greenhouse gas emissions,[3] which is the key to combating climate change. To prevent environmental pollution, we are also working to reduce the use of CFCs and HCFCs to halt the destruction of the ozone layer, and to prevent the leakage of environmental pollutants. In waste management, we aim

Mid-Term Environmental Goals (Target year: 2020)	• Energy consumption per employee: 20% reduction compared with 2010 • Average fuel efficiency of MR fleet: 16 km/L or higher • Discontinue use of chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs) • Zero emissions of waste:[5] Three facilities
Environmental Goals for 2019	• Energy consumption: Reduction of 2% or more compared with the previous year ..... 2% reduction • CO_2 emissions: Reduction of 2% or more compared with the previous year ..... 3% reduction • Ratio of eco-friendly cars:[6] 80% or higher ..... 81% • Average fuel efficiency of MR fleet: 16 km/L or higher ..... 19.6 km/L • Recycling ratio: 95% or higher ..... 91.6% • Final disposal ratio: Lower than the previous year (2018: 1.2%) ..... 1.1% • On-site verification of waste disposal contractor facilities: 100% over a three-year period ..... 49% over a two-year period • Plain paper copier (PPC) paper purchased: Less than the previous year (2018: 147 tons) ..... 126 tons • Recycling ratio for PPC paper: 80% or higher ..... 76% • WET tests: Conduct at each plant and research laboratory once every year ..... Conducted once during the year
Mid-Term Health and Safety Goals	• Cancer screening participation rate:[7] 90% or higher • Percentage of employees at high risk for lifestyle diseases: 2% or lower by 2020 • Awareness of Company programs: 90% or higher • EHS risk assessment: Conduct at each site at least once every three years

5. A waste recycling ratio of 99% or higher
6. Includes hybrids and fuel-efficient vehicles
7. Screening rate for lung, breast, gastric, colon and cervical cancer

Initiatives by Theme

Theme	Details of Initiatives
Implementation of EHS risk assessment Workplace safety measures	Create work environments that are free from unacceptable EHS risks.
Climate change countermeasures Energy conservation	Reduce greenhouse gas emissions by reducing energy consumption. Focus not only on reducing energy consumption at plants and laboratories but also promoting eco-friendly cars in the MR fleet and other Company-wide initiatives.
Resource conservation Waste management	Achieve zero emissions of waste by improving recycling ratio and further reducing landfill waste. Promote awareness of effective use of water resources by monitoring water consumption and wastewater discharge.
Biodiversity protection Prevention of environmental pollution	Curb destruction of the ozone layer by eliminating usage of specific CFCs. Prevent emissions of pollutants into the environment by observing laws, regulations, agreements and other rules for air, water quality and soil. To protect the water environment, conduct whole effluent toxicity (WET) tests and participate in river water and environmental conservation activities for rivers used by plants and laboratories.
Improvement of environmental literacy	Circulate information on laws and regulations among related staff and raise awareness through ISO 14001 internal auditor training.
Chemical substance management	Advance the establishment of a system for proper management of chemical substances, and promote safety and the prevention of environmental pollution. Continue risk assessments to prevent exposure to substances handled.
Reduction of environmental risk	Ensure thorough compliance with environmental laws and regulations by conducting extensive environmental law checks through external consultants.
Employee health management Improvement of health literacy	Maintain a support system based on cooperation with the health management organization and related departments. Improve health literacy as the basis for all health and safety activities, and conduct training for all employees.
Support for employees with cancer	Step up recommendations for screening for early detection of cancer and provide enhanced support for continuing to work while undergoing cancer treatment.
Measures to prevent and treat lifestyle diseases among employees	Recommend check-ups for high-risk individuals and provide health guidance to those diagnosed to reduce leaves of absence, job departures and accidents caused by lifestyle diseases.
Measures for employee mental health	Conduct a return-to-work program for employees on leave due to mental health issues and implement working environment improvement measures based on the results of stress checks in cooperation with related departments.
Measures to address employee presenteeism (working while sick)	Plan, implement and determine the effectiveness of measures based on health survey results.

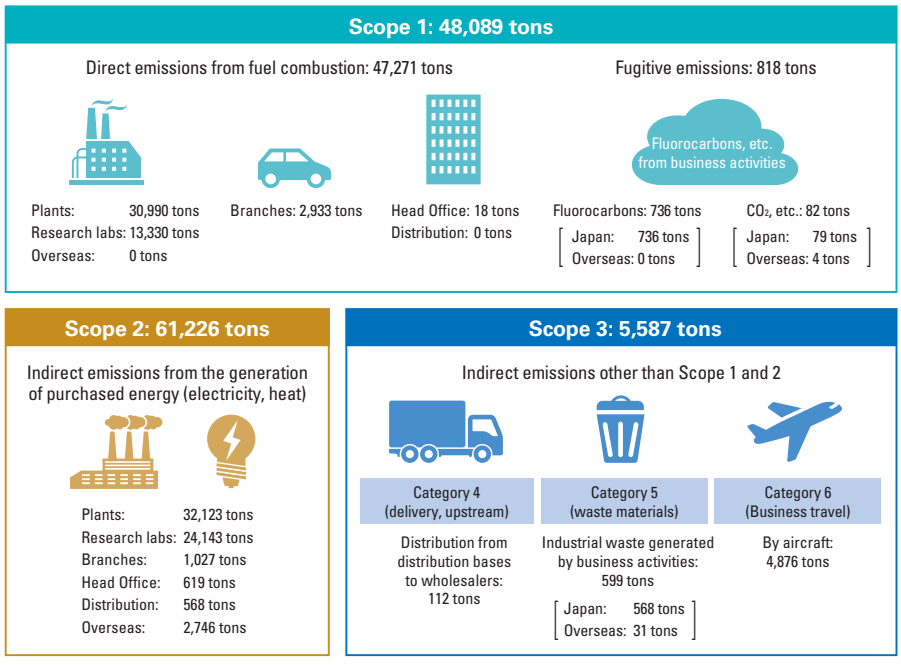
to increase the waste recycling ratio and further reduce landfill waste to achieve zero emissions of waste, and our initiatives are yielding results.

We are conducting risk management for water, given its importance as a raw material in pharmaceutical manufacturing and as a crucial global resource. As water-related risks, Chugai considers raw material procurement risks and water damage risks in distribution. Although Chugai believes its procurement-related risks to be low at present, it monitors the volume of water it uses and the wastewater it discharges each year, and is building awareness of the effective use of water resources. Chugai's countermeasures for the risks to stable supply posed by water damage include diversification of risk such as by storage and management at multiple storage facilities.

Moreover, from the standpoint of protecting biodiversity, we began conducting WET tests[4] in 2013 to ascertain the ecological impact of wastewater discharged from our facilities. The purpose of this additional test is not only meeting the effluent standards of laws and regulations, but also making a general judgment of the ecological impact of chemicals involved in wastewater. In 2019, we again conducted a WET test once at each plant and research laboratory, and confirmed that there were no problems. We also took our initiatives one step further as employees assisted with tree thinning in the wooded highlands of Kawanehoncho in Shizuoka Prefecture, the source of water for the Fujieda Plant, as part of efforts to conserve water at production facilities. As well as minimizing the environmental impact of production activities, we want to help conserve the water resources Chugai shares with local residents. In our business activities, we use water with care and release it in a clean state, and we will continue with activities to maintain forests that sustain clean water.

3. We received independent verification of our 2019 greenhouse gas emissions associated with energy consumption, leakage of CFCs and HCFCs, use of aircraft for business travel, transport and delivery from logistics centers to wholesalers, and industrial waste generated.
4. Whole effluent toxicity test: A method for comprehensive evaluation of the safety of wastewater and the aquatic environment by determining the impact on crustaceans (*Daphnia*), algae and fish (*Oryzias latipes* and others) immersed in diluted wastewater

GHG Emissions



Promotion and Progress of Health and Safety Activities

Chugai engages in health and safety activities as one aspect of its health and productivity management, in the belief that sound employee physical and mental health and a satisfying and rewarding work environment where all employees can do their jobs with enthusiasm are the foundation for growth.

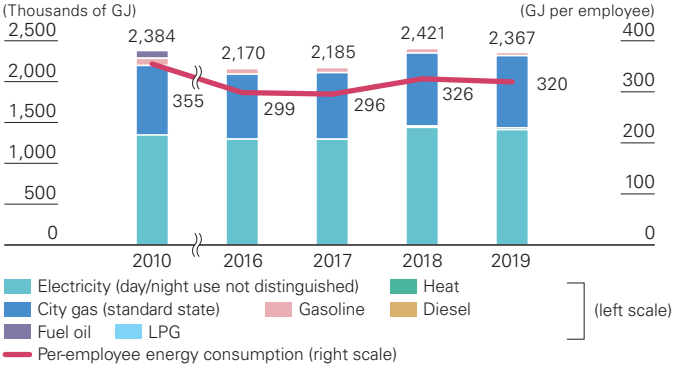
To create such an environment, we established a Company-wide health and safety promotion framework in 2017 based on a policy of cooperating with the health insurance society and the labor union in simultaneous pursuit of both individual and organizational health. We also established six priority items: support for employees with cancer, measures to prevent and treat lifestyle diseases among employees, measures for employee mental health, measures to address employee presenteeism (working while sick), improvement of health literacy and workplace safety measures. In September 2019, the Chugai Group announced the "Chugai Group Non-Smoking Declaration" to promote health management and further strengthen measures against smoking, which is strongly linked to cancer and lifestyle-related diseases. With the aim of reducing the smoking rate among employees to zero percent by December 31, 2030, we have decided to prohibit smoking altogether throughout the Company. To improve health literacy, we provided education on lifestyle-related diseases as part of the Chugai Group Code of Conduct (CCC) and human rights training. We are working with related departments to improve organizational health using the results of stress check organizational analysis.

Of course, in addition to these preventive measures, we continue to conduct our existing programs to support employees during cancer treatment and after they return to work, as well as mental health awareness activities.

Climate Change Countermeasures

Total and Per-Employee Energy Consumption

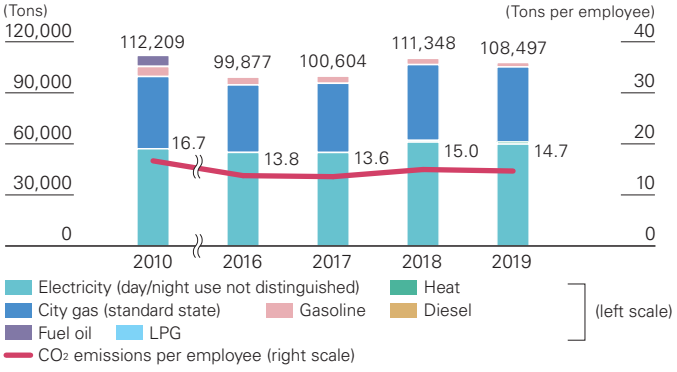
The Chugai Group's energy consumption and energy consumption per employee in 2019 decreased 2 percent respectively compared with the previous year. In addition to introducing highly energy-efficient equipment and switching fuels, the Group introduced a system for visualizing energy use as measures to promote energy saving in daily business activities.



Note: 2010 is the base year for mid-term environmental goals. Overseas energy consumption (electricity and heat) is included from 2018. Overseas energy consumption was 57,000 GJ in 2019.

CO_2 Emissions and CO_2 Emissions per Employee

Total CO_2 emissions decreased 3 percent from 2018 to 108,497 tons. CO_2 emissions per employee decreased 0.3 tons. Factors included significant progress on measures to reduce gasoline and diesel oil consumption in the MR fleet, such as introduction of eco-friendly cars and promotion of eco-driving.

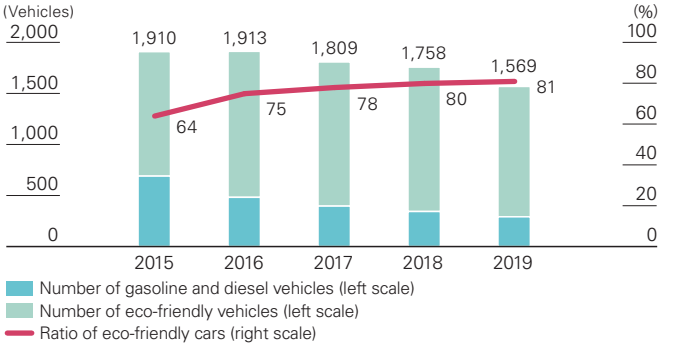


Note: 2010 is the base year for mid-term environmental goals. Overseas emissions (electricity and heat) are included from 2018. Overseas emissions were 2,745 tons in 2019.

Resource Saving and Waste Reduction

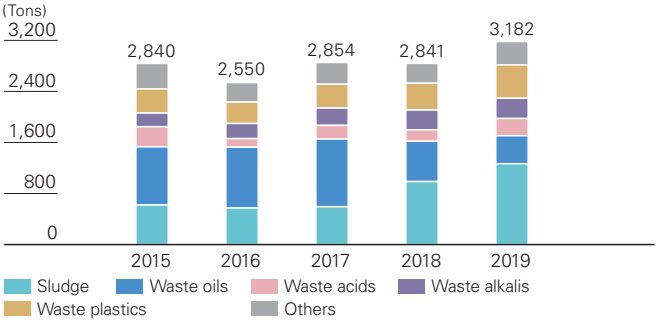
Ratio of Eco-Friendly Cars

As of December 31, 2019, Chugai had introduced a cumulative total of 1,278 hybrid and fuel-efficient vehicles in its MR fleet. The ratio of eco-friendly cars was 81 percent, remaining above the target of 60 percent. Since the MR fleet is being continuously reduced, the number of gasoline and diesel vehicles is also decreasing.



Industrial Waste

The amount of industrial waste generated increased 12 percent compared with 2018 to 3,182 tons, although progress was made on several measures to reduce that amount, such as at Fujieda Plant, the largest generator of waste oil, which enhanced its wastewater treatment facilities to separate water from aqueous waste oil.



Note: The amount of waste generated overseas is included from 2018. The amount of waste generated overseas was 11 tons in 2019.

Social Contribution and Global Health

Key Points of IBI 21
(2019-2021)

- International contribution in the field of global health
- Contribution to health in local communities
- Promotion of understanding of diversity to achieve a society of co-existence

Performance in 2019

Promoted awareness of and supported para-sports	**592** Participants in 24-hour charity event Relay for Life Japan (Chugai employees and their family members) (2019)	Conducted projects to promote safer childbirth and maternity healthcare in Myanmar, and measures for people living with noncommunicable diseases	Participated with Roche in the World Federation of Hemophilia Humanitarian Aid Program[1]

1. Together with Roche, Chugai Joins the World Federation of Hemophilia Humanitarian Aid Program
https://www.chugai-pharm.co.jp/english/news/detail/20190206150000_594.html

Chugai's Social Contribution Activities

As a responsible pharmaceutical company in healthcare, we work to raise awareness of diseases.

In the area of social welfare, in conjunction with our business activities in the renal and bone and joint areas, we conduct ongoing donations of specially equipped para-transit vehicles as we understand the importance of transportation assistance services for people who require in-home nursing care. Regarding support for the next generation, as a company that deals with leading-edge science we conduct activities to raise awareness of science and medicine among students, from elementary school children to university students, as well as among adults.

Moreover, we cooperate with local communities and engage in disaster preparedness education, mainly in areas where our research laboratories and plants are located. We also support para-sports to help create a society where everyone can participate in sports.

Basic Concept of Social Contribution Activities
https://www.chugai-pharm.co.jp/english/sustainability/community/concept.html

Main Initiatives for Social Contribution

Disease Awareness

Chugai participates in a variety of activities to support cancer patients and their families. One such activity is Relay For Life Japan, an awareness support campaign that forges ties in the fight against cancer. This event, a 24-hour walk-a-thon in which cancer patients, their families and supporters participate as relay teams, was held in 48 locations throughout Japan in 2019. Chugai employees have participated as volunteers in Relay For Life Japan since 2007. A total of 600 employees took part as "Team Chugai" at 31 locations in 2019.

This year, we also conducted the awareness raising activity of screenings with the "Try! Scope," which uses a fiberscope, and participants in various locations enjoyed the experience. As Team Chugai members provided explanations, participants experienced a simulated endoscopy, gaining an understanding of the importance of screening and early detection and treatment. We also promoted understanding of the importance of screening by using "Try! Scope" in health events hosted by local governments.

Initiatives for Generation AYA

Chugai launched the website AYA Life for young cancer patients in March 2017 and has been continuously updating its content. Recognition of generation AYA has been gradually growing, but there are still many patients facing a wide range of issues alone, including higher education, employment and marriage. In 2018, Chugai added new content in the form of roundtable discussions. As a leader in the area of oncology, Chugai will continue improving the website to help provide an environment where generation AYA cancer patients can receive treatment with peace of mind.

AYA Life
https://aya-life.jp/ (Japanese only)

Promotion of Measures against Locomotive Syndrome

Locomotive syndrome is a condition in which muscles, bones, joints, cartilage, intervertebral discs and other parts of the musculoskeletal system become impaired and motor function declines. The progression of the syndrome is highly likely to impede daily life. The Japanese Orthopaedic Association proposed it as a concept in 2007 and has been working to prevent the syndrome, establish measures for coping with it, and improve awareness. In cooperation with the prefectural chapters of the Japanese Clinical Orthopaedic Association, Chugai holds the Musculoskeletal Disorder/Bone and Joint Forum 10 or more times a year to deliver the latest information to healthcare professionals. We will continue helping to promote healthy life expectancy through this activity.

Support for Para-Sports

Chugai co-sponsors the Japanese Para-Sports Association (JPSA) as an official partner, and cooperates in activities to help realize the JPSA's philosophy of "creating a vital and inclusive society." The main activities Chugai conducted in 2019 are as follows.

Dispatch of Volunteers to Competitive Sports Events

Chugai held the Chugai Pharmaceutical 2019 Wheelchair Softball Tournament in Tokyo as the title sponsor, and provided support by sending 24 employee volunteers to assist with set-up, event management, English interpreting and other matters.

Raising Awareness of Para-Sports

- Co-sponsorship of a chair ski school for parents and children held by the Japan Chair Ski Association
- Operated a booth for experiencing wheelchair softball and handcycling at local community events and other venues
- Presentation of the para-sports related webpages "Another Sport" and "ATHLETE MOTHERS" on the Chugai website (Japanese only)

Parent and child enjoying chair skiing class

Initiatives for Employees and Their Families

To deepen understanding of para-sports and people with disabilities, Chugai held a hands-on event for experiencing blind sports in cooperation with the Yokohama City Special Support School for the Visually Impaired. There were 23 participants from Chugai, including employees and their family members.

Disaster Relief

Support for Children in Stricken Areas

Chugai once again participated in the global charity event Roche Children's Walk conducted by Roche to support children in need. In this annual initiative, Chugai matches the total amount of funds raised by its employees, with half of the total amount donated to Malawi and other countries, and the remainder donated to an organization in a stricken area in Japan. In 2019, the recipient organization was the non-profit organization Ayumu, which offers day service for disabled children in Ozu City, Ehime Prefecture.

Charity Sale

As part of its support for recovery from the 2011 Great East Japan Earthquake, Chugai held a charity sale at its Head Office and Kamakura Research Laboratories. As employees at each location looked over the goods and conversed with sales staff and local producers, they renewed their hopes and prayers for the restoration and recovery of the affected areas.

Para-Transit Vehicle Donations

Chugai's program to donate specially equipped para-transit vehicles began in 1985 as part of activities to commemorate the Company's 60th anniversary. The program marked its 35th year in 2019. A total of 258 vehicles have been donated since the start of the program, including five vehicles in 2019.

Securing the means for senior citizens and disabled people living at home to go to places such as hospitals, day service centers and day care centers and for staff from these facilities to visit homes to perform in-house care is significant from the viewpoint of enhancing welfare services.

The para-transit vehicle donation program is conducted in cooperation with the Japan National Council of Social Welfare and Central Community Chest of Japan, and through it vehicles have been donated to recipients in all of Japan's 47 prefectures.

Global Health Activities

There are still many people around the world suffering from diseases that currently have no effective treatments, and even when treatments do exist, people lack access due to poverty or for reasons pertaining to healthcare systems. To fulfill its Mission of benefiting the medical community and human health around the world, Chugai considers it essential to contribute to global health by improving access to healthcare. Accordingly, in addition to discovering and providing new drugs on our own, we proactively cooperate with a variety of organizations. Our priority initiatives as set in Chugai's Basic Approach to Global Health are (1) developing new products for diseases with no treatments by utilizing our pharmaceutical technologies and expertise, and (2) improving quality of healthcare and access to pharmaceuticals by improving the capabilities of healthcare professionals, promoting disease awareness in local communities, and establishing social infrastructure, particularly in low- and middle-income countries.

Chugai's Basic Approach to Global Health
https://www.chugai-pharm.co.jp/english/sustainability/globalhealth/concept.html

Reports: Global Health
https://www.chugai-pharm.co.jp/english/sustainability/activity/index.html?year=&category=2

Main Initiatives for Global Health

GHIT Fund

Jointly established with funding from Japanese pharmaceutical companies, the Japanese government, the Bill & Melinda Gates Foundation and the United Nations Development Programme, the Global Health Innovative Technology Fund (GHIT Fund) is Japan's first public-private partnership to support and promote research and development of drugs, vaccines and diagnostics for infectious diseases in developing countries.

In addition to joining the GHIT Fund and contributing capital in December 2014, Chugai has also been using its innovative discovery technologies and research resources to conduct a program to develop drugs to prevent and treat dengue fever and joint research to develop a treatment for tuberculosis.

GHIT Fund
https://www.ghitfund.org/

Access Accelerated

Access Accelerated was established in January 2017 by 22 global pharmaceutical companies including Chugai at the annual meeting of the World Economic Forum. In partnership with the World Bank Group and the City Cancer Challenge foundation, Access Accelerated is working to achieve the SDG target of reducing premature mortality from non-communicable diseases by one-third by 2030.

Through Access Accelerated, Chugai is conducting its own projects in Myanmar with AMDA-MINDS (AMDA Multisectoral & Integrated Development Services) to promote safer hospital childbirth and maternity healthcare and measures for people living with non-communicable diseases. We visit local communities to listen directly to the opinions and requests of patients, healthcare professionals and local health departments in order to gain an accurate understanding of their needs. We aim to use this information to continue helping to improve access to healthcare even after these projects are completed.

Update and feedback session on funding for emergency transportation of pregnant women

Access Accelerated website
http://www.accessaccelerated.org/

World Federation of Hemophilia Humanitarian Aid Program

The World Federation of Hemophilia (WFH) Humanitarian Aid Program, comprising a network of patient organizations in 140 countries, aims to improve access to care and treatment for people with inherited bleeding disorders in developing countries, where there is a severe lack of access to healthcare. As the originator of Hemlibra, Chugai is participating in the program as a member of the Roche Group. Through this five-year program, the Roche Group will fund the establishment of infrastructure and conditions for the proper use of treatments by healthcare professionals and will provide prophylactic treatment by donating Hemlibra for about 1,000 people with hemophilia A.

Data Section

Basic Information

Basic Information on the Pharmaceutical Industry

Overview of Domestic Pharmaceutical Market and NHI Drug Prices

Trends in National Medical Expenses

Without medical system reforms, Japan's national medical expenses will increase at an annual rate of approximately 2 to 4 percent going forward. In fiscal 2018 (the year ended March 2019), national medical expenses[1] totaled ¥42.6 trillion, a ¥0.4 trillion or 0.8 percent increase from the previous year. The accelerating pace of aging of Japan's society presents serious challenges to efficiently managing the increase in medical expenses for the elderly.

1. Source: Trends of recent medical expenditure (FY 2018) by Ministry of Health, Labour and Welfare

Promotion of the Use of Generics

The Japanese government is promoting the use of generics with the primary objective of reducing the cost burden on patients and improving the finances of the health insurance system. Various measures have been carried out under the action program announced in October 2007 to promote the worry-free use of generics. In April 2013, the new "Roadmap to Further Promote the Use of Generics" was formulated. A Cabinet decision in June 2017 set the new goal of raising the volume market share of generics, which was 76.7 percent[2] as of September 2019, to 80 percent by the end of September 2020. The government is also aiming to double the number of biosimilars by the end of March 2021.

2. Preliminary results of the Drug Price Survey

National Health Insurance (NHI) Drug Price Revision

The Ministry of Health, Labour and Welfare (MHLW) generally reviews drug reimbursement prices every two years and sets new standard prices (reimbursement prices) so that the official prices of pharmaceuticals prescribed under the health insurance system approximate their actual market price. MHLW does this by investigating the prices and volumes of all prescription drug transactions during a given period.

A special revision of drug reimbursement prices was implemented in conjunction with the consumption tax increase in October 2019. In its fiscal 2019 budget, the Japanese government reduced reimbursement prices by 0.51 percent on a government spending basis (+0.42 percent to reflect the consumption tax and a -0.93 percent revision based on actual market prices and other factors).

The Japanese government decided to reduce reimbursement prices in April 2020 by 0.99 percent on a government spending basis (including -0.43 percent from revision of actual market prices and -0.01 percent from repricing based on market expansion).

Repricing Based on Market Expansion

Under this repricing rule introduced in 1994, drugs priced by the cost calculation method with annual sales exceeding ¥10.0 billion and more than 10 times the original forecast at the time of price revision, or with annual sales exceeding ¥15.0 billion and more than two times the original forecast, are subject to a price reduction of up to 25.0 percent.

NHI Drug Price Revision Rate (%)

	2008	2010	2012	2014*	2016	2018	2019/Oct.*
Industry Average	(5.2)	(6.5)	(6.25)	(2.65)	(7.8)	(7.48)	(2.4)
Chugai	(7.2)	(6.8)	(6.0)	0.8	(5.5)	(6.7)	(0.2)

*Includes provision for increase in consumption tax
Source: Chugai data

Drugs priced by methods other than the cost calculation method (including the similar efficacy comparison method) with annual sales exceeding ¥15.0 billion and more than two times the original forecast at the time of the price revision are subject to a price reduction of up to 15.0 percent. In addition, the prices of drugs that have pharmacological action similar to a drug subject to this repricing rule are reduced by the same rate. In the NHI drug pricing system fundamental reforms of fiscal 2018, it was decided to use the NHI listing of new drugs that takes place four times a year as an opportunity for repricing of drugs with annual sales exceeding ¥35.0 billion. The purpose of this change is to respond more quickly when sales expand rapidly due to an additional indication or other reasons.

Special Market-Expansion Repricing

In the reforms to the drug pricing system in fiscal 2016, an additional repricing rule for drugs with very high annual sales was introduced as a special measure from the standpoint of balancing reward for innovation with the sustainability of the National Health Insurance system. This rule lowers prices by up to 25.0 percent for drugs with annual sales of ¥100.0-150.0 billion and more than 1.5 times the original forecast, and lowers prices by up to 50.0 percent for drugs with annual sales exceeding ¥150.0 billion and more than 1.3 times the original forecast. In addition, the prices of drugs that have pharmacological action similar to a drug subject to the special repricing rule and were comparator drugs at the time of the NHI price listing are reduced by the same rate. In the NHI drug pricing system fundamental reforms of fiscal 2018, it was decided to use the NHI listing of new drugs that takes place four times a year as an opportunity for repricing under this scheme.

Premium to Promote the Development of New Drugs and Eliminate Off-Label Use

As part of the NHI drug pricing system reforms of fiscal 2010 (the year ended March 2011), a new pricing scheme was implemented on a trial basis to promote the creation of innovative medical products and solve the drug lag[3] problem. In this scheme, at the time of the NHI drug price revisions, prices are maintained on drugs for which no generics are available (provided that they have been in the NHI price list for no more than 15 years), and which satisfy certain conditions.

This premium pricing for new drugs was continued on a trial basis in subsequent NHI drug pricing system reforms. However, in the NHI drug pricing system fundamental reforms of fiscal 2018, the decision was made to revise the requirements for companies and products and list them in the drug repricing rules.

Companies that do not respond appropriately to development requests from MHLW will continue to be excluded from eligibility for premium pricing. In addition, indicators have been set for (A) creation of innovative drugs and treatments for antimicrobial-resistant bacteria, (B) drug lag countermeasures, and (C) development of novel drugs ahead of other

Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs

(As of January 30, 2020)

Development request	Product	Indication	Development status
First development request	Xeloda	Advanced or recurrent gastric cancer	Approved in February 2011
	Tarceva	Advanced or recurrent pancreatic cancer	Approved in July 2011
	Avastin	Advanced or recurrent breast cancer	Approved in September 2011
	CellCept	Pediatric renal transplant	Approved in September 2011
	Herceptin	Q3W dosage metastatic breast cancer overexpressing HER2	Approved in November 2011
		Neoadjuvant breast cancer overexpressing HER2	
	Kytril	Gastrointestinal symptoms associated with radiotherapy	Approved in December 2011
	Pulmozyme	Improvement of pulmonary function in patients with cystic fibrosis	Approved in March 2012
	Bactramin	Treatment and prevention of pneumocystis pneumonia	Approved in August 2012
	Avastin	Ovarian cancer	Approved in November 2013
Second development request	Avastin	Recurrent glioblastoma	Approved in June 2013 (Malignant glioma)
	Herceptin	Q1W dosage postoperative adjuvant breast cancer overexpressing HER2	Approved in June 2013
	CellCept	Lupus nephritis	Approved in May 2016
Third development request	Tamiflu	Additional dosage for neonates and infants younger than 12 months	Approved in March 2017
	Xeloda	Adjuvant chemotherapy in rectal cancer	Approved in August 2016
	Avastin	Additional Q2W dosage and administration for ovarian cancer	Submitted company opinion and waiting for evaluation by committee
Fourth development request	Copegus	Improvement of viraemia associated with genotype 3 chronic hepatitis C or compensated cirrhosis related to hepatitis C when administered in combination with sofosbuvir	Approved in March 2017
	Xeloda	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by committee
	Avastin	Cerebral edema induced by radiation necrosis	Submitted company opinion and waiting for evaluation by committee
	Neutrogin	Combination therapy with chemotherapy including fludarabine for relapsed/refractory acute myeloid leukemia	Submitted company opinion and waiting for evaluation by committee
	CellCept	Prevention of graft-versus-host disease in hematopoietic stem cell transplantation	Submitted company opinion and waiting for evaluation by committee

countries, and the pricing premiums may vary according to the level of achievement or fulfillment of these indicators. Healthcare related ventures are expected to play an important role in the creation of innovative drugs, and will be evaluated accordingly, irrespective of the company indicators.

Regarding the product requirements, the percentage price difference requirement will be abolished, and the price premium will be limited to novel drugs during their patent period, and drugs that are truly innovative and useful. More specifically, it will be limited to orphan drugs; drugs for which development was publicly requested; drugs to which the premium was applied because of their usefulness, such as at the time they were newly listed; drugs with novel mechanisms of action that are innovative or useful (limited to the top three first-in-class drugs within three years from listing) or that have newly added efficacy or effectiveness deemed equivalent to novel modes of action; drugs that have Sakigake designation; and treatments for antimicrobial-resistant bacteria.

Among new drugs subject to premium pricing, including those for which generics (including biosimilars) have been launched or 15 years have elapsed since their drug price listing, the cumulative amount of premium pricing is deducted from the NHI drug price in the subsequent initial drug price revision. Furthermore, a reduction or other adjustment due to the actual market price of the new drug during the fiscal year is made to the NHI drug price less the cumulative amount.

3. The inability of Japanese patients to gain access to global standard or most advanced treatments because the drugs are not developed in Japan

Solving the Drug Lag Problem

In January 2005, MHLW established the Investigational Committee for Usage of Unapproved Drugs as one means of helping solve the drug lag problem. The committee is charged with investigating the clinical necessity and the appropriateness of usage of drugs already approved in Europe and the United States, but not yet approved in Japan. The aim of these investigations is to promote the development of those drugs in Japan. In February 2010, MHLW established the Review Committee on Unapproved Drugs and Indications with High Medical Needs. This committee evaluates the medical necessity of drugs and indications that are not yet approved in Japan and investigates matters such as the applicability of filings for approval based on evidence in the public domain. As a result of continuous efforts to strengthen the review function of the Pharmaceutical and Medical Devices Agency, an independent administrative institution responsible for reviewing drugs and medical devices for approval, the median total review time for new drugs in fiscal 2018 was 11.9 months. For new drug applications filed in Japan during fiscal 2018, the median review time was 0.2 years longer than that of the United States, but shorter than the average year lag.

Annual Drug Price Survey and Annual NHI Drug Price Revision

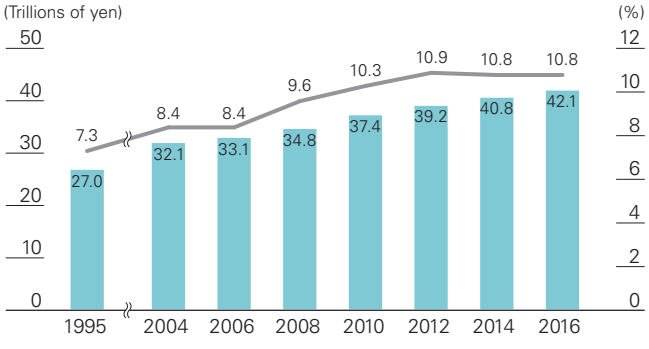
Due to the growing public financial burden of the current situation, in which drug prices are maintained for up to two years even if the market price declines, it was decided in the NHI drug pricing system fundamental reforms of fiscal 2018 that drug price surveys and drug price revisions will be carried out even in interim years when there would ordinarily be no price revisions. Fiscal 2018 and fiscal 2020 (the year ending March 2021) are price revision years even under the current system, and it is expected that a price revision will be implemented in conjunction with the consumption tax rate increase in October 2019. Therefore, the interim-year price revisions under the new rules will take place starting from fiscal 2021 (the year ending March 2022). The scope of items subject to interim-year price revisions will be deliberated by the Central Social Insurance Medical Council (Chuikyo) and other organizations.

Creation of a System for Cost-Effectiveness Assessments

A system of price adjustments based on cost-effectiveness assessments has been approved by Chuikyo, and was implemented in April 2019. The system primarily applies to products that meet the requirements of the selection criteria at the time of their NHI price listing. Cost-effectiveness assessments will be conducted for a certain period after the listing, and the price will be adjusted according to the results. The extent of the price adjustment is the portion corresponding to the amount of the corrective premium for usefulness applied at the time of the drug's initial pricing (for products with a degree of disclosure under 50 percent, as calculated by the cost calculation method, the portion corresponding to operating profit is also subject to adjustment). Price adjustments will be made according to the incremental cost effectiveness ratio (ICER).[4] The corrective premium will be maintained if the ICER is less than ¥5 million (less than ¥7.5 million for anticancer agents), but will be reduced in stages by up to 90 percent if the ICER is ¥5 million or more. The price adjustment will be limited to 10-15 percent of the total drug price.

4. The ICER indicates the extent to which additional investment would be necessary to obtain the additional benefit from replacing existing drug (technology) B with new drug A.

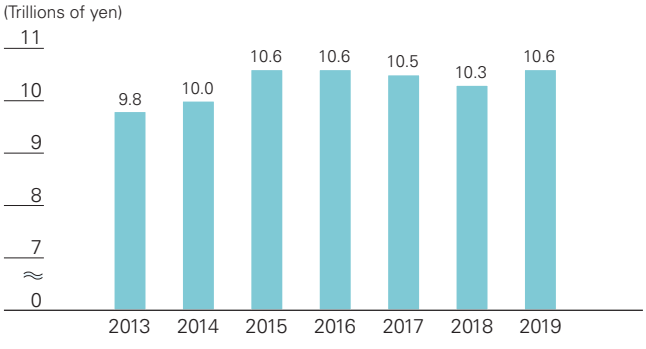
Trends of Medical Care Expenditure



Source: Overview of Estimates of National Medical Care Expenditure, FY2016 by Ministry of Health, Labour and Welfare

Note: National income is based on the actual results of the System of National Accounts announced by the Cabinet Office.

Prescription Drug Market



Oncology

Overview of Disease and Treatment Methods

Leading Cause of Death in Japan

Cancer has been the single most common cause of death in Japan since 1981. In 2018, 373,584 people[1] died of cancer, accounting for 27.4 percent[1] of all deaths in that year and the highest number since government surveys began in 1899.

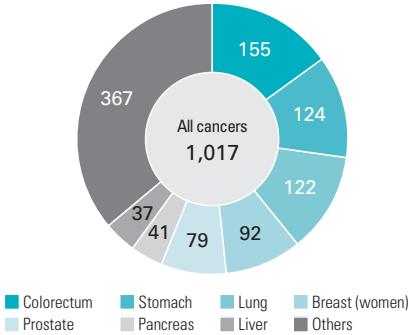
1. Source: Outline of Vital Statistics (2018) by Ministry of Health, Labour and Welfare

Establishment of the Basic Act for Anticancer Measures and Improvement in the Healthcare Environment

The Cancer Control Act was enacted in June 2006 to establish a system so that patients can receive appropriate treatment based on scientific knowledge regardless of the region in which they reside and with respect paid to their wishes, as well as to implement the Basic Plan to Promote Cancer Control Programs (the "Basic Plan"). Since the enactment of the Cancer Control Act, some results have been obtained, including establishment of designated cancer hospitals and a reduction of the cancer mortality rate and improvement of the five year survival rate owing to advances in cancer treatment. The goal of reducing the age-adjusted cancer mortality rate by 20 percent over the 10-year period from fiscal 2007 was judged difficult to achieve, and therefore, in December 2015, the Plan for Acceleration of Cancer Control Programs was formulated. This plan specified concrete measures that should be implemented intensively in a short period of time.

Projected Cancer Incidence (2019)

(Thousands of cases)



Source: National Cancer Center Cancer Information Service, "Cancer Registries/Statistics"

Note: Projections were performed with a model incorporating age, calendar year at diagnosis, and their interactions as independent variables, utilizing frequency of incidence of cancer by age bracket from Monitoring of Cancer Incidence in Japan (1975-2015 nationwide estimates) and cancer mortality figures from the Outline of Vital Statistics (1975-2017 estimates). The total may not add up because projections have been performed by cancer type and figures have been rounded.

Reference: *Japanese Journal of Clinical Oncology* 2014, 44: 36-41

In recent years, it has become apparent that new measures are necessary to fight rare cancers, difficult-to-treat cancers, childhood cancers, and cancers in adolescents and young adults (AYA); to promote new treatments such as genomic medicine; and to address societal problems including employment. The principles of the Cancer Control Act revised in 2016 require that the national and local governments make effective use of healthcare and welfare resources and implement cancer control measures from the viewpoint of serving the public in order to achieve the stated goal of creating a society in which cancer patients can live with peace of mind and dignity. In the 3rd Basic Plan to Promote Cancer Control Programs released in March 2018, measures are being implemented to educate the public, including patients, about cancer and help them to overcome it. These measures are based on four pillars – cancer prevention, improvement of cancer care, living with cancer and deployment of infrastructure to support those measures.

Changes in Treatment Methods

Cancer treatment is increasingly being based on a multidisciplinary approach that combines surgery, radiation therapy and drug therapy. In particular, the field of anticancer agents is evolving, and highly innovative medicines such as molecular targeted drugs have been introduced. This has brought dramatic improvement in treatment outcomes for various types of cancer.

Advances are being made in personalized healthcare (PHC), which involves testing patients with companion diagnostics when administering molecular targeted drugs to identify patients who are likely to benefit with minimal strain on the body and few side effects. In addition to enabling physicians to propose the optimal treatment tailored to each patient, this approach offers a number of other benefits. For example, it can reduce national healthcare expenditures by reducing the administration of drugs when their effect cannot be determined.

Diagnosis with comprehensive genomic profiling (CGP), such as genomic testing using next-generation sequencing, is also becoming important. In improvement of cancer care, one of the pillars of the above-mentioned Basic Plan, cancer genomic medicine heads the list of measures, and practical application of CGP testing was promoted as an important government-led initiative. As a result, in June 2019 CGP, which entails comprehensive analysis and profiling of genes in a single test using solid tumor tissue from the patient, became eligible for health insurance coverage. The provision of optimal treatments based on each patient's genomic profile has thus become a reality. Genomic medicine started in the oncology field, but is now being promoted for intractable diseases and other diseases, in line with the "Action Plan of the Growth Strategy," "Follow-up on the Growth Strategy" and "Action Plan for Innovative Business Activities" in FY 2019, which were approved by the Cabinet in June 2019. This is expected to further advance precision medicine in ways such as promoting the development of treatment approaches that utilize genomic information obtained not only through genomic analysis of cancer tissue, but through entire genome analysis.

Cancer immunotherapy, which takes advantage of the body's own immune cells to fight cancer, is another important emerging field of treatment. Immune checkpoint inhibitors, one type of immunotherapy now in use, are a promising new direction in cancer treatment. Cancer has the ability to suppress (apply brakes to) immune functions to avoid attack from the immune system, but immune checkpoint inhibitors block the immune "brakes" (the binding of PD-1 to PD-L1) known as the immune checkpoint, thereby awakening immune cells to attack cancer cells. In clinical study results, immune checkpoint inhibitors have shown promise for long-term survival and cure, even in advanced cancer. Their high therapeutic efficacy is also recognized in clinical settings, and they are increasingly used as treatments for a wide range of cancers. However, some patients do not respond to cancer immunotherapy, so screening to select patients for whom this therapy is likely to be effective is also being examined, as are various combinations with existing anticancer agents and development candidates, and development for use in early-stage cancer.

FoundationOne CDx Cancer Genomic Profile

Basic Information

FoundationOne CDx Cancer Genomic Profile (F1CDx), developed by U.S.-based Foundation Medicine, Inc., is a next-generation sequencing-based diagnostic device. It detects substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability

(MSI) and tumor mutational burden (TMB). The program is available as a companion diagnostic for multiple molecular-targeted drugs approved in Japan. Chugai launched the program and began providing testing services in June 2019.

Avastin (RG435)

Anti-VEGF humanized monoclonal antibody
(Generic name: bevacizumab)
Launch in Japan: June 2007

Basic Information

Avastin is a humanized monoclonal antibody targeting vascular endothelial growth factor (VEGF). It is the first therapeutic agent in the world that inhibits angiogenesis (the growth of the network of blood vessels that supply nutrients and oxygen to the cancer). Unlike conventional anticancer agents that act directly on cancer cells, Avastin acts on the cancer microenvironment. In Japan, Avastin was launched in 2007 for the treatment of unresectable advanced or recurrent colorectal cancer. In 2009, Chugai obtained approval for a new dosage and administration for colorectal cancer and the additional indication of unresectable advanced or recurrent non-squamous non-small cell lung cancer (NSCLC), followed in 2011 by inoperable or recurrent breast cancer. Chugai also obtained approval for the additional indications of malignant glioma and ovarian cancer in 2013, and advanced or recurrent cervical cancer in May 2016.

Review of 2019 Performance

Sales of Avastin were unchanged from the previous year at ¥95.6 billion. Avastin has built a solid position in the treatment of colorectal cancer and lung cancer, but the competitive environment in the field of lung cancer has been changing due to the introduction of immune checkpoint inhibitors and other products. On the other hand, the use of Avastin for other indications, including breast cancer, has increased steadily. Global phase III studies in combination with Tecentriq in renal cell carcinoma and hepatocellular carcinoma patients are under way.

In February 2020, we filed applications for the combination of Tecentriq and Avastin for the treatment of unresectable hepatocellular carcinoma.

Herceptin

Anti-HER2 humanized monoclonal antibody
(Generic name: trastuzumab)
Launch in Japan: June 2001

Basic Information

Herceptin is a humanized monoclonal antibody that targets human epidermal growth factor receptor type 2 (HER2),[2] which contributes to tumor cell growth.
The earliest PHC-based anticancer agent, Herceptin has built a solid reputation as an essential treatment for HER2-positive breast cancer since its launch in 2001.

Overexpression of HER2 is found in about 20 percent of breast cancers. Such cancer is diagnosed as HER2-positive. HER2-positive breast cancer progresses rapidly, and has been associated with a poor prognosis. However, treatment outcomes have improved significantly with the emergence of Herceptin and other medicines that target HER2. In 2011, Herceptin obtained approval for the additional indication of advanced or recurrent gastric cancer overexpressing HER2, not amenable to curative resection, bringing PHC to the field of gastric cancer.

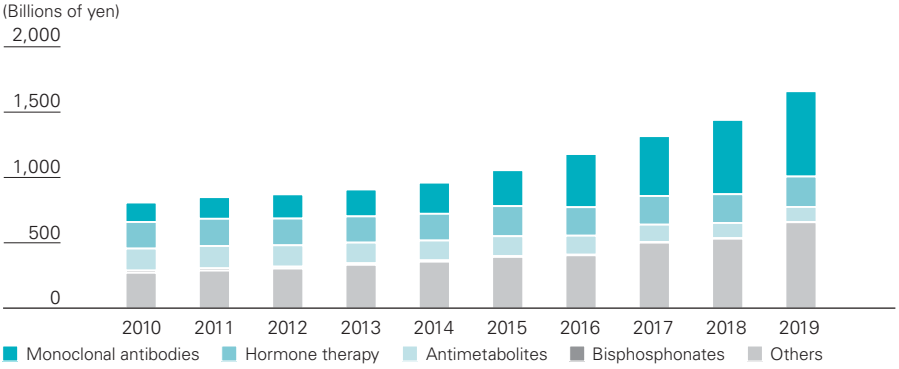
Review of 2019 Performance

Sales of Herceptin decreased ¥1.4 billion, or 5.0 percent, year on year to ¥26.7 billion. The decrease reflected the substantial NHI drug price revision (-20.4 percent) that resulted from the exclusion from eligibility for the premium for new drug creation.

Widely used in first-line treatment of HER2-positive advanced or recurrent breast cancer in combination with Perjeta, Herceptin is also used for more than 90 percent of lymph-node positive patients undergoing postoperative (adjuvant) therapy for HER2-positive early breast cancer. Since October 2018, it has been widely used in combination with Perjeta, after Perjeta became available as a neoadjuvant and adjuvant therapy in early breast cancer. For gastric cancer, although Herceptin maintained its established position in first-line treatment, sales decreased slightly due to competition in second-line treatment.

2. A diagnostic test can determine if a patient's breast or gastric cancer cells have overexpression of a protein called HER2. Herceptin, Perjeta and Kadcyla target HER2 and are administered only to patients whose tumors are identified as HER2-positive.

Anticancer Agent Market in Japan



Source: JPM 2010-2019
Reprinted with permission.
The scope of the market is defined by Chugai.

Perjeta (RG1273)

HER2 dimerization inhibitory humanized monoclonal antibody
(Generic name: pertuzumab)
Launch in Japan: September 2013

Basic Information

Perjeta is a humanized monoclonal antibody and is the first molecular targeted therapy that inhibits the dimerization of HER2. The combination of Perjeta and Herceptin, which also targets HER2, provides a more comprehensive blockade of HER signaling pathways associated with the proliferation of tumor cells. Chugai launched Perjeta for the indication of HER2-positive inoperable or recurrent breast cancer in September 2013, after obtaining approval in June 2013. In 2018, Perjeta obtained approval for the additional indication of neoadjuvant and adjuvant therapy for HER2-positive breast cancer.

Review of 2019 Performance

Sales of Perjeta increased ¥14.6 billion, or 90.7 percent, year on year to ¥30.7 billion, exceeding projections by a wide margin. The combination of Herceptin and Perjeta with a chemotherapy agent for neoadjuvant and adjuvant for HER2-positive early breast cancer, an additional indication approved in October 2018, penetrated the market faster than expected. In addition, a global phase III study is under way for RG6264 (subcutaneous injection), a fixed-dose combination of Herceptin and Perjeta, for HER2-positive breast cancer.

Kadcyla (RG3502)

Anti-HER2 antibody-tubulin polymerization inhibitor conjugate
(Generic name: trastuzumab emtansine)
Launch in Japan: April 2014

Basic Information

Kadcyla is an antibody-drug conjugate of the anti-HER2 humanized monoclonal antibody trastuzumab (product name: Herceptin) and

the potent chemotherapeutic agent DM1, joined together with a stable linker. Chugai filed an application for approval for HER2-positive inoperable or recurrent breast cancer in January 2013, obtained approval in September 2013 after priority review, and launched the product in April 2014.

Review of 2019 Performance

Sales of Kadcyla increased ¥0.5 billion, or 5.9 percent, year on year to ¥9.0 billion. Kadcyla is used as a second-line treatment in patients whose cancer worsened in first-line treatment with Herceptin and Perjeta plus chemotherapy. In development, a global phase III study for the potential treatment of HER2- positive early breast cancer (adjuvant therapy) is under way. In August 2019, Chugai also filed an application for approval of Kadcyla for adjuvant monotherapy in patients with HER2-positive early breast cancer based on the results of a global phase III clinical study of the agent for this indication with certain patients.

Rituxan

Anti-CD20 monoclonal antibody
(Generic name: rituximab)
Launch in Japan: September 2001

Basic Information

Rituxan is a monoclonal antibody targeting the CD20 antigen found on the surface of lymphocytes. As a standard therapy for CD20-positive, B-cell non-Hodgkin's lymphoma (hematological cancer), it has substantially improved clinical outcomes in combination with chemotherapy or in monotherapy. In Japan, Rituxan is marketed jointly by Chugai and Zenyaku Kogyo Co., Ltd. In recent years, the usefulness of Rituxan has been recognized in treating CD20-positive, B-cell lymphoma in immunosuppressed patients, granulomatosis with polyangiitis (GPA) (formerly known as Wegener's granulomatosis) and microscopic polyangiitis (MPA), refractory nephrotic syndrome with frequent relapses or steroid dependence, suppression of antibody-mediated rejection in ABO-incompatible kidney and liver transplantation, and idiopathic thrombocytopenic purpura (ITP). It has also become a valuable treatment option for patients with autoimmune diseases and other conditions. Rituxan obtained approval for the additional indications of CD20-positive chronic lymphocytic leukemia (CLL) in 2019 and acquired thrombotic thrombocytopenic purpura in February 2020.

Review of 2019 Performance

Sales of Rituxan decreased ¥9.4 billion, or 44.1 percent, year on year to 11.9 billion. The decrease was due to more intense competition resulting from the launch of a generic product.

Alecensa (AF802/RG7853)

ALK inhibitor
(Generic name: alectinib)
Launch in Japan: September 2014

Basic Information

Alecensa, an oral, small molecule targeted molecular therapy created by Chugai, inhibits the activity of the tyrosine kinase anaplastic lymphoma kinase (ALK) with *EML4-ALK* fusion gene expressed in about 2 to 5 percent of NSCLC. It was designated as an orphan drug in Japan in September 2013 for the treatment of *ALK* fusion gene-positive unresectable, recurrent/advanced NSCLC. In October 2013, Chugai filed an application for approval. Following approval in July 2014, Alecensa was launched first in Japan in September 2014. In addition to being the first product from Chugai research to be granted breakthrough therapy designation by the U.S. Food and Drug Administration (FDA) as a second-line treatment in 2013, Alecensa received the same designation as a first-line treatment in 2016, and it is contributing to the treatment of patients around the world. Outside Japan, after obtaining approval in the United States in December 2015 and in Europe in February 2017 for the indication of ALK-positive metastatic (advanced) NSCLC in patients whose disease has progressed or who are intolerant to crizotinib, Alecensa obtained approval as a first-line treatment in the United States in November 2017 and Europe in December 2017. In February 2020, Alecensa obtained approval for the additional indication of recurrent or refractory *ALK* fusion gene-positive anaplastic large cell lymphoma (ALK-positive ALCL).

Review of 2019 Performance

Market penetration proceeded further with the announcement of positive results that led to the early stopping for benefit of a study comparing the efficacy and safety of Alecensa and a competing product on patients in Japan (J-ALEX study). Sales of Alecensa in Japan increased ¥2.4 billion, or 11.7 percent, year on year to ¥23.0 billion, due to a high rate of continuation of treatment. Overseas sales of Alecensa (including exports to Roche) increased ¥15.8 billion, or 53.6 percent, year on year to ¥45.3 billion. In development, a global phase III study for adjuvant therapy of ALK-positive NSCLC is under way.

Xeloda

Antimetabolite, 5-FU derivative
(Generic name: capecitabine)
Launch in Japan: June 2003

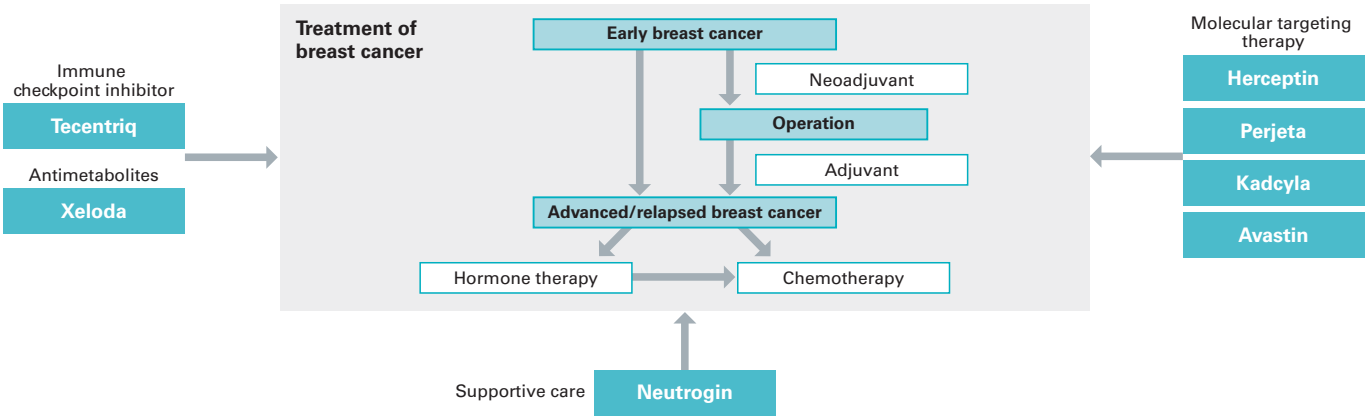
Basic Information

Xeloda is a 5-fluorouracil (5-FU) anticancer agent developed at the research laboratories of the former Nippon Roche. Orally administered Xeloda is absorbed by the body, then gradually metabolized by certain highly active enzymes in liver and tumor tissue, and is eventually converted into active 5-FU within tumor tissue. Xeloda has obtained approval for the treatment of inoperable or recurrent breast cancer, colorectal cancer and gastric cancer.

Review of 2019 Performance

Sales of Xeloda decreased ¥4.5 billion, or 36.0 percent, year on year to ¥8.0 billion. Uptake of a generic launched in January 2019 was greater than expected, resulting in the

Extensive Contribution to Cancer Treatment (Breast Cancer)



sharp decline in sales of Xeloda. However, in adjuvant therapy performed to inhibit recurrence after surgery for colon cancer, Xeloda is the most prescribed drug because of its recommendation in the guidelines for the treatment of colorectal cancer and the results of a large-scale global study.

Tarceva

Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor
(Generic name: erlotinib)
Launch in Japan: December 2007

Basic Information

Tarceva is an oral targeted small molecule drug that inhibits the activation of epidermal growth factor receptor (EGFR) tyrosine kinase, which is associated with the growth, progression and metastasis of cancer. In Japan, Tarceva had been used for second-line or later treatment of NSCLC since its launch in 2007, but the approval of an additional indication in June 2013 allowed its use in first-line treatment of NSCLC patients with *EGFR* mutations, in whom high efficacy is expected. About 15 percent of NSCLC patients in Europe and about 40 percent in Asia are diagnosed *EGFR* mutation-positive. In 2011, Tarceva obtained approval for the additional indication of pancreatic cancer not amenable to curative resection.

Review of 2019 Performance

Sales of Tarceva decreased ¥3.8 billion, or 45.8 percent, year on year to ¥4.5 billion. In NSCLC, sales decreased sharply compared with the previous year due to competition from other products.

Neutrogin

Recombinant human granulocyte colony-stimulating factor (G-CSF)
(Generic name: lenograstim; overseas product name: Granocyte)
Launch in Japan: December 1991

Basic Information

Neutrogin is a recombinant human granulocyte colony-stimulating factor (G-CSF) created by Chugai. One common side effect of anticancer drugs is neutropenia, a decrease in the white blood cell count that heightens the risk of developing serious infections. Neutrogin stimulates the differentiation and growth of neutrophils, enabling the safer use of chemotherapy, thus helping to improve treatment outcomes. Neutrogin is also essential in hematopoietic stem cell transplantation, which is performed for illnesses that affect production of normal blood cells, such as leukemia.

Review of 2019 Performance

Overseas sales of Neutrogin decreased ¥1.2 billion, or 10.8 percent, year on year to ¥9.9 billion due to intensified competition.

Tecentriq (RG7446)

Engineered anti-PD-L1 monoclonal antibody
(Generic name: atezolizumab)
Launch in Japan: April 2018

Basic Information

Tecentriq is an engineered anti-PD-L1 monoclonal antibody in-licensed from Roche. One way that tumor cells evade the immune system is by expressing a protein called programmed death-ligand (PD-L1) on their surface, which is believed to shield them from immune system attacks by binding to T cells. Tecentriq restores and maintains the immune response of T cells by binding to PD-L1, and is expected to demonstrate efficacy against cancer cells. Its mode of action differs from conventional treatments that attack cancer cells directly. Since it takes advantage of the patient's own immune response, it is also promising for use in combination with existing drugs and for various cancer types. Chugai obtained approval in January 2018 for the treatment of unresectable advanced or recurrent NSCLC, and obtained approval in December 2018 for the treatment of chemotherapy-naive people with unresectable advanced or recurrent non-squamous NSCLC in combination with Avastin and chemotherapy. In 2019, Chugai obtained approval for the additional indications of extensive-stage small cell lung cancer (SCLC) in August, PD-L1-positive inoperable or recurrent triple-negative breast cancer (TNBC) in September, and unresectable, advanced or recurrent NSCLC (new dosage/form) in November. Tecentriq is the first immune checkpoint inhibitor to be approved in the SCLC and breast cancer areas in Japan, the United States and Europe. Characterized by rapid progression and poor prognosis, SCLC and metastatic TNBC are diseases with high unmet medical need. SCLC is an area that has long had limited therapeutic options, and Tecentriq received orphan drug designation as the first new drug in 17 years that improved treatment outcomes. Furthermore, additional dosage forms for NSCLC in November 2019 enable a regimen that does not limit combination with other anticancer agents in first-line therapy, and some of those additional dosages obtained approval in Japan ahead of other countries.

In addition, Chugai is participating in global phase III studies for NSCLC (neoadjuvant and adjuvant), urothelial carcinoma, muscle invasive urothelial carcinoma (adjuvant), renal cell carcinoma, renal cell carcinoma (adjuvant), early breast cancer, ovarian cancer, hepatocellular carcinoma (adjuvant), and head and neck carcinoma (including adjuvant treatment). In February 2020, Chugai filed applications for Tecentriq and Avastin in combination for unresectable, advanced or recurrent hepatocellular carcinoma (HCC).

Review of 2019 Performance

Sales of Tecentriq increased ¥11.5 billion, or 126.4 percent, year on year to ¥20.6 billion, substantially higher than expected. Sales increased because in its position in second-line treatment and beyond for NSCLC, it can be prescribed regardless of PD-L1 expression, and because of steady uptake in combination with Avastin and chemotherapy in first-line treatment of unresectable, advanced or recurrent NSCLC.

Gazyva (GA101)

Glycoengineered type II anti-CD20 monoclonal antibody
(Generic name: obinutuzumab)
Launch in Japan: August 2018

Basic Information

Gazyva is a glycoengineered type II monoclonal antibody in-licensed from Roche that, like Rituxan, targets CD20. A study that directly compared its efficacy and safety with Rituxan, currently the most widely used monoclonal antibody, in patients in Japan and overseas (the GALLIUM study) was terminated early for benefit after positive results were reported. Gazyva obtained approval for the treatment of CD20-positive follicular lymphoma in July 2018, and was launched in August 2018. In November 2012, Chugai entered into an agreement with Nippon Shinyaku Co., Ltd. to co-develop and co-market this agent in Japan.

Review of 2019 Performance

Sales of Gazyva, which was launched in August 2018, increased ¥3.0 billion, or 500.0 percent, year on year to ¥3.6 billion. Steady sales growth was driven by uptake in Rituxan-naïve or recurrent patients.

Rozlytrek (RG6268)

ROS1/TRK inhibitor
(Generic name: entrectinib)
Launch in Japan: September 2019

Basic Information

Rozlytrek, in-licensed from Roche, is an orally bioavailable CNS-active tyrosine kinase inhibitor that potently and selectively inhibits ROS1 and the TRK family, and also acts on brain metastases. Targeting *NTRK* fusion gene-positive solid tumors, RG6268 has been granted breakthrough therapy designation in the United States, PRIorityMEdicines (PRIME) designation in the EU, and Sakigake designation in Japan. Chugai obtained the world's first approval for the treatment of *NTRK* fusion gene-positive advanced/recurrent solid tumors in Japan in June 2019, and launched the product in September 2019. Rozlytrek is a tumor-agnostic therapy that uses a next-generation sequencing-based companion diagnostic to identify target genomic alterations that drive cancer, thus embodying the advanced PHC that Chugai is promoting. F1CDx obtained approval in June

2019 as a companion diagnostic for Rozlytrek. Chugai obtained approval for *ROS1* unresectable, advanced, or recurrent fusion gene-positive NSCLC in February 2020.

GC33 (RG7686) Development project

Anti-glypican-3 humanized monoclonal antibody
(Generic name: codrituzumab)

GC33, a humanized monoclonal antibody created by Chugai, targets glypican-3 (GPC3), which is specifically expressed in hepatocellular carcinoma. GC33 did not meet the primary endpoint in a global phase II monotherapy study started in March 2012. A phase I clinical study for hepatocellular carcinoma in combination with Tecentriq has been under way since August 2016, and the study results were presented at the European Society of Medical Oncology (ESMO) 2018 Congress.

ERY974 Development project

Anti-glypican-3/CD3 bispecific antibody

ERY974 is the first T-cell redirecting antibody (TRAB) developed by Chugai. TRAB is a bispecific antibody that creates a short bridge between CD3 on T cells and tumor antigen on tumor cells to activate T cells in a tumor antigen-dependent manner, and is expected to demonstrate strong cytotoxicity against tumor cells. GPC3, a tumor antigen targeted by ERY974, is reported to be expressed in multiple types of tumor cells including hepatocellular carcinoma, lung cancer, gastric cancer and esophageal cancer. A phase I clinical trial is under way.

RG7596 Development project

Anti-CD79b antibody-drug conjugate
(Generic name: polatuzumab vedotin)

RG7596 is an antibody-drug conjugate of an anti-CD79b monoclonal antibody and the microtubule inhibitor MMAE, joined together with a linker. In-licensed from Roche, the conjugate is designed to deliver MMAE directly into B cells via CD79b, which is expressed on B cells, so that the inhibitor can act. To demonstrate a cytostatic effect on tumor cells, a global phase III study for previously untreated diffuse large B-cell lymphoma (DLBCL) started in November 2017. In addition, a phase II clinical study for relapsed or refractory DLBCL started in Japan in October 2018 and achieved a primary endpoint in February 2020. In November 2019, RG7596 received MHLW orphan drug designation for the treatment of DLBCL.

RG7440 Development project

AKT inhibitor
(Generic name: ipatasertib)

RG7440 is an AKT inhibitor in-licensed from Roche. Global phase III studies started in June 2017 for prostate cancer and in January 2018 for breast cancer. For breast cancer, a number of new global phase III studies are either beginning or in preparation with the aim of adding further indications.

RG7421 Development project

MEK inhibitor
(Generic name: cobimetinib fumarate)

RG7421 is an MEK inhibitor in-licensed from Roche. Chugai started a phase I clinical study for the treatment of solid tumors in Japan in July 2017.

RG7802 Development project

Anti-CEA/CD3 bispecific antibody
(Generic name: cibisatamab)

RG7802, a bispecific antibody in-licensed from Roche, is expected to activate T-cells and attack tumor cells by cross-linking CD3 on T-cells to carcinoembryonic antigen (CEA) on tumor cells. With a novel structure engineered to bind simultaneously with one arm to CD3 on T-cells and two arms to CEA on tumor cells, it exhibits higher tumor selectivity and stronger binding to CEA. CEA is reported to be overexpressed in a variety of cancers, including colorectal cancer.

RG7802-mediated intra-tumor T-cell proliferation may yield efficacy in tumor types that are not responsive to current cancer immunotherapies because there are few T-cells in the tumor. In addition, combination immunotherapy of RG7802 with Tecentriq is expected to yield a potent antitumor effect in various CEA-positive cancers by inducing further T-cell activation. Chugai started a phase I clinical study of RG7802 for the treatment of solid tumors in Japan in January 2018.

RG7828 Development project

Anti-CD20/CD3 bispecific antibody
(Generic name: mosunetuzumab)

RG7828 is a bispecific antibody in-licensed from Roche. Similar to RG7802, it is expected to activate T cells and attack tumor cells by cross-linking CD3 on T cells to CD20 on B cells. Chugai started a phase I clinical study for the treatment of hematologic tumors in Japan in March 2018.

RG7461 Development project

Anti-FAP humanized antibody-engineered IL-2 variant fusion protein

RG7461 is an anti-FAP humanized antibody-engineered IL-2 variant fusion protein in-licensed from Roche. Targeting an interleukin-2 (IL-2) variant in tumor stroma that overexpress fibroblast activation protein (FAP), it is expected to demonstrate efficacy against tumor cells by inducing activation of immune effector cells in the tumor microenvironment. In October 2019, Chugai began a phase I clinical trial of RG7461 for solid tumors in Japan.

RG6058 Development project

Anti-TIGIT fully humanized monoclonal antibody
(Generic name: tiragolumab)

RG6058 is an anti-TIGIT monoclonal antibody in-licensed from Roche. TIGIT is an immune checkpoint expressed on the surface of NK cells and T cells that binds to poliovirus receptors (PVR) expressed on tumor cell surfaces. This binding is thought to allow the cancer cells to evade attack by immune cells. RG6058 restores and maintains the immune response of NK cells and T cells by blocking the binding of TIGIT to PVR, and is thus expected to demonstrate efficacy against cancer cells. In November 2019, Chugai began a phase I clinical trial of RG6058 for solid tumors in Japan.

Bone and Joint Diseases/Autoimmune Diseases

Osteoporosis

Osteoporosis is a disease in which the bones become weak due to advanced age or other factors, increasing the risk of fractures. Osteoporosis patients may incur fractures through normal daily activities. Among these, compression fractures of the spine and femoral neck fractures can decrease quality of life by leaving patients bedridden and can also increase mortality risk. About 13 million people in Japan suffer from osteoporosis. However, the treatment rate stands at around only 20 percent of the estimated number of sufferers because there are usually no symptoms until a fracture occurs. The availability of superior new drugs that have higher efficacy, safety and convenience has brought promise for improvement in the quality of life of patients.

Treatment Methods

Osteoporosis drug therapies include active vitamin D_3 derivatives, which improve bone metabolism, bisphosphonates, which are bone resorption inhibitors, an anti-RANKL antibody, selective estrogen receptor modulators (SERMs), human parathyroid hormone (PTH), which is a bone formation agent, anti-sclerostin antibodies, and calcitonin.

Regulatory Trends

National prevention and treatment guidelines for osteoporosis were revised in October 2006. Subsequently, advances have been made in basic and clinical research into osteoporosis; evaluation of fracture risk and criteria for the initiation of drug treatment have been reviewed; and osteoporosis caused by lifestyle-related diseases has been addressed. In the interim, Edirol and other medicines have been approved for insurance coverage. Revisions issued in December 2011 added preventive and diagnostic items in light of the importance of early prevention to broaden the overall scope of osteoporosis treatment. Since then, the 2012 revised Diagnostic Criteria for Primary Osteoporosis and Management and Treatment Guidelines of Steroid-induced Osteoporosis have been adopted. Bonviva IV Injection and other medicines have been launched and covered by insurance, and revised guidelines were issued in July 2015.

Recently, an osteoporosis liaison service (OLS) initiated by the Japan Osteoporosis Society was introduced for the purpose of preventing osteoporosis and inhibiting bone fractures by coordinating the efforts of various healthcare professionals, including doctors, nurses, pharmacists and physical therapists. Medical staff involved in liaison and possessing extensive knowledge related to osteoporosis are called osteoporosis managers. This education program has been ongoing since 2012, and more than 3,061 osteoporosis managers were active as of April 2019.

Edirol

Active vitamin D_3 derivative
(Generic name: eldecalcitol)
Launch in Japan: April 2011

Basic Information

Edirol, a vitamin D_3 preparation born out of Chugai's many years of research in vitamin D, is an agent that improves bone metabolism in addition to calcium metabolism. Chugai started sales of Edirol in April 2011 as the successor drug to Alfarol for the indication of osteoporosis. Under an agreement signed in May 2008, Edirol has been co-developed and is currently co-marketed with Taisho Pharmaceutical Co., Ltd. Clinical trials have confirmed that Edirol has a similar safety profile to alfacalcidol with a statistically significant greater effect in preventing fractures. In the 2015 osteoporosis prevention and treatment guidelines, Edirol received a Grade A recommendation, the only one for an active vitamin D_3 derivative, for its effectiveness in increasing bone density and preventing vertebral fractures.

Review of 2019 Performance

Sales of Edirol increased ¥3.8 billion, or 11.6 percent, to ¥36.7 billion. It has become the most widely used active vitamin D_3 preparation because of its superior efficacy in increasing bone mass and preventing fractures compared with existing products. Recognition and understanding of Edirol as a base treatment has broadened. As a result, its use in combination with other drugs is expanding, as are prescriptions, primarily for new cases.

In China, an application has been filed for approval of Edirol for osteoporosis.

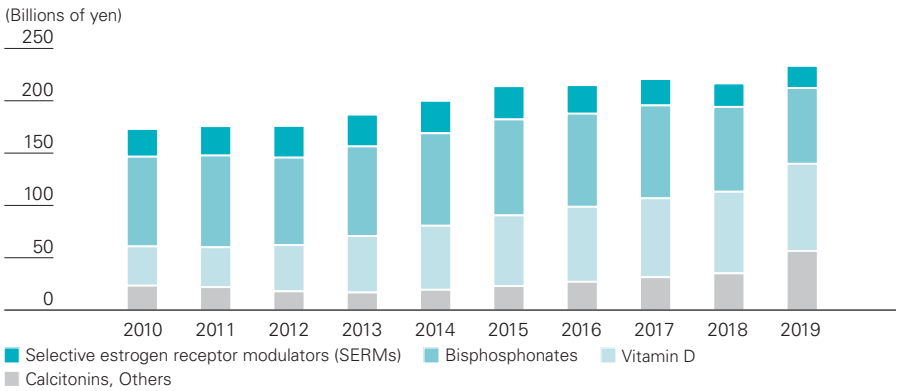
Bonviva

Bisphosphonate anti-resorptive agent
(Generic name: ibandronate)
Launch in Japan: August 2013

Basic Information

Bonviva is a bisphosphonate in-licensed from Roche. Bonviva IV Injection was launched in August 2013. Under an agreement signed in September 2006, Bonviva is being co-developed and co-marketed with Taisho Pharmaceutical Co., Ltd. Bonviva IV Injection can be given as a rapid intravenous injection once a month, and thus may significantly reduce the burden on patients. It is also expected to benefit patients who have difficulty taking oral formulations or who tend to forget to take their medication. In addition, Bonviva Tablet, a once-monthly oral formulation, demonstrated non-inferiority to Bonviva IV Injection in a phase III clinical trial, and Chugai began sales in April 2016. By enabling drug selection according to patient lifestyle, monthly Bonviva IV Injection and Bonviva Tablet are expected to help improve patient adherence, convenience for healthcare providers and the rate of continuation of treatment.

Osteoporosis Market in Japan



Source: JPM 2010-2019
Reprinted with permission.
The scope of the market is defined by Chugai.

Review of 2019 Performance

Sales of Bonviva increased ¥0.3 billion, or 3.2 percent, to ¥9.7 billion. The intravenous injection and oral formulations have the same high level of efficacy, and the ability to select the formulation according to the patient's condition has helped to differentiate Bonviva from other bisphosphonates.

Rheumatoid Arthritis/ Osteoarthritis

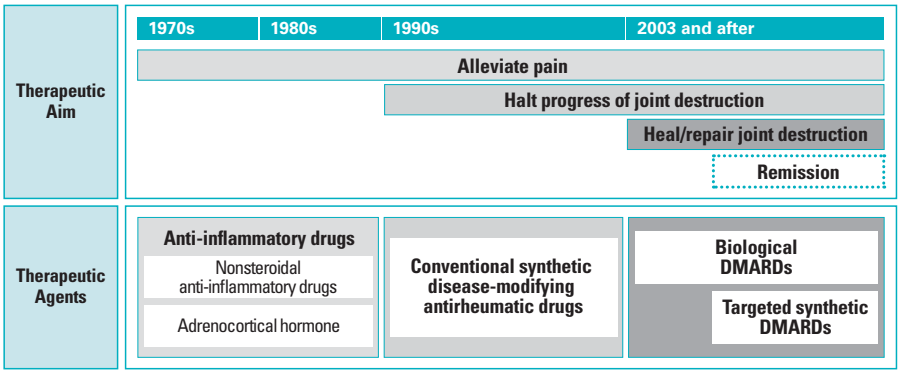
Rheumatoid arthritis (RA) is a systemic disease characterized by painful inflammation and deformation of joints leading to dysfunction. Without appropriate treatment, the patient's condition deteriorates over time. There are currently an estimated 700,000 to 800,000 patients in Japan suffering from RA, of whom some 330,000 are currently receiving drug treatment. The aging of the patient population has also become a problem in recent years. On the other hand, there are about 8,000 patients in Japan with juvenile idiopathic arthritis (JIA), a form of RA suffered by children under 16 years of age.

Treatment Methods and Market Conditions

In drug therapy for RA, the introduction of biologics has made high remission rates a realistic treatment goal. Research in recent years suggests that the administration of biologics at the early onset stage is effective in inhibiting bone and joint damage.

The global market for these agents is forecast to reach U.S.56.7 billion* by 2024. The market continues to change, and the range of treatment options for RA is expanding. In 2013, biological DMARDs, a new class of oral drugs, were launched in the United States and Japan, and in 2014, a biosimilar was launched in Japan after previously being launched in Europe.

Changes in Rheumatoid Arthritis Drug Therapy



With the advent of biologics, the aim of therapy for rheumatoid arthritis has shifted to achieving and maintaining remission.

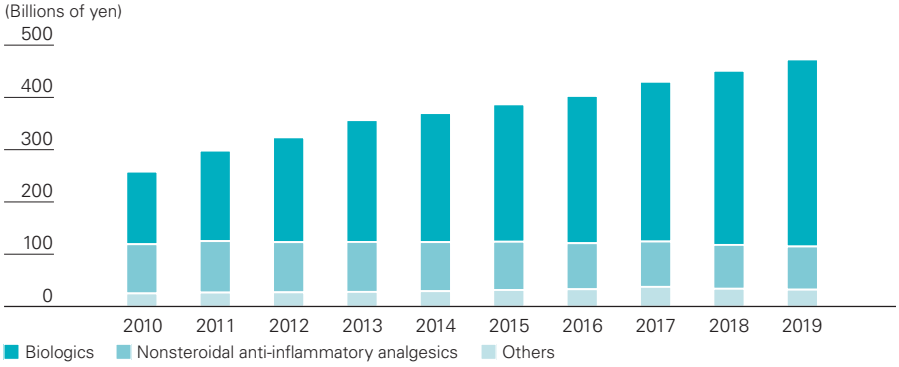
Systemic juvenile idiopathic arthritis (sJIA) accounts for 30 to 40 percent of all JIA cases, but steroids, the main treatment for sJIA, can cause growth impairment and other adverse reactions. Consequently, the approval and launch of Actemra for sJIA in April 2008 provided a significant advance in therapy.

* Source: Evaluate Pharma

Regulatory Trends

In November 2018, MHLW released an update of the Report of the Rheumatism and Allergy Countermeasure Committee, which was previously issued in 2005 and 2011. To maximize long-term quality of life of RA patients through appropriate treatment that controls disease activity, and to provide comprehensive support in daily life at workplaces and schools, and for life events such as pregnancy and childbirth, the report calls for (1) enhancement of medical service systems; (2) improvement of the patient environment, including consultation opportunities and access to information, and (3) promotion of research and development and other activities. In Europe, revised treatment recommendations in 2013 added Actemra and Abatacept to the biologic drugs recommended in first-line therapy, which were previously limited to anti-TNF agents. In 2015, a proposed update of clinical practice guidelines was announced at the American College of Rheumatology, with biologics including Actemra added as first-line therapy along with anti-TNF agents. Moreover, the updated European League Against Rheumatism (EULAR) recommendations that were announced in June 2016 state the superiority of interleukin-6 (IL-6) inhibitor therapy over other biologics in cases where MTX and other therapies cannot be used.

Rheumatoid Arthritis Market in Japan



Source: JPM 2010-2019
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The scope of the market is defined by Chugai.

Castleman's Disease

Castleman's disease is a lymphoproliferative disease characterized by symptoms such as systemic lymphadenopathy, fever and general fatigue, as well as various abnormal laboratory test values including anemia, hypergammaglobulinemia and hypoalbuminemia. It has been confirmed that these manifestations result from the excessive production of IL-6, one of the cytokines that causes inflammation. Castleman's disease is very rare, affecting approximately 1,500 people in Japan.

Large-Vessel Vasculitis

Large-vessel vasculitis belongs to a group of autoimmune diseases called vasculitis syndromes. It refers to vasculitis in the aorta and the major aortic branches to the limbs and head and neck, and includes Takayasu arteritis and giant cell arteritis (temporal arteritis).

Takayasu arteritis leads to inflammation of the aortic arch and its branch vessels. It affects women more than men, at a ratio of 9:1, and age of onset is between 20 and 50 years. It occurs most commonly in Asia, including Japan, and the Middle East. Initial symptoms are reduced head and cerebral blood flow related conditions, primarily dizziness, lightheadedness and headaches, as well as neck pain, chest pain and vascular pain along the limb arteries.

Giant cell arteritis is a granulomatous vasculitis occurring primarily in the aorta and aortic branches, mainly the temporal arteries. It also affects women more than men, at a ratio of 1.6:1, and the age of onset is 55 years or older. It occurs most commonly in Western countries and is rare in Japan. Common initial symptoms include headache, systemic conditions such as fever, and loss of vision.

Adult Still's Disease

Adult Still's disease is an autoimmune disease that typically presents with a high spiking fever, aching joints and a light-pink rash. Leukocytosis, increased C-reactive protein (CRP) levels, and elevated erythrocyte sedimentation rates are frequently observed in laboratory findings. Inflammation suppression with corticosteroids is the standard therapy, but until recently, no drug covered by the National Health Insurance was available for steroid-resistant patients.

Actemra (MRA/RG1569)

Humanized anti-human IL-6 receptor monoclonal antibody
(Generic name: tocilizumab)
Launch in Japan: June 2005

Basic Information

Actemra, created by Chugai and the first therapeutic antibody originating in Japan, blocks the activity of IL-6, a type of cytokine. It was launched in Japan in June 2005 as a treatment for Castleman's disease. In April 2008, Chugai obtained approval in Japan for the additional indications of RA, polyarticular juvenile idiopathic arthritis (pJIA) and sJIA. In May 2013, Chugai launched a new subcutaneous formulation that improves convenience for patients in addition to the existing drip infusion formulation. This subcutaneous formulation includes the first auto-injector in the Japanese RA market.

Actemra is marketed globally through Roche. In Europe, where the medicine is known as RoActemra, sales for the treatment of RA started in 2009. Chugai's marketing subsidiary co-promotes RoActemra with Roche in the United Kingdom, France and Germany. In the United States, Actemra obtained approval in January 2010 for the treatment of adult patients with moderate to severe active RA who have had an inadequate response to one or more anti-TNF agents, and obtained approval in October 2012 as a first-line biologic treatment. In Taiwan and South Korea, where Chugai has marketing rights, Actemra obtained approval in July 2011 and April 2012, respectively. Following its launch in Japan, the subcutaneous formulation obtained approval in the United States in October 2013 and in Europe in April 2014, and has been launched in both markets. RoActemra was also approved for early RA in Europe in September 2014.

Furthermore, Actemra obtained approval for the additional indication of treatment of sJIA in the United States in April 2011 and in Europe in August 2011. Actemra also received breakthrough therapy designation from the U.S. FDA in 2016 for giant cell arteritis. In Japan, it became possible in June 2017 to reduce the dose interval of Actemra from two weeks to one week in patients with an inadequate response to use of the subcutaneous formulation for RA. Actemra obtained approval in Japan for the additional indications of Takayasu arteritis and giant cell arteritis in August 2017, and In the United States, in November 2018 an autoinjector obtained approval as an additional formulation for the treatment of RA, giant cell arteritis, sJIA and pJIA. Actemra also obtained approval in the United States in August 2017 and in Europe in August 2018 for the additional indication of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome, and in Japan in March 2019 for the additional indication of cytokine release syndrome induced by tumor-specific T cell infusion therapy.

Review of 2019 Performance

Sales of Actemra in Japan increased ¥3.6 billion, or 9.4 percent, to ¥41.8 billion. The increase continued to be driven by the strong growth of the subcutaneous formulation after Chugai obtained approval for an additional dosage and administration with a shorter dose interval of the subcutaneous formulation for RA, and for the additional indications of Takayasu arteritis and giant cell arteritis. Sales of the subcutaneous formulation accounted for more than 60 percent of the total.

Sales of Actemra outside Japan (including exports to Roche) increased ¥7.7 billion, or 9.6 percent, to ¥88.3 billion. Roche's global sales increased 6.0 percent year on year with steady market penetration, including solid uptake of the subcutaneous formulation in all regions.

RG7845 Development project

BTK Inhibitor
Generic name: fenebrutinib

RG7845, is an oral, small molecule drug in-licensed from Roche that inhibits Bruton's tyrosine kinase (BTK). BTK is expressed in B cells and bone marrow, and is believed to be involved in arteritis and joint destruction associated with RA. RG7845 is expected to improve RA symptoms because it selectively and reversibly binds to the BTK molecule, thereby having an inhibiting effect on its activity. A phase I clinical trial started in June 2017.

RG7880 Development project

Human IL-22 fusion protein
Generic name: undetermined

RG7880 is a human IL-22 fusion protein in-licensed from Roche. It is expected to demonstrate efficacy in treating inflammatory bowel disease by directly promoting the regenerative and protective functions of IL-22 in epithelial tissue. A phase I clinical trial began in July 2019.

Osteoarthritis

The most common joint disease is osteoarthritis. It leads to degeneration of the cartilage in the joints and surrounding areas, causing joint pain and reduced mobility. The prevalence of this disease increases with age. Knee osteoarthritis is particularly common among women, and is reported to affect an estimated 30 percent of women in their fifties, 57 percent in their sixties, and 80 percent at 80 years of age or older.

Academic societies have been aggressively promoting research, diagnosis and treatment of osteoarthritis as an underlying cause of "locomotive syndrome," a term proposed in the field of orthopedics to designate the condition of individuals at high risk of suffering loss of motor function due to advanced age that leaves them requiring nursing care and bedridden.

The main drug therapies for osteoarthritis include non-steroidal anti-inflammatory analgesics, steroids and hyaluronic acid preparations, with intraarticular administration of hyaluronic acid preparations used as a treatment in the early and middle stages. Intraarticular administration of hyaluronic acid preparations has also demonstrated effectiveness in improving periarthritis of the shoulder and knee joint pain associated with rheumatoid arthritis.

Suvenyl

Agent for joint function improvement
(Generic name: sodium hyaluronate)
Launch in Japan: August 2000

Basic Information

Suvenyl, a drug that improves joint function through injection into the joint cavity, is a high molecular weight sodium hyaluronate drug that alleviates knee osteoarthritis, shoulder periarthritis and knee joint pain caused by RA. With physical and chemical properties close to that of hyaluronic acid found in the body, Suvenyl has been recognized for its superior performance, including its anti-inflammatory and analgesic effects.

Review of 2019 Performance

Sales decreased ¥0.6 billion, or 7.7 percent, to ¥7.2 billion, due to the impact from NHI drug price revisions and competing products. In China, phase III clinical studies are under way for knee osteoarthritis and shoulder periarthritis.

Renal Diseases

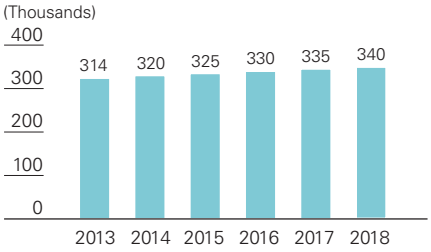
Renal Anemia

Complications of Renal Dysfunction

In dialysis patients and end-stage chronic kidney disease (CKD) patients, a key issue is treating the various complications of advanced renal dysfunction, such as renal anemia, secondary hyperparathyroidism, and abnormal calcium and phosphorus metabolism. Of these complications, renal anemia is one of the most frequent, occurring not only in renal disease patients undergoing dialysis but also in pre-dialysis CKD patients. Renal anemia is associated with reduced quality of life, and is also a factor in the progress of organ damage, including decreased cardiac function and renal function.

The importance of treatment and the appropriate management of renal anemia and chronic kidney disease - mineral and bone disorder (CKD-MBD) were indicated in the Guideline for Renal Anemia in Chronic Kidney Disease (2015) and the Clinical Practice Guidelines for the Management of CKD-MBD (2012) issued by the Japanese Society for Dialysis Therapy and in the Evidence-based Practice Guidelines for the Treatment of CKD (2018) issued by the Japanese Society of Nephrology.

Number of Dialysis Patients in Japan



Source: Overview of Regular Dialysis Treatment in Japan (as of December 31, 2018) by Statistical Survey Committee, The Japanese Society for Dialysis Therapy

Erythropoiesis-Stimulating Agent (ESA)

Erythropoietin (EPO) is a hemopoietic factor produced mainly in the kidneys. It stimulates erythrocyte production by binding to EPO receptors on erythroid progenitor cells in bone marrow. An erythropoiesis-stimulating agent (ESA) is effective in treating renal anemia caused primarily by the decline in EPO production due to CKD, and is thought to help improve quality of life. ESAs are currently used by approximately 80 percent of dialysis patients as well as by some pre-dialysis CKD patients with renal anemia. ESAs are thus an essential drug for the treatment of renal anemia.

Flat-Sum Reimbursement System for ESAs

Since the 2006 revisions of medical fees, ESAs have been included in medical fee points for hemodialysis (artificial kidney). The integrated fee points are reviewed with each revision of medical fees, and were reduced in 2018, which has led to intensified price competition for ESAs in the dialysis market.

Mircera

Long-acting erythropoiesis-stimulating agent
(Generic name: epoetin beta pegol)
Launch in Japan: July 2011

Basic Information

Mircera is a drug that raises the stability of epoetin beta in the bloodstream through pegylation. It is a new type of renal anemia treatment with the longest serum half-life among ESAs, enabling stable and sustained control of anemia. It stimulates erythropoiesis through a different interaction with the EPO receptor on burst-forming unit erythroid (BFU-E) cells in the bone marrow. Mircera was launched in Japan in July 2011 as a treatment for renal anemia. Outside Japan, Mircera obtained approval in Europe in 2007 and is currently sold in more than 100 countries, including the United States.

The serum half-life of Mircera is virtually the same for intravenous or subcutaneous administration, and the drug demonstrates efficacy in relieving the symptoms of anemia when administered at four-week intervals during the maintenance period. Consequently, it is expected to reduce the burden of hospital visits on the aging population of patients with pre-dialysis CKD and to contribute to better treatment adherence. Furthermore, as a dialysis-related treatment, Mircera is expected to reduce the burden on medical staff and improve medical safety by dramatically reducing administration frequency, and is one of the options for the treatment of renal anemia.

Review of 2019 Performance

Sales of Mircera decreased ¥0.9 billion, or 3.9 percent, to ¥22.2 billion. While the use of Mircera in pre-dialysis CKD patients expanded, sales decreased because of an NHI drug price revision as well as intensified price competition in the dialysis market after integrated fee points for hemodialysis (artificial kidney) were reduced due to the revision of medical fees.

Others

Oxarol

Agent for secondary hyperparathyroidism
(Generic name: maxacalcitol)
Launch in Japan: September 2000

Basic Information

Synthesized by Chugai, Oxarol is the first intravenous active vitamin D_3 derivative agent in Japan. It treats secondary hyperparathyroidism, a result of conditions such as impaired vitamin D activation associated with renal dysfunction, by acting directly on the parathyroid gland to control parathyroid hormone synthesis and secretion,

and by improving bone metabolic conditions. With its short serum half-life, Oxarol shows efficacy and enables treatment in patients who previously could not be treated adequately with oral vitamin D_3 derivatives due to the onset of hypercalcemia.

Review of 2019 Performance

Sales of Oxarol decreased ¥0.4 billion, or 5.5 percent, to ¥6.9 billion due to the impact of the NHI drug price revision, despite slower uptake of a generic product.

EOS789 Development project

EOS789 is an oral drug created by Chugai with a molecular weight of over 500 g/mol. A phase I clinical trial of EOS789 for hyperphosphatemia has been completed.

Neurology

Alzheimer's Disease

Alzheimer's disease (AD) is the most common form of dementia. Pathologically, it is a progressive neurodegenerative disease that causes neuron death in the brain and brain atrophy. It leads to a general and progressive loss of memory and other cognitive functions, which can interfere with daily life. While existing AD treatments have some effect in slowing the progression of dementia symptoms, they do not slow pathological progress and are unable to stop neuron death, and a treatment for the underlying cause does not yet exist. Consequently, unmet medical need is high, and there is strong demand for a more effective drug.

RG1450 Development project

Anti-amyloid-beta human monoclonal antibody
(Generic name: gantenerumab)

RG1450 targets aggregate amyloid beta, with a high binding affinity to plaques in particular. It is expected to reduce cognitive deterioration by removing amyloid beta in the brain. Global phase III multinational studies of RG1450 for AD began in June and July 2018.

RG6100 Development project

Anti-tau humanized monoclonal antibody
(Generic name: semorinemab)

RG6100 binds to tau proteins found in the extracellular space of the brain, and is expected to slow the deterioration of cognitive functions in AD by halting the propogation of tau via neurons. A phase I clinical trial for AD began in April 2019.

Neuromyelitis Optica Spectrum Disorder

Neuromyelitis optica spectrum disorder (NMOSD) is a neurological autoimmune disorder characterized by severe optic neuritis and transverse myelitis. The disease affects 0.3 to 4.4 in 100,000 people, and there are about 4,000 patients in Japan. It is an incurable disease that typically appears around the age of 40 years and affects women more than men, at a ratio of 9:1. Symptoms include loss of vision (in some cases progressing to blindness) and impairment of motor function and sensation. In some cases, the disease results in death. However, NMOSD is an orphan disease with high unmet medical need. It is believed to occur mainly when aquaporin-4 (AQP4) in the central nervous system is attacked by autoantibodies called anti-AQP4 antibodies. Formerly, the diagnostic criteria of neuromyelitis optica (NMO) accompanied by optic neuritis and myelitis, and NMOSD accompanied by either optic neuritis or myelitis were proposed. Recently, however, it was proposed to reorganize and unify the definitions of both disorders under the term NMOSD. This term is now widely used to refer to a broader spectrum of disease.

SA237 Development project

Anti-IL-6 receptor humanized monoclonal antibody
(Generic name: satralizumab)

SA237 is a next-generation therapeutic antibody that has shown success in blocking IL-6 receptors with a longer duration of action. Chugai created SA237 by applying its novel antibody engineering technology (Recycling Antibody engineering technology) that enables a single antibody molecule to block the target antigen repeatedly. As a result, a prolonged serum half-life has been demonstrated in clinical trials, which will make a lower dosing frequency possible. Because IL-6 promotes the production of the anti-AQP4 antibodies that are the primary cause of NMOSD, this drug is expected to improve (reduce recurrence of) the symptoms of these diseases as it inhibits the production of those antibodies by blocking the IL-6 signal. Two Chugai-sponsored global phase III studies in NMOSD patients achieved their primary endpoints. Chugai has licensed exclusive rights to Roche for the development and marketing of SA237 worldwide, with the exception of Japan and Taiwan. SA237 has been designated as an orphan drug in Japan, the United States and Europe, and was granted breakthrough therapy designation by the FDA in December 2018 for the treatment of NMOSD. Applications for approval of SA237 for of NMOSD were filed in the United States and Europe in August 2019 and in Japan in November 2019.

Huntington's Disease

Huntington's disease is a hereditary, intractable, progressive neurodegenerative disease that causes nerve cells in the brain to break down. Characterized mainly by involuntary movements (most commonly chorea), neuropsychiatric symptoms and dementia, this disease profoundly affects the lives of affected individuals. As the disease progresses, people with Huntington's disease may develop walking and swallowing difficulties, personality changes and loss of cognitive functions.

The prevalence of Huntington's disease varies by ethnicity and geographical location. It is reported to affect 4 to 8 out of every 100,000 people in Western countries, but in Japan it is a rare disease, affecting 0.7 out of every 100,000 people, about 1/10 the rate in Western Countries. Existing drug therapies treat chorea and other involuntary movements, as well as neuropsychiatric symptoms, but a treatment for the underlying cause does not yet exist.

RG6042 Development project

Antisense oligonucleotide (ASO) targeting human huntington messenger ribonucleic acid (*HTT* mRNA)
(Generic name: tominersen)

RG6042 is an ASO targeting human *HTT* mRNA, which is believed to be the cause of Huntington's disease. It has the potential to delay or slow disease progression in people with Huntington's disease by binding specifically to *HTT* mRNA, after which synthesis of the *HTT* protein is inhibited. A global phase III study began in March 2019. RG6042 has received orphan drug designation as a treatment for Huntington's disease in Japan, the United States and Europe, and was granted PRIME designation by the European Medicines Agency in 2018.

Spinal Muscular Atrophy

Spinal muscular atrophy (SMA) is a lower motor neuron disease characterized by amyotrophy and progressive muscle weakness caused by degeneration of anterior horn cells in the spinal cord. The estimated number of patients in Japan is reported to be around 1,000. The disease is caused by a defect in the SMN1 gene, and onset usually occurs in childhood. In severe cases it is fatal.

RG7916 Development project

SMN2 splicing modifier
(Generic name: risdiplam)

RG7916 is an SMN2 splicing modifier that increases generation of a protein derived from the SMN2 gene. This protein is nearly identical to the protein made from the SMN1 gene, which is not functional in SMA patients. RG7916 shows promise in improving neural and muscular function. Global phase II/III studies are under way, and RG7916 met its primary endpoint in the SUNFISH study in patients with Type 2 or 3 SMA and the FIREFISH study in patients with Type I SMA, respectively. RG7916 was granted PRIME designation by the European Medicines Agency in December 2018, and received orphan drug designation in Japan in March 2019.

Parkinson's Disease

Parkinson's disease is a progressive neurodegenerative disease characterized by aggregation of α-synuclein in the central nervous system and peripheral nervous system. A wide range of motor symptoms (tremor, muscle rigidity, akinesia, impairment of postural reflexes, etc.) and non-motor symptoms (sleep disorders, autonomic dysfunction, cognitive and mental disorders, etc.) occur. The estimated number of patients in Japan is 200,000. A progressive disease seen mainly in people age 50 or older, it can lead to becoming bedridden as the condition worsens.

RG7935 Development project

Anti-α-synuclein monoclonal antibody
(Generic name: prasinezumab)

RG7935 is a monoclonal antibody that targets α-synuclein. It slows the expansion of nerve cell death by inhibiting the cell-to-cell propagation of aggregated forms of neurotoxic α-synuclein, and is expected to reduce and delay progression of the disease. In a phase I clinical trial that began in 2018, RG7935 demonstrated good tolerability, and there were no significant racial differences in pharmacokinetics.

Autism Spectrum Disorder

Autism spectrum disorder (ASD) is a lifelong neurodevelopmental disorder presenting impairments of social interaction and communication and repetitive behaviors (restricted interests), and is thought to be mainly caused by a genetic factor. ASD is estimated to affect about 1 percent of the population.

RG7314 Development project

Vasopressin 1a receptor antagonist
(Generic name: balovaptan)

RG7314 is expected to improve social interaction and communication in people with ASD by suppressing the activity of the vasopressin 1a receptor in the brain. A phase I clinical trial of RG7314 for ASD began in May 2019.

Others

GYM329/RG6237 Development project

Anti-latent myostatin sweeping antibody

GYM329, created by Chugai, is a next-generation antibody that applies Chugai's proprietary antibody engineering technologies, including its recycling antibody and sweeping antibody technologies. Latent myostatin is an inactive form that is mainly secreted from muscle cells, and is activated by BMP-1 and other protein degrading enzymes. Activated myostatin inhibits muscle growth and hypertrophy, and by inhibiting myostatin, GYM329/RG6237 is expected to improve the various conditions associated with muscle atrophy and loss of muscular strength. Currently under development for neuromuscular disease, this antibody began a phase I clinical trial in October 2018. Chugai out-licensed GYM329 to Roche at an early stage before the start of clinical testing in order to accelerate global development by taking advantage of Roche's experience and expertise.

RG7906 Development project

RG7906 is a small molecule drug in development for psychiatric disorders. A phase I clinical trial began in January 2019.

Other Diseases

Hemophilia

Hemophilia is a disease that leads to bleeding in the joints, muscles and other areas in the body due to a congenital deficiency or abnormal function of blood coagulation factors. A low level or absence of blood coagulation factor VIII is known as hemophilia A, while a low level or absence of blood coagulation factor IX is referred to as hemophilia B. Treatment of hemophilia A is centered on replacement therapy to supplement factor VIII. However, since it involves intravenous injections two to three times a week, treatment is a significant burden, particularly on children. Moreover, patients must be monitored for the development of autoantibodies, called inhibitors, to the supplemented factor. Patients with inhibitors are treated by means such as bypass therapy or immune tolerance therapy, but these therapies are limited in terms of convenience and the stability of their effects. A more useful treatment method is therefore needed.

Hemlibra (ACE910/RG6013)

Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody
(Generic name: emicizumab)
Launched in Japan: May 2018

Hemlibra is a bispecific antibody that employs Chugai's innovative antibody engineering technologies. Like factor VIII, which is low or missing in hemophilia A, Hemlibra simultaneously binds to factor IXa and factor X, stimulating the activation of factor X by activated factor IX and promoting normal blood coagulation for hemostasis. Unaffected by inhibitors, Hemlibra can prevent bleeding with subcutaneous injections once a week, once every two weeks, or once every four weeks, and is promising as a drug that can change the existing system of treatment. Another key feature is that Chugai's proprietary technology ART-Ig is applied to Hemlibra, enabling industrial production of bispecific antibodies.

Chugai concluded an out-licensing agreement with Roche in July 2014 and in May 2017 entered into a license agreement with JW Pharmaceutical Corporation for the exclusive marketing rights in South Korea. The drug received breakthrough therapy designation from the U.S. FDA in September 2015 for its potential to prevent bleeding in hemophilia patients with inhibitors, and in April 2018 for its potential to prevent bleeding in patients without inhibitors. In the United States, Hemlibra received priority review designation in August 2017, and in November 2017 obtained approval for routine prophylaxis with once-weekly subcutaneous administration in adult and pediatric patients with hemophilia A with factor VIII inhibitors. Hemlibra was also granted accelerated assessment in Europe, and received regulatory approval from the European Commission in February 2018. In Japan, it obtained approval in March 2018 and was launched in May 2018. It also obtained approval in Taiwan in December 2018 and was launched there in November 2019.

Applications were filed in the United States, Europe and Japan in April 2018, and in Taiwan in January 2019, for routine prophylaxis of bleeding episodes, as well as for additional dosage and administration as a biweekly or four-weekly treatment, for people with hemophilia A without inhibitors. In the United States, Hemlibra was granted priority review status in June 2018, and in October 2018, it obtained approval for prophylactic treatment by subcutaneous administration once weekly, every two weeks, or every four weeks in adults or children with hemophilia A without inhibitors, as well as additional dosing options of every two weeks or every four weeks in adults and children with hemophilia A with inhibitors. Hemlibra also obtained approval in Japan in December 2018, and in the EU in March 2019.

Review of 2019 Performance

Sales of Hemlibra increased ¥22.2 billion, or 740 percent, year on year to ¥25.2 billion. Hemlibra has a different mode of action than factor VIII and a long half-life, supporting a steady increase in uptake for patients without inhibitors. In particular, switches to Hemlibra took place early on in pediatric patients with difficult venous access, surpassing expectations.

NXT007 Development project

Anti-coagulation factor IXa/X bispecific antibody

NXT007, created by Chugai, is a bispecific antibody that stimulates blood coagulation using the same mode of action as Hemlibra. One difference from Hemlibra is the application of Chugai's antibody engineering technologies FAST-Ig, which enhances large-scale production of the bispecific antibody and ACT-Fc, which is expected to improve antibody pharmacokinetics. NXT007 is expected to achieve the levels of hemostasis found in healthy adults and children, and is being developed to improve convenience, including the administration device. A phase I/II clinical trial for hemophilia A began in August 2019.

Influenza

Influenza is an acute infectious disease characterized by the rapid onset of high fever (38 degrees centigrade or higher) and severe systemic symptoms. It is highly infectious, and epidemics can develop quickly. In some cases, secondary infections can lead to very serious illness and death. Influenza is classified into types A, B and C based on differences in the antigenicity of the underlying virus. Types A and B can infect humans and cause major outbreaks.

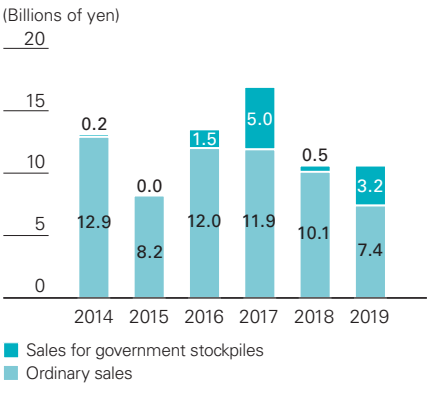
Tamiflu

Anti-influenza agent
(Generic name: oseltamivir)
Launch in Japan: February 2001

Basic Information

Tamiflu is an oral anti-influenza agent that is effective against both type A and type B infections. It inhibits viral replication by blocking the action of neuraminidase, an enzyme essential for the multiplication of the influenza virus. Launched in capsule form in February 2001 and dry syrup form in July 2002, dosages are available for patients one year of age and older. From March 2007, restrictions on the use of Tamiflu in teenage patients with seasonal influenza were in force in Japan. The measure was introduced as a safety precaution following several reports of abnormal behavior in influenza patients who had taken Tamiflu. In May 2018, the Subcommittee on Drug Safety of the Ministry of Health, Labour and Welfare confirmed that abnormal behavior occurs

Tamiflu Sales



regardless of whether anti-influenza drugs have been given, and in July 2018, the same subcommittee decided that the restrictions should be removed. Accordingly, the package insert was revised and restrictions on the use of Tamiflu in teenage patients were removed in August 2018.

The shelf life of Tamiflu capsules was extended to 10 years from seven years for capsules manufactured after July 2013, and the shelf life of Tamiflu dry syrup was extended to 10 years starting with the portion shipped in 2015. In March 2017, Chugai obtained approval for additional dosage and administration of Tamiflu dry syrup for neonates and infants younger than 12 months.

Review of 2019 Performance

Ordinary sales of Tamiflu decreased ¥2.7 billion, or 26.7 percent, to ¥7.4 billion, while sales for government stockpiles were ¥3.2 billion. The decrease in sales in 2019 reflected the market entry of (baloxavir marboxil), which has a novel mode of action, and a generic version of Tamiflu. The market share of Tamiflu recovered in December 2019 because relevant scientific societies recommended restricting the use of (baloxavir marboxil) in children under 12 years of age due to concerns about drug-resistant viruses.

Others

CellCept

Immunosuppressant
(Generic name: mycophenolate mofetil)
Launch in Japan: November 1999

Sales of CellCept increased ¥0.3 billion, or 3.3 percent, to ¥9.3 billion. CellCept is used to treat refractory rejection after kidney transplants and to prevent rejection after kidney, heart, liver, lung and pancreas transplants. The need for transplantation medication has been rising in Japan, driven by advances in transplantation therapy. In May 2016, CellCept received approval for the indication of lupus nephritis, a refractory disease associated with the autoimmune disease systemic lupus erythematosus.

Atopic Dermatitis

A type of allergic disorder, atopic dermatitis is a chronic skin disease characterized by an itchy rash that alternately improves and worsens. Scratching the affected area exacerbates the skin symptoms and makes the itching worse, leading to an itch-scratch cycle. The basic treatment is drug therapy using topical steroid preparations and/or immunosuppressants to control the inflammation and a skin care regimen to prevent the inflammation from recurring.

Prurigo Nodularis

Prurigo nodularis is a chronic skin disorder that causes thick papules or nodules accompanied by intensive itching. Patients with prurigo nodularis worry that the severe itching will interfere with their daily lives. The cause of prurigo nodularis is not yet fully understood, and control of the symptoms is difficult, and thus an effective treatment is needed.

CIM331 Development project

Anti-IL-31 receptor A humanized monoclonal antibody
(Generic name: nemolizumab)

Nemolizumab (CIM331) is an anti-IL-31 receptor A humanized monoclonal antibody originating from Chugai. The drug is expected to improve itching and skin inflammation in atopic dermatitis by blocking IL-31, a proinflammatory cytokine, from binding to its receptor.

In July 2016, Chugai entered into a global license agreement granting Galderma S.A. of Switzerland exclusive rights for the development and marketing of nemolizumab worldwide, with the exception of Japan and Taiwan. In September 2016, Chugai entered into a license agreement granting Maruho Co., Ltd. the rights for the development and marketing of nemolizumab in the skin disease area for the Japanese market. In the development of CIM331 for atopic dermatitis, in 2019 Maruho achieved the primary endpoints in a phase III clinical study and Galderma started a global phase III study. In addition, CIM331 was granted breakthrough therapy designation by the FDA for pruritus associated with prurigo nodularis. Galderma plans to start a phase III clinical study for prurigo nodularis in 2020.

Paroxysmal Nocturnal Hemoglobinuria

Paroxysmal nocturnal hemoglobinuria (PNH) is a disorder that leads to complications such as thrombosis and CKD, in addition to anemia and dark brown urine caused by hemolysis as well as infections and bleeding tendency associated with a decrease in white blood cells and platelets. It is an acquired genetic disorder that affects hematopoietic stem cells, causing the creation of red blood cells that have no complement resistance, and hemolysis occurs when complements are activated in vivo. An estimated 430 patients suffer from PNH in Japan (according to a fiscal 1998 epidemiological survey by the Ministry of Health, Labour and Welfare), and the disease reportedly affects approximately 5,000 people globally. Although this number is small, PNH is a progressive disease with a high risk of mortality.

SKY59/RG6107 Development project

Anti-C5 recycling antibody
(Generic name: crovalimab)

SKY59 is a recycling antibody discovered by Chugai that inhibits the C5 complement component.

The onset of a number of diseases is reported to be caused by complement activation. SKY59 is expected to inhibit cleavage of C5 to C5a and C5b, thus suppressing complement activation and improving disease conditions. In PNH, SKY59 may have a suppressive effect on hemolysis by preventing the destruction of red blood cells. Application of multiple Chugai proprietary antibody engineering technologies resulted in a prolonged half-life (in preclinical trials), and the antibody is being developed as a subcutaneous self-injection. Due to the severity of the disease, regular administration is necessary, but making self-injection possible is expected to lessen the burden on patients by reducing the frequency of hospital visits. Chugai is co-developing SKY59 with Roche, and a global phase I/II study began in November 2016. In September 2017, SKY59 received orphan drug designation in the United States for PNH.

wAMD/DME

Wet age-related macular degeneration (wAMD) is a disease in which abnormal blood vessel growth (choroidal neovascularization) caused by age-related accumulation of waste products extends into the space under the retinal pigment epithelium (RPE) or between the retina and the RPE, leading to retinal tissue damage. If the choroidal neovascularization and the associated effusion progress into the fovea centralis, which governs vision, it may lead to deterioration of visual acuity along with the symptoms of image distortion, vision loss and central scotoma. Left untreated, wAMD may lead to irreversible visual impairment.

Diabetic macular edema (DME) is a retinal disease associated with diabetic retinopathy. In diabetes, consistently high blood sugar causes blockage of retinal capillaries, ischemic change, and edema induced by vascular hyperpermeability. Blurred vision occurs when swelling extends to the central part of the macula, which governs vision. Left untreated, DME may lead to irreversible visual impairment.

RG7716 Development project

Anti-VEGF/Ang-2 bispecific antibody
(Generic name: faricimab)

RG7716, which Chugai in-licensed from Roche, is the first bispecific antibody for ophthalmology diseases. It selectively binds to vascular endothelial growth factor A (VEGF-A), a key mediator of angiogenesis and vascular permeability, and angiopoietin-2 (Ang-2, an antagonist of Ang-1, which contributes to the stability of mature vessels), a destabilizer of chorioretinal vessels and inducer of vascular permeability. By simultaneously neutralizing intraocular VEGF-A and Ang-2 in wAMD and DME patients, RG7716 is expected to demonstrate better treatment outcomes and a more sustained effect than the anti-VEGF drugs that are the current standard of care. Global phase III studies for the potential treatment of DME and wAMD began in September 2018 and February 2019, respectively.

Endometriosis

Affecting one out of 10 women in their twenties to forties, endometriosis is the repeated proliferation and shedding of endometrial tissue outside the uterus, accompanied by dysmenorrhea and chronic lower abdominal pain, and is a cause of infertility. The disease can interfere with daily life, including absences from work or school, as sufferers find it difficult to do more than lie still when symptoms are severe. The only existing medications are hormonal agents. Moreover, if the pain cannot be controlled by drugs, the only treatment is surgical removal, and many patients experience a recurrence several years after surgery, making this a disease with a high level of unmet medical need.

AMY109 Development project

AMY109 is the third therapeutic antibody to apply the recycling antibody engineering technology created by Chugai. Its approach differs from hormone therapy, which is the standard treatment for endometriosis, and its anti-inflammatory action is expected to provide new value to patients. A phase I clinical trial started in February 2018.

Type 2 Diabetes

Type 2 diabetes is an illness in which genetic predisposition and lifestyle cause impaired insulin secretion and resistance to insulin action, resulting in high plasma glucose concentration. There are no symptoms in the early stages, but if the condition is left untreated, the risk of cardiovascular diseases such as stroke and myocardial infarction increases. The disease can also cause complications such as retinopathy, nephropathy and neuropathy, which lead to blindness, dialysis and leg amputation, respectively, significantly reducing quality of life. According to the International Diabetes Federation, the number of people with diabetes worldwide, including prediabetes, is 463 million in 2019, and is projected to increase to 700 million in 2045. Treatment of this condition is thus a worldwide issue.

OWL833 Development project

OWL833 is an oral non-peptidic GLP-1 receptor agonist discovered by Chugai. GLP-1 agonists have potent hypoglycemic action and induce weight loss, but convenience for patients has been an issue because they are conventionally administered in a subcutaneous injection. Because OWL833 is orally bioavailable, it is easier for patients to take, and is thus expected to contribute to the treatment of diabetes, including through improvement of drug adherence. In September 2018, Chugai licensed the worldwide development and commercialization rights for OWL833 to Eli Lilly and Company. A phase I clinical study by Eli Lilly is under way.

8-Year Financial Summary

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/Years ended December 31

International Financial Reporting Standards (IFRS)	2019		2018		2017		2016	
	IFRS	Core[1]	IFRS	Core	IFRS	Core	IFRS	Core
Results								
Revenues[2]	686.2		579.8		534.2		491.8	
Sales	588.9		527.8		499.3		472.7	
Royalties and other operating income	97.3		51.9		34.9		19.1	
Cost of sales	(266.1)	(265.1)	(262.8)	(261.9)	(254.2)	(252.9)	(247.9)	(246.7)
Operating expenses	(209.5)	(196.2)	(192.6)	(187.6)	(181.1)	(178.1)	(167.0)	(164.5)
Marketing and distribution	(77.2)	(73.5)	(73.7)	(73.7)	(72.8)	(72.8)	(69.8)	(69.8)
Research and development	(107.9)	(102.1)	(99.2)	(94.2)	(92.9)	(88.9)	(85.0)	(82.6)
General and administration	(24.4)	(20.6)	(19.7)	(19.7)	(15.3)	(16.3)	(12.2)	(12.1)
Operating profit	210.6	224.9	124.3	130.3	98.9	103.2	76.9	80.6
Profit before taxes	207.9	222.2	121.4	127.5	97.0	101.3	74.4	78.1
Net income	157.6	167.6	93.1	97.3	73.5	76.7	54.4	56.8
Attributable to Chugai shareholders	157.6	167.6	92.5	96.7	72.7	75.9	53.6	56.1
Core EPS (Yen)	—	305.80	—	176.42	—	138.68	—	102.50
Cash dividends per share (Yen)	140		86		62		52	
Core payout ratio	—	45.8%	—	48.7%	—	44.7%	—	50.7%
Financial Position								
Net operating assets	547.0		505.3		440.2		431.1	
Total assets	1,058.9		919.5		852.5		806.3	
Total liabilities	(204.9)		(163.0)		(159.6)		(159.8)	
Total net assets	854.0		756.5		692.9		646.5	
Investments in property, plant and equipment	54.0		71.8		34.3		19.4	
Depreciation	17.8		14.6		14.5		14.8	
Main Indicators								
Cost to sales ratio	45.2%	45.0%	49.8%	49.6%	50.9%	50.7%	52.4%	52.2%
Ratio of operating profit to revenues	30.7%	32.8%	21.4%	22.5%	18.5%	19.3%	15.6%	16.4%
Ratio of research and development expenditures to revenues	15.7%	14.9%	17.1%	16.2%	17.4%	16.6%	17.3%	16.8%
Core return on invested capital (Core ROIC)[3,4]	30.1%	31.9%	20.3%	21.2%	17.3%	18.1%	—	14.6%
Ratio of net income to equity attributable to Chugai shareholders (ROE)[5]	19.6%	—	12.8%	—	10.9%	—	8.4%	—
Ratio of profit before taxes to total assets (ROA)[6]	21.0%	—	13.7%	—	11.7%	—	9.3%	—
Equity per share attributable to Chugai shareholders (BPS) (Yen)	1,559.72	—	1,381.26	—	1,265.46	—	1,181.67	—
Ratio of equity attributable to Chugai shareholders	80.6%	—	82.2%	—	81.2%	—	80.1%	—
Number of employees	7,394		7,432		7,372		7,245	

1. Core basis results are the results after adjusting non-Core items to IFRS basis results. Core basis results are used by Chugai as internal performance indicators, for representing recurring profit trends both internally and externally, and as indices for establishing profit distributions such as returns to shareholders.
2. Revenues do not include consumption tax.
3. Core ROIC = Core net operating profit after taxes / Net operating assets (Core ROIC is calculated by using Core income taxes)
4. ROIC = Net operating profit after taxes / Net operating assets (Net operating profit after taxes = Operating profit – Income taxes)
5. Ratio of net income to equity attributable to Chugai shareholders (ROE) = Net income attributable to Chugai shareholders / Capital and reserves attributable to Chugai shareholders (average of beginning and end of fiscal year)
6. Ratio of profit before taxes to total assets (ROA) = Profit before taxes / Total assets (average of beginning and end of fiscal year)

(Billions of yen)

2015		2014		2013		2012	
IFRS	Core	IFRS	Core	IFRS	Core	IFRS	Core
498.8		461.1		423.7		386.6	
468.4		436.9		401.3		375.2	
30.4		24.2		22.4		11.3	
(240.2)	(238.9)	(218.1)	(217.0)	(187.0)	(186.1)	(168.2)	(167.3)
(171.8)	(169.3)	(167.2)	(166.8)	(157.9)	(157.7)	(143.7)	(143.7)
(74.8)	(74.7)	(71.7)	(71.7)	(71.6)	(71.5)	(67.9)	(67.9)
(83.8)	(81.9)	(80.8)	(80.6)	(74.3)	(74.1)	(66.6)	(66.6)
(13.2)	(12.8)	(14.6)	(14.6)	(12.1)	(12.1)	(9.2)	(9.2)
86.8	90.7	75.9	77.3	78.7	79.9	74.7	75.6
87.3	91.2	76.2	77.6	76.9	78.1	72.7	73.6
62.4	64.9	52.1	53.0	51.9	52.6	46.8	47.4
61.1	63.7	51.0	51.9	50.9	51.6	46.1	46.6
—	116.42	—	95.04	—	94.69	—	85.64
58		48		45		40	
—	49.8%	—	50.5%	—	47.5%	—	46.7%
380.4		357.7		325.2		307.9	
787.4		739.5		697.2		645.3	
(160.1)		(141.8)		(124.0)		(116.2)	
627.3		597.8		573.2		529.2	
28.7		16.3		13.0		14.2	
14.0		13.7		13.5		13.3	
51.3%	51.0%	49.9%	49.7%	46.6%	46.4%	44.8%	44.6%
17.4%	18.2%	16.5%	16.8%	18.6%	18.9%	19.3%	19.6%
16.8%	16.4%	17.5%	17.5%	17.5%	17.5%	17.2%	17.2%
—	—	—	—	—	—	—	—
10.0%	—	8.7%	—	9.3%	—	9.0%	—
11.4%	—	10.6%	—	11.5%	—	11.8%	—
1,146.17	—	1,092.90	—	1,049.47	—	970.08	—
79.5%	—	80.6%	—	82.0%	—	81.8%	—
7,169		7,023		6,872		6,836	

(Billions of yen)

Japanese GAAP	2012
Results	
Revenues[1]	391.2
Sales	375.2
Other operating revenues	16.0
Cost of sales	167.7
Selling, general and administrative expenses	147.1
Marketing and distribution expenses	92.0
Research and development expenditures	55.1
Operating income	76.4
Net income (loss)	48.2
Net income per share (basic) (Yen)	88.58
Net income per share (diluted) (Yen)	88.54
Cash dividends per share (Yen)	40
Payout ratio	45.2%
Financial Position	
Total assets	587.7
Total net assets[2]	490.1
Capital investments	14.2
Depreciation and amortization	15.3
Main Indicators	
Cost to sales ratio	44.7%
Ratio of operating income to revenues	19.5%
Ratio of research and development expenditures to revenues	14.1%
Return on equity[3]	10.2%
Return on assets[4]	8.6%
Net assets per share (Yen)	896.02
Shareholders' equity to total assets	83.0%
Number of employees	6,836

1. Revenues do not include consumption tax.
2. Net assets include minority interests.
3. Return on equity = Net income / Shareholders' equity (average of beginning and end of fiscal year)
4. Return on assets = Net income / Total assets (average of beginning and end of fiscal year)

Management's Discussion and Analysis

Management Policy

Chugai's Mission is to dedicate itself to adding value by creating and delivering innovative products and services for the medical community and human health around the world based on its strategic alliance with Roche. Aiming at becoming a top innovator for advanced and sustainable patient-centric healthcare, we set up our fundamental management policy of growing together with society. To achieve our goal, we have leveraged our close relationship with Roche and built systems capable of efficiently and continuously developing and launching new drugs. Refining our strengths has also contributed to achieving innovation that has enabled us to create state-of-the-art drug discovery technology and maintain the top share of the domestic oncology area.

In mid-term business plan IBI 21, we aim to accelerate the growth of society and the Company through innovation focusing on the creation of innovative new drugs, with Core EPS CAGR over three years as a quantitative target. In light of favorable performance in the initial year of IBI 21, including strong sales of in-house global products, Chugai revised its target of Core EPS CAGR from the high single digits (based on constant exchange rates) to around 30 percent (based on constant exchange rates and assuming no stock split). In addition, after taking into account future investment opportunities and funding plans, Chugai changed its dividend policy from a target Core EPS payout ratio of 50 percent on average to 45 percent on average to maintain its policy of a stable allocation of profit.

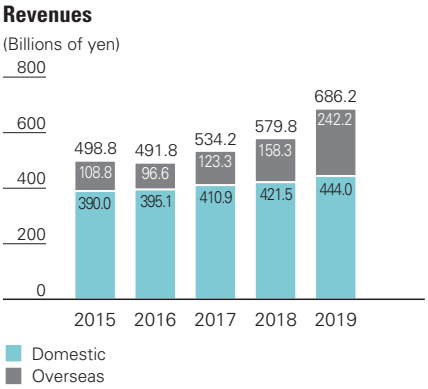
Overview of Results

Revenues

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Revenues	534.2	579.8	**686.2**	+18.4%
Sales	499.3	527.8	**588.9**	+11.6%
Royalties and other operating income (ROOI)	34.9	51.9	**97.3**	+87.5%

- Revenues exceeded the level of the previous year because of strong sales in Japan of mainstay products and new products Hemlibra and Tecentriq, and increases in ROOI and exports to Roche.
- ROOI increased year on year due to a significant increase in royalty and profit-sharing income associated with Hemlibra.
- Overseas revenues increased steadily with the growth of global products from Chugai research.

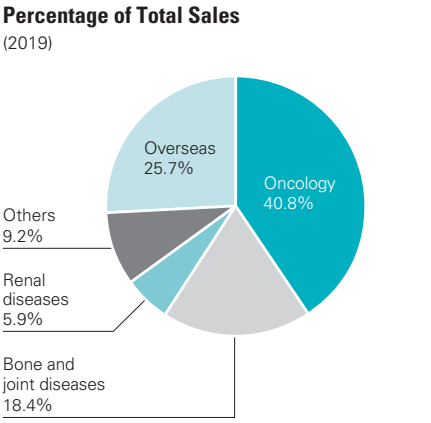


Domestic Sales by Area

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Domestic sales	405.3	399.9	**437.6**	+9.4%
Oncology	225.9	225.7	**240.5**	+6.6%
Bone and joint diseases	93.3	100.5	**108.4**	+7.9%
Renal diseases	39.3	36.3	**34.6**	-4.7%
Others	46.8	37.5	**54.1**	+44.3%

- Domestic sales increased 9.4 percent year on year in 2019, led by firm sales of new and mainstay products in the oncology area, mainstay products in the bone and joint diseases area, and new products in other areas.
- We maintained our number-one share in the mainstay domestic oncology market (16.4 percent)*. Strong sales of mainstay product Perjeta and new product Tecentriq more than offset a decrease in sales of Rituxan and other products mainly due to the impact of biosimilars and generics.
- In the bone and joint diseases area, sales of mainstay products such as Actemra and Edirol were firm.
- In the others area, sales increased due to firm sales of new product Hemlibra.



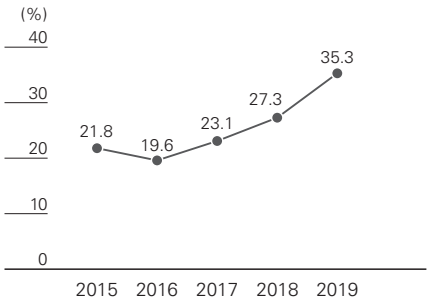
Overseas Sales

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Overseas sales	94.0	127.9	**151.3**	+18.3%
Actemra (exports to Roche)	59.4	78.7	**86.5**	+9.9%
Alecensa (exports to Roche)	13.9	28.9	**44.6**	+54.3%

- Overseas sales increased year on year. Contributing factors included solid sales of Actemra due to increased prescriptions for giant cell arteritis and continued market penetration of the subcutaneous formulation, and increased exports of Alecensa to Roche due to significant penetration of the first-line market in Europe.

Overseas Sales Ratio



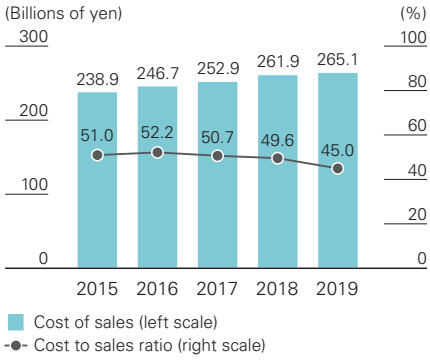
Cost of Sales (Core basis)

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Cost of sales	(252.9)	(261.9)	**(265.1)**	+1.2%
Cost to sales ratio	50.7%	49.6%	**45.0%**	-4.6% pts

- The cost to sales ratio decreased year on year in 2019, mainly because Chugai products, which have a lower cost to sales ratio than products in-licensed from Roche, accounted for a higher percentage of the sales mix.

Cost of Sales/Cost to Sales Ratio



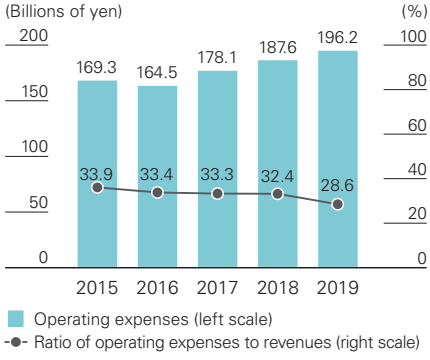
Operating Expenses (Marketing and Distribution Expenses, R&D Expenditures and General and Administration Expenses) (Core Basis)

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Total operating expenses	(178.1)	(187.6)	**(196.2)**	+4.6%
Marketing and distribution expenses	(72.8)	(73.7)	**(73.5)**	-0.3%
R&D expenditures	(88.9)	(94.2)	**(102.1)**	+8.4%
General and administration expenses	(16.3)	(19.7)	**(20.6)**	+4.6%

- The year-on-year growth rate for total operating expenses in 2019 was significantly lower than the growth rate for revenues.
- R&D expenditures increased year on year due to factors including the progress of development projects.
- General and administration expenses increased year on year due mainly to an increase in the enterprise tax (pro forma standard taxation).

Operating Expenses/ Ratio of Operating Expenses to Revenues



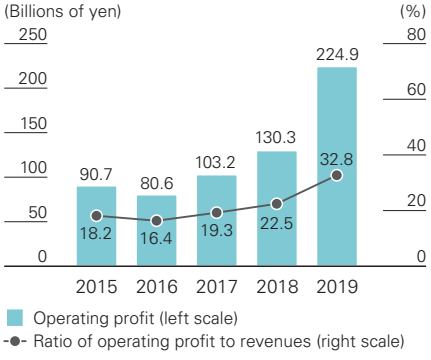
Operating Profit and Net Income (Core Basis)

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Operating profit	103.2	130.3	**224.9**	+72.6%
Ratio of operating profit to revenues	19.3%	22.5%	**32.8%**	+10.3% pts
Net income	76.7	97.3	**167.6**	+72.3%
Net income attributable to Chugai shareholders	75.9	96.7	**167.6**	+73.3%

- Operating profit and net income in 2019 increased substantially year on year with an increase in ROOI due to Hemlibra and lower cost of sales due to the higher percentage of Chugai products in the sales mix, which increased the ratio of operating profit to revenues significantly.

Operating Profit/ Ratio of Operating Profit to Revenues



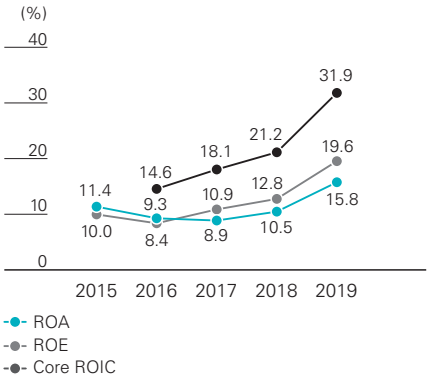
Profitability Indicators

	2017	2018	2019	2018/2019 Change
Gross profit to revenues (%) (Core)	52.7	54.8	**61.4**	+6.6% pts
Operating profit to revenues (%) (Core)	19.3	22.5	**32.8**	+10.3% pts
Ratio of profit before taxes to total assets (ROA) (%) (IFRS)	8.9	10.5	**15.8**	+5.3% pts
Ratio of net income attributable to Chugai shareholders (ROE) (%) (IFRS)	10.9	12.8	**19.6**	+6.8% pts
Core return on invested capital (Core ROIC) (%)	18.1	21.2	**31.9**	+10.7% pts

1. ROA = Net income attributable to Chugai shareholders / Total assets
2. ROE = Net income attributable to Chugai shareholders / Capital and reserves attributable to Chugai shareholders
3. Core ROIC = Core net operating profit after taxes / Net operating assets (Core ROIC is calculated by using Core income taxes)

- While net operating assets (NOA) increased significantly due to aggressive strategic investments such as Chugai Life Science Park Yokohama, Core ROIC rose steadily due to growth in Core net operating profit after taxes.

ROA/ROE/Core ROIC



Financial Position

Assets, Liabilities and Net Assets

In conjunction with its decision to apply IFRS from 2013, Chugai has reorganized the consolidated balance sheets and discloses assets and liabilities including net operating assets for use as internal performance indicators (Roche discloses the same indicators). No items have been excluded from the IFRS balance sheet, as the Core basis results concept only applies to the income statement.

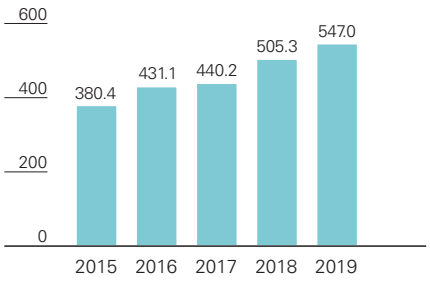
Net Operating Assets (NOA)

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Net working capital	250.7	235.1	**237.2**	+0.9%
Long-term net operating assets	189.5	270.1	**309.8**	+14.7%
Net operating assets (NOA)	440.2	505.3	**547.0**	+8.3%

- Long-term net operating assets increased from the end of the previous year due to an increase in property, plant and equipment resulting mainly from investment in Chugai Life Science Park Yokohama and an increase in right-of-use assets due to the application of IFRS 16 "Leases."
- NOA as of December 31, 2019 increased from the end of the previous year due to investments for the future.

Net Operating Assets



NOA are the total of net working capital and long-term net operating assets. Net working capital is composed of accounts receivable, inventories, accounts payable and other payables and receivables. Long-term net operating assets are composed of property, plant and equipment, intangible assets, and other items.

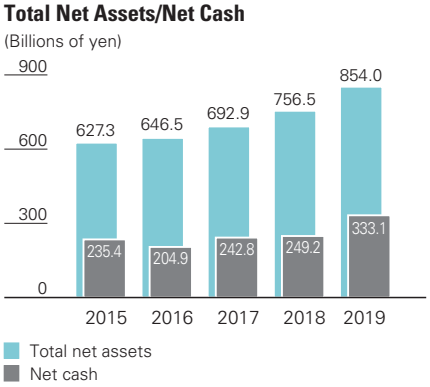
Total Net Assets

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Net operating assets (NOA)	440.2	505.3	**547.0**	+8.3%
Net cash	242.8	249.2	**333.1**	+33.7%
Other non-operating assets – net	9.9	2.1	**(26.1)**	—
Total net assets	692.9	756.5	**854.0**	+12.9%

- Total net assets at December 31, 2019 increased from a year earlier due to factors including an increase in property plant and equipment resulting from investment in Chugai Life Science Park Yokohama and an increase in net cash.
- Our ability to generate cash is continuously increasing, and net cash exceeded ¥300 billion as of December 31, 2019. In anticipation of an increasingly challenging business environment, we will consider and implement flexible and focused strategic investments to generate value in our businesses through the creation of new digital and life science technologies.

Total Net Assets/Net Cash



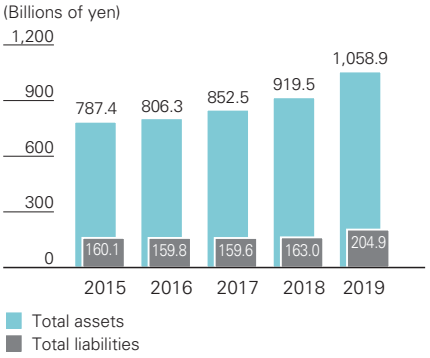
Total Assets and Total Liabilities

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Total assets	852.5	919.5	**1,058.9**	+15.2%
Total liabilities	(159.6)	(163.0)	**(204.9)**	+25.7%

- The Group began applying IFRS 16 "Leases" from 2019. As a result, leased assets totaling ¥15.2 billion, including right-of-use assets and lease receivables, and lease liabilities totaling ¥14.6 billion were recognized on the balance sheet as of January 1, 2019.

Total Assets/Total Liabilities

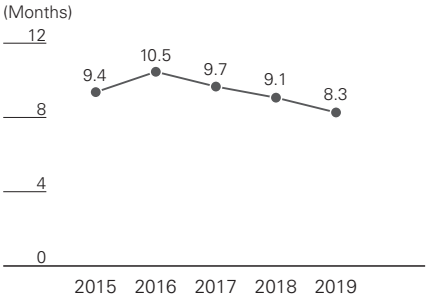


Financial Position Indicators

	2017	2018	2019	2018/2019 Change
Ratio of equity attributable to Chugai shareholders (%)	81.2	82.2	**80.6**	-1.6% pts
Cash conversion cycle (months)	9.7	9.1	**8.3**	-0.8 months
Net cash turnover period (months)	5.5	5.2	**5.8**	+0.6 months
Current ratio (%)	487.5	443.8	**390.3**	-53.5% pts
Debt-to-equity ratio (%)	0.0	0.0	**0.0**	—

Notes: 1. Ratio of equity attributable to Chugai shareholders = Capital and reserves attributable to Chugai shareholders (fiscal year-end) / Total assets (fiscal year-end)
2. Cash conversion cycle = [Trade accounts receivable / Sales + (Inventories – Trade accounts payable) / Cost of sales] x Months passed
3. Net cash turnover period = Net cash / Revenues x Months passed
4. Current ratio = Current assets (fiscal year-end) / Current liabilities (fiscal year-end)
5. Debt-to-equity ratio = Interest-bearing debt (fiscal year-end) / Capital and reserves attributable to Chugai shareholders (fiscal year-end)

Cash Conversion Cycle



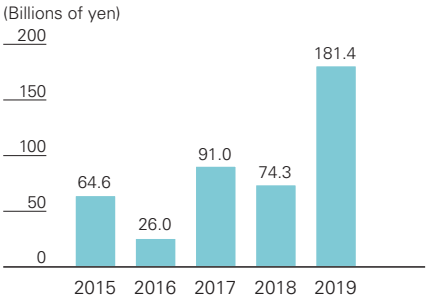
Cash Flows

In conjunction with its decision to apply IFRS from 2013, Chugai has reorganized the consolidated statements of cash flows and uses free cash flows as internal performance indicators (Roche discloses the same indicators). No items have been excluded from cash flows, as the Core basis results concept only applies to the income statement.

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Movement of Free Cash Flows				
Operating profit	98.9	124.3	**210.6**	+69.4%
Operating profit, net of operating cash adjustment	121.0	147.4	**245.2**	+66.4%
Operating free cash flow	91.0	74.3	**181.4**	+144.1%
Free cash flow	64.7	43.7	**142.6**	+226.3%
Net increase/decrease in cash	37.9	6.4	**83.9**	13.1 times
Consolidated Statement of Cash Flows				
Cash flows from operating activities	107.6	119.1	**206.6**	+73.5%
Cash flows from investing activities	(36.7)	(74.1)	**(81.7)**	+10.3%
Cash flows from financing activities	(29.6)	(35.0)	**(66.9)**	+91.1%
Net increase in cash and cash equivalents	43.7	7.8	**57.0**	+630.8%
Cash and cash equivalents at end of year	139.1	146.9	**203.9**	+38.8%

Operating Free Cash Flow



Operating free cash flow

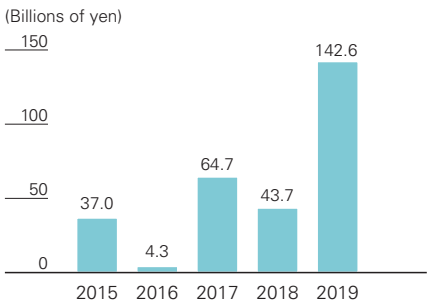
- Operating profit, net of operating cash adjustment, is calculated by adjusting for depreciation and other items that are included in operating profit but are not accompanied by cash inflows or outflows and all inflows and outflows related to net operating assets (NOA) that are not accompanied by profit or loss.

- Operating free cash flow amounted to a net inflow of ¥181.4 billion due to factors including a significant increase in operating profit, despite expenditures of ¥61.2 billion for the purchase of property, plant and equipment and intangible assets. Purchase of property, plant and equipment included investment in Chugai Life Science Park Yokohama.
- With the application of IFRS 16 "Leases," operating free cash flow includes expenditures of ¥8.9 billion for lease liabilities paid.

Free cash flow (FCF)

- Free cash flow increased year on year after subtracting expenditures including income taxes paid of ¥34.8 billion, settlement for transfer pricing taxation of ¥3.1 billion, and payments made for defined benefit plans of ¥11.5 billion.
- Net cash as of December 31, 2019, after subtracting expenditures including dividends paid of ¥56.4 billion and purchase of non-controlling interests of ¥2.3 billion, increased ¥83.9 billion compared with the end of the previous year to ¥333.1 billion.

Free Cash Flow



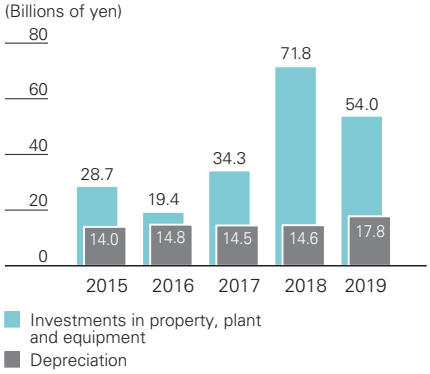
Capital Investments

(Billions of yen)

	2017	2018	2019	2018/2019 Change
Investments in property, plant and equipment	34.3	71.8	54.0	-24.8%
Depreciation	14.5	14.6	17.8	+21.9%

- Capital investments in 2019 included investment in Chugai Life Science Park Yokohama and investments in manufacturing facilities at the Fujieda Plant.
- Chugai plans to make capital investments of ¥72.5 billion during 2020, consisting primarily of new investment in the main facilities below, and expects depreciation to total ¥21.0 billion.

Capital Investments in Property, Plant and Equipment/Depreciation



Major Capital Investments – Current and Planned

(Chugai Pharmaceutical Co., Ltd.)

Facilities (Location)	Description	Planned investment (Billions of yen)		Fund-raising method	Start of construction	Planned transfer/ completion date
		Total amount	Investment to date			
Chugai Life Science Park Yokohama (Totsuka-ku, Yokohama, Kanagawa)	Pharmaceutical research	127.3	22.9	Self-financing	June 2019	August 2022
Fujieda Plant (Fujieda, Shizuoka)	Small and middle molecule API manufacturing	18.2	9.0	Self-financing	May 2019	March 2022
Ukima Research Laboratories (Kita-ku, Tokyo)	Construction of a new synthetic research building for strengthening the process development function of small and middle molecule APIs	4.5	3.1	Self-financing	May 2018	January 2020

Outlook for 2020

Forecast Assumptions

For 2020, Chugai assumes exchange rates of ¥110/CHF, ¥121/EUR, ¥107/USD and ¥80/SGD.

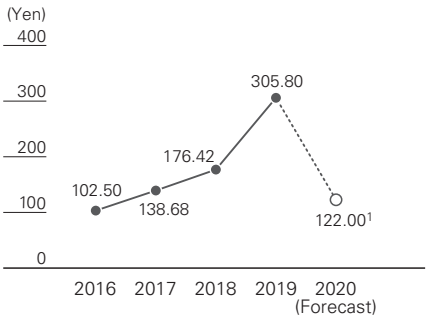
Results Forecast (Core Basis)

(Billions of yen)

	2018	2019	2020 Forecast	2019/2020 Change
Revenues	579.8	686.2	740.0	+7.8%
Sales	527.8	588.9	580.0	-1.5%
Domestic	399.9	437.6	411.6	-5.9%
Overseas	127.9	151.3	168.4	+11.3%
Royalties and other operating income (ROOI)	51.9	97.3	160.0	+64.4%
Royalty and profit-sharing income	24.1	76.5	141.0	+84.3%
Other operating income	27.9	20.8	19.0	-8.7%
Core operating profit	130.3	224.9	275.0	+22.3%
Core EPS (Yen)	176.42	305.80	122.00[1]	—[1]

- Despite expected sales growth from new products including Tecentriq and Hemlibra, domestic sales are forecast to decrease compared with 2019 due to the effect of NHI drug price revisions and competing products including generics.
- Overseas sales are forecast to increase, mainly due to the start of Hemlibra exports to Roche at the regular shipment price.
- ROOI is forecast to increase substantially because royalties and profit-sharing income are expected to increase, primarily in connection with Hemlibra. Other operating income is also expected to decrease due to factors including a decrease in one-time income.
- The cost to sales ratio is forecast to decrease because the share of products from Chugai research in the product mix in Japan and overseas will continue to increase and Hemlibra exports to Roche at the regular shipment price will begin. These factors should more than offset any negative impact from NHI price revisions.
- We expect operating expenses to increase overall due mainly to an increase in research and development activity, including the progress of development projects and related expenses to produce investigational drugs.
- We forecast that Core operating profit and Core EPS will increase despite the expected decrease in domestic sales, mainly as a result of growth in exports of Hemlibra to Roche, increased royalty income, and the lower cost of sales.

Core EPS[2]



1. The forecast presented for Core EPS for 2020 is the amount following the stock split effective July 1, 2020. When calculated assuming no stock split, Core EPS would be ¥366.00 (an increase of 19.7% year on year). Because of the planned stock split, no figure is presented for change in Core EPS.
2. Core EPS = Core net income attributable to Chugai shareholders / Diluted weighted average shares outstanding

Fundamental Profit Distribution Policy and Dividends

After taking strategic funding needs and the results forecast into account, Chugai has changed from a target Core EPS payout ratio of 50 percent on average to 45 percent on average to provide for stable allocation of profit to all shareholders. Internal reserves will be used to increase corporate value through investments for further growth in existing strategic areas and to explore future business opportunities.

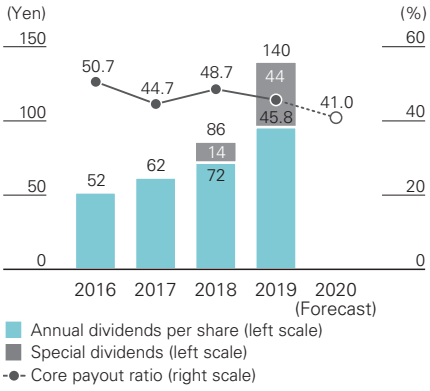
(Yen)

	2017	2018	2019	2020 Forecast
Basic net income per share (EPS)	133.04	169.08	287.84	—
Core EPS	138.68	176.42	305.80	122.00*
Equity per share attributable to Chugai shareholders (BPS)	1,265.46	1,381.26	1,559.72	—
Cash dividends per share	62	86	140	—
Core payout ratio	44.7%	48.7%	45.8%	41.0%
Core payout ratio (five-year average)	48.4%	48.6%	47.4%	45.0%

- Cash dividends per share for 2019 totaled ¥140, and the five-year average Core EPS payout ratio was 47.4 percent.
- On January 21, 2020, the Board of Directors resolved to implement a three-for-one split of the common stock of Chugai Pharmaceutical Co., Ltd effective July 1, 2020.
- The dividend forecast for the year ending December 31, 2020 is ¥75 per share at the end of the second quarter, prior to the stock split, and ¥25 per share at the end of the year, after the stock split. When calculated assuming no stock split, dividends per share for the year would be ¥150.

Note: The forecast presented for Core EPS for 2020 is the amount following the planned stock split. When calculated assuming no stock split, Core EPS would be ¥366.00.

Dividends per Share/Core Payout Ratio



Business Risks

Chugai's corporate performance is subject to material impact from a range of possible future events. Below, we list what we consider the principal sources of risk to our business operations. We recognize the possibility of these risk events actually occurring, and have prepared policies to forestall such events and take appropriate measures when they do occur.

The categories of future risks identified in this section are based on assessments made by Chugai Pharmaceutical on a consolidated basis as of December 31, 2019.

1. Potential Risks in Management Strategy

1) New Product Research and Development

With the aim of becoming a top innovator for advanced and sustainable patient-centric healthcare, Chugai aggressively pursues research and development in Japan and overseas. Powered by our unique strength in science and technology, our development pipeline is well stocked, especially in the field of oncology. However, in recent years intensifying competition in R&D has made the creation of new drugs more challenging, and R&D expenses have increased significantly. Therefore, bringing all drug candidates smoothly through to the market from the development stage may not be possible, and we expect to have to abandon development in some cases. This could have a material impact on business performance, depending on the drug candidate.

2) Changes in Product Environments

In recent years, there have been rapid technological advancements in the pharmaceutical industry, and Chugai faces fierce competition from pharmaceutical companies in Japan and overseas. Competing products, generics and biosimilars are penetrating the market, and therapeutic modalities including regenerative medicine, cellular and genomic therapies, therapeutic nucleic acids, and digital therapies are evolving beyond the scope of conventional drugs. Moreover, the emergence of a digital oligopoly brought on by the entry of IT platform providers into the healthcare industry is engendering new technologies and threats in life science and digital markets. The competitive environment in the healthcare industry is therefore changing rapidly. Changes in the environment surrounding the Group's products that exceed the Group's expectations, such as the emergence of new technologies and treatment modalities that significantly alter the treatment of diseases targeted by Chugai's drugs and development candidates could have a material impact on business performance.

3) Healthcare System Reform

Japan and other countries are strengthening measures to reduce drug prices as issues such as aging populations and surging healthcare costs put strains on their finances. Steadily growing pressure to curb healthcare costs is particularly apparent in Japan, where the government is holding meetings on social security reform to discuss the benefits and premiums of Japan's universal healthcare insurance system. Value-based healthcare will continue to advance as the trend toward pursuing only solutions that offer true value for patients gains momentum. Healthcare system reforms and market trends in countries around the world may have a material impact on business performance, including reduced revenues due to drug price reductions, restricted access to drugs and increased expenses for demonstrating the value of drugs including healthcare economics.

4) Strategic Alliance with Roche

Under its strategic alliance with Roche, Chugai is the only pharmaceutical partner of Roche in the Japanese market and has granted Roche first refusal rights with respect to Chugai's products in global markets outside Japan, excluding South Korea and Taiwan. Consequently, Chugai has in-licensed and out-licensed many products and projects from and to Roche. Changes in Chugai's strategic alliance with Roche for any reason could have a material impact on business performance.

2. Operational Risks

1) Side Effects

Pharmaceutical products and medical devices are approved by regulatory authorities in each country after strict review. However, because of the characteristics of the products, it is difficult to completely prevent adverse outcomes such as side effects from their use even if all possible safety measures are taken. The Group monitors drug safety. However, in cases where side effects occur, particularly newly discovered serious side effects, in addition to publishing precautions, the Group may have to terminate sales and recall products, which could have a material impact on business performance.

2) Intellectual Property Rights

Chugai recognizes that it applies intellectual property rights in pursuing its business activities, and takes care to distinguish its own proprietary intellectual property rights and licensing arrangements recognized under law. However, the possibility remains of unintentional infringement on third-party intellectual property rights. Major disputes involving intellectual property rights associated with our business could have outcomes that have a material impact on business performance, including the suspension of production and sale, or expenses for countermeasures.

3) International Business Activities

Chugai actively conducts international operations including overseas marketing and research and development, and export and import of bulk drug products. These business activities expose Chugai to risks associated with legal and regulatory changes, political instability, economic uncertainty, local labor-management relations, changes in and diverse interpretations of systems of taxation, changes in foreign currency markets, differences in commercial practices and other issues. Compliance and other problems arising from these issues could have a material impact on business performance.

4) Information Technology Security and Information Control

Chugai makes full use of a wide range of information technology systems in its business activities. Consequently, its operations may be disrupted due to negligence or willful misconduct among employees or service providers, or by system malfunctions caused by cyberattacks or other external factors. In addition, the leakage of material and confidential information associated with private individuals or intellectual property may result in liability for damages, loss of trust, loss of competitive advantage or other outcomes that have a material impact on business performance.

To prepare for these risks, the Group takes measures including establishing and disseminating related rules, conducting security education for employees, and safeguarding against cyberattacks and system failures (prevention and monitoring as well as countermeasures and preparations for recovery), and strives to reduce risk by maintaining an annual process of evaluating and enhancing these countermeasures Group-wide.

5) Impact from Large-Scale Disasters and Other Events

Factors such as disruption of business activities due to severe damage to Chugai's business sites or sales locations, or to those of its business partners caused by natural disasters such as earthquakes or typhoons and accidents such as fires, or a significant drop in employee attendance caused by pandemics such as novel influenza outbreaks, and significant expenses for the repair of damaged buildings and facilities, could have a material impact on business performance. The Group has prepared for the risks associated with such disasters and works to reduce those risks with measures to protect employees and ensure an uninterrupted supply of pharmaceuticals. Measures include the use of property and casualty insurance, the implementation of business continuity plans (BCPs) and drills, the use of aseismic construction, and the maintenance of safety stock.

6) Litigation

The Group may be subject to litigation or investigation by regulatory authorities because of pharmaceutical side effects, product liability, labor issues, fair trade or other issues associated with its business activities. This could result in the suspension of manufacturing and sale or in remedial expenses or other outcomes that could have a material impact on business performance.

7) Human Rights

Delays in addressing workplace harassment or human rights issues including occupational health and safety could weaken the Group's human resources in ways such as negatively affecting the physical and mental health of employees and increasing employee turnover, and damaging public trust in the Group, which could have a material impact on business performance. The Group addresses these human rights issues with training for executives and employees, as well as with harassment hotlines. It also conducts health and safety programs as part of its health and productivity management. In addition, the Group asks suppliers to respect human rights and works with them to resolve issues related to human rights.

8) Supply Chains

Natural disasters such as large-scale earthquakes or typhoons and heavy rain due to climate change could damage suppliers, including raw material suppliers or contract manufacturers. Moreover, delays in addressing supply chain compliance or environmental issues could create problems in procuring raw materials or maintaining production, thereby reducing public trust in the Group or reducing market share, which could have a material impact on business performance. The Group has prepared for these supply chain risks. Measures for the uninterrupted supply of pharmaceuticals include the use of property and casualty insurance, the formulation of business continuity plans (BCPs), maintenance of safety stock and the establishment of systems for sharing information with suppliers. We also work with suppliers to resolve issues such as supply chain compliance and environmental issues that the Group cannot resolve on its own.

9) Environmental Pollution and the Global Environment

The Group complies with relevant laws and regulations and has established a set of even higher voluntary standards that it is committed to achieving and will continue to strengthen and enhance. However, the Group may have to bear expenses for countermeasures or liability for damages should unexpected contamination by harmful substances or collateral damage occur, which could have a material impact on business performance. We consider climate change to be a key challenge in protecting the global environment, and are therefore committed to reducing greenhouse gas emissions. However, natural disasters or other events resulting from climate change caused by continued global warming could damage the Group's logistics network and manufacturing facilities, resulting in outcomes such as the suspension or significant delay of product supply, which could have a material impact on business performance. In addition, more stringent environmental regulations in the future may limit Group business activities including research, development and manufacturing.

Consolidated Financial Statements

1. Consolidated income statement and consolidated statement of comprehensive income

(1) Consolidated income statement in millions of yen

	Year ended December 31	
	2019	2018
Revenues	**686,184**	**579,787**
Sales (Notes 2 and 3)	588,896	527,844
Royalties and other operating income (Notes 2 and 3)	97,288	51,943
Cost of sales	(266,071)	(262,847)
Gross profit	**420,113**	**316,940**
Marketing and distribution	(77,183)	(73,706)
Research and development	(107,942)	(99,202)
General and administration	(24,391)	(19,710)
Operating profit	**210,597**	**124,323**
Financing costs (Note 4)	(125)	(111)
Other financial income (expense) (Note 4)	545	449
Other expense (Note 5)	(3,124)	(3,212)
Profit before taxes	**207,893**	**121,449**
Income taxes (Note 6)	(50,333)	(28,370)
Net income	**157,560**	**93,079**
Attributable to:		
Chugai shareholders (Note 22)	157,560	92,488
Non-controlling interests (Note 23)	-	591
Earnings per share (Note 27)		
Basic (yen)	287.84	169.08
Diluted (yen)	287.43	168.80

(2) Consolidated statement of comprehensive income in millions of yen

	Year ended December 31	
	2019	2018
Net income recognized in income statement	**157,560**	**93,079**
Other comprehensive income		
Remeasurements of defined benefit plans (Notes 6 and 22)	329	(2,472)
Financial assets measured at fair value through OCI (Notes 6 and 22)	(255)	363
Items that will never be reclassified to the income statement	**74**	**(2,109)**
Financial assets measured at fair value through OCI (Notes 6 and 22)	(17)	0
Cash flow hedges (Notes 6 and 22)	(1,317)	(225)
Currency translation of foreign operations (Notes 6 and 22)	(1,172)	(3,158)
Items that are or may be reclassified to the income statement	**(2,506)**	**(3,383)**
Other comprehensive income, net of tax (Note 6)	**(2,433)**	**(5,492)**
Total comprehensive income	**155,127**	**87,587**
Attributable to:		
Chugai shareholders (Note 22)	155,127	87,078
Non-controlling interests (Note 23)	-	509

2. **Consolidated balance sheet** in millions of yen

	December 31, 2019	December 31, 2018
Assets		
Non-current assets:		
Property, plant and equipment (Note 7)	255,559	222,388
Right-of-use assets (Note 8)	9,749	-
Intangible assets (Note 9)	23,540	22,699
Financial non-current assets (Note 10)	2,958	9,723
Deferred tax assets (Note 6)	42,680	35,568
Other non-current assets (Note 11)	24,750	29,077
Total non-current assets	**359,235**	**319,455**
Current assets:		
Inventories (Note 12)	168,122	159,360
Accounts receivable (Note 13)	181,641	179,556
Current income tax assets (Note 6)	0	3
Marketable securities (Note 14)	129,117	102,533
Cash and cash equivalents (Note 15)	203,941	146,860
Other current assets (Note 16)	16,858	11,781
Total current assets	**699,680**	**600,093**
Total assets	**1,058,915**	**919,548**
Liabilities		
Non-current liabilities:		
Long-term debt (Note 17)	-	(82)
Deferred tax liabilities (Note 6)	(9,304)	(9,031)
Defined benefit plan liabilities (Note 25)	(7,094)	(14,671)
Long-term provisions (Note 18)	(2,348)	(2,072)
Other non-current liabilities (Note 19)	(6,914)	(1,946)
Total non-current liabilities	**(25,662)**	**(27,802)**
Current liabilities:		
Short-term debt (Note 17)	-	(133)
Current income tax liabilities (Note 6)	(41,047)	(19,567)
Short-term provisions (Note 18)	(4)	(1)
Accounts payable (Note 20)	(77,635)	(71,706)
Other current liabilities (Note 21)	(60,582)	(43,810)
Total current liabilities	**(179,268)**	**(135,218)**
Total liabilities	**(204,930)**	**(163,019)**
Total net assets	**853,985**	**756,529**
Equity:		
Capital and reserves attributable to Chugai shareholders (Note 22)	853,985	755,864
Equity attributable to non-controlling interests (Note 23)	-	664
Total equity	**853,985**	**756,529**
Total liabilities and equity	**1,058,915**	**919,548**

3. **Consolidated statement of cash flows** in millions of yen

	Year ended December 31	
	2019	2018
Cash flows from operating activities		
Cash generated from operations (Note 28)	249,500	151,857
(Increase) decrease in working capital	6,205	4,486
Payments made for defined benefit plans	(11,540)	(2,652)
Utilization of provisions (Note 18)	(2)	(29)
Other operating cash flows	(2,741)	(3,022)
Cash flows from operating activities, before income taxes paid	**241,423**	**150,639**
Income taxes paid	(34,782)	(31,565)
Total cash flows from operating activities	**206,641**	**119,074**
Cash flows from investing activities		
Purchase of property, plant and equipment	(53,009)	(71,785)
Purchase of intangible assets	(8,168)	(5,886)
Disposal of property, plant and equipment	119	49
Interest and dividends received (Note 28)	197	200
Purchases of marketable securities	(256,768)	(263,503)
Sales of marketable securities	230,158	264,711
Purchases of investment securities	(1,013)	(709)
Sales of investment securities	6,743	2,863
Other investing cash flows	0	(0)
Total cash flows from investing activities	**(81,741)**	**(74,060)**
Cash flows from financing activities		
Purchase of non-controlling interests	(2,307)	-
Interest paid	(27)	(5)
Lease liabilities paid	(8,861)	-
Dividends paid to Chugai shareholders	(56,370)	(35,010)
Dividends paid to non-controlling shareholders	-	(791)
Exercises as part of equity compensation plans (Note 26)	735	996
(Increase) decrease in own equity instruments	(25)	(19)
Other financing cash flows	(16)	(187)
Total cash flows from financing activities	**(66,872)**	**(35,014)**
Net effect of currency translation on cash and cash equivalents	(947)	(2,215)
Increase (decrease) in cash and cash equivalents	**57,081**	**7,785**
Cash and cash equivalents at January 1	146,860	139,074
Cash and cash equivalents at December 31 (Note 15)	**203,941**	**146,860**

4. Consolidated statement of changes in equity in millions of yen

	Attributable to Chugai shareholders						
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal	Non-controlling interests	Total equity
Year ended December 31, 2018							
At January 1, 2018	**72,970**	**64,815**	**550,974**	**3,166**	**691,924**	**973**	**692,897**
Impact of changes in accounting policies	**-**	**-**	**10,606**	**-**	**10,606**	**-**	**10,606**
At January 1, 2018 (revised)	**72,970**	**64,815**	**561,580**	**3,166**	**702,530**	**973**	**703,503**
Net income	-	-	92,488	-	92,488	591	93,079
Financial assets measured at fair value through OCI (Notes 6 and 22)	-	-	-	363	363	-	363
Cash flow hedges (Notes 6 and 22)	-	-	-	(225)	(225)	-	(225)
Currency translation of foreign operations (Notes 6, 22 and 23)	-	-	-	(3,077)	(3,077)	(82)	(3,158)
Remeasurements of defined benefit plans (Notes 6 and 22)	-	-	(2,472)	-	(2,472)	-	(2,472)
Total comprehensive income	**-**	**-**	**90,016**	**(2,938)**	**87,078**	**509**	**87,587**
Dividends (Notes 22 and 23)	-	-	(35,003)	-	(35,003)	(817)	(35,820)
Equity compensation plans (Note 22)	31	(97)	-	-	(66)	-	(66)
Own equity instruments (Note 22)	-	1,325	-	-	1,325	-	1,325
Transfer from other reserves to retained earnings	-	-	1,498	(1,498)	-	-	-
At December 31, 2018	**73,000**	**66,043**	**618,091**	**(1,270)**	**755,864**	**664**	**756,529**
Year ended December 31, 2019							
At January 1, 2019	**73,000**	**66,043**	**618,091**	**(1,270)**	**755,864**	**664**	**756,529**
Net income	-	-	157,560	-	157,560	-	157,560
Financial assets measured at fair value through OCI (Notes 6 and 22)	-	-	-	(272)	(272)	-	(272)
Cash flow hedges (Notes 6 and 22)	-	-	-	(1,317)	(1,317)	-	(1,317)
Currency translation of foreign operations (Notes 6, 22 and 23)	-	-	-	(1,172)	(1,172)	-	(1,172)
Remeasurements of defined benefit plans (Notes 6 and 22)	-	-	329	-	329	-	329
Total comprehensive income	**-**	**-**	**157,889**	**(2,761)**	**155,127**	**-**	**155,127**
Dividends (Notes 22 and 23)	-	-	(56,373)	-	(56,373)	-	(56,373)
Equity compensation plans (Note 22)	16	52	-	-	68	-	68
Own equity instruments (Note 22)	-	941	-	-	941	-	941
Changes in non-controlling interests	-	-	(1,662)	19	(1,643)	(664)	(2,307)
Transfer from other reserves to retained earnings	-	-	4,131	(4,131)	-	-	-
At December 31, 2019	**73,016**	**67,037**	**722,076**	**(8,143)**	**853,985**	**-**	**853,985**

Notes to Consolidated Financial Statements

1. General accounting principles and significant accounting policies

(1) Basis of preparation of the consolidated financial statements

These financial statements are the annual consolidated financial statements of Chugai Pharmaceutical Co., Ltd., ("Chugai") a company registered in Japan, and its subsidiaries ("the Group"). The common stock of Chugai is publicly traded and is listed on the Tokyo Stock Exchange under the stock code "TSE: 4519". The consolidated financial statements were approved by Tatsuro Kosaka, Representative Director, Chairman & CEO, and Toshiaki Itagaki, Executive Vice President & CFO on March 30, 2020.

Roche Holding Ltd. is a public company registered in Switzerland and the parent company of the Roche Group, which discloses its results in accordance with International Financial Reporting Standards ("IFRS"). The shareholding percentage of Roche Holding Ltd. in Chugai is 59.89% (61.22% of the total number of shares issued excluding own equity instruments). The Group became a principal member of the Roche Group after entering into a strategic alliance in October 2002.

The Group meets all of the requirements for a "Specified Company under Designated International Financial Reporting Standards" as stipulated under Article 1-2 of the "Regulations Concerning Terminology, Forms, and Preparation Methods of Consolidated Financial Statements" (Ministry of Finance of Japan Regulation No. 28, 1976). Hence, in accordance with Article 93 of the Regulation, the Consolidated Financial Statements have been prepared in accordance with IFRS.

The consolidated financial statements are presented in Japanese yen, which is Chugai's functional currency, and amounts are rounded to the nearest ¥1 million. As a result, the totals shown in the consolidated financial statements do not necessarily agree with the sum of the individual amounts. They have been prepared using the historical cost convention except for items that are required to be accounted for at fair value.

(2) Key accounting judgments, estimates and assumptions

The preparation of the consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities and contingent amounts. Actual outcomes could differ from those management estimates. The estimates and underlying assumptions are reviewed on an ongoing basis and are based on historical experience and various other factors. Revisions to estimates are recognized in the period in which the estimate is revised. The following are considered to be the key accounting judgments, estimates and assumptions made and are believed to be appropriate based upon currently available information.

Revenue.

Sales are recorded net of allowances for estimated rebates, cash discounts and estimates of product returns, all of which are established at the time of sale. The estimated rebates, chargebacks, cash discounts and estimates of product returns are recorded as current liabilities. The Group makes accruals for expected sales rebates, which are estimated based on analyses of existing contractual or legislatively-mandated obligations, historical trends and the Group's experience. As these deductions are based on management estimates, they may be subject to change as better information becomes available. Such changes that arise could impact the accruals recognized in the balance sheet in future periods and consequently the level of sales recognized in the income statement in future periods.

Out-licensing agreements may be entered into with no further obligation or may include commitments to conduct research, late-stage development, regulatory approval, co-marketing or manufacturing. These may be settled by a combination of upfront payments, milestone payments, and reimbursements for services provided. Whether to consider these commitments as a single performance obligation or separate ones, or even being in scope of IFRS 15 'Revenues from Contracts with Customers', is not straightforward and requires some judgment. Depending on the conclusion, this may result in all revenue being calculated at inception and either being recognized at once or spread over the term of a longer performance obligation.

As a practical expedient, the Group does not adjust the promised amount of consideration for the effects of a significant financing component, if the group expects, at contract inception, that the period between when the group transfers a promised good or service to a customer and when the customer pays for that good or service will be one year or less.

Impairment. Intangible assets not yet available for use are reviewed annually for impairment. Property, plant and equipment, right-of-use assets and intangible assets in use are assessed for impairment when there is a triggering event that provides evidence that an asset may be impaired. To assess whether any impairment exists estimates of expected future cash flows are used. Actual outcomes could vary significantly from such estimates of discounted future cash flows. Factors such as changes in discount rates, the planned use of buildings, machinery or equipment, closure of facilities, the presence or absence of competition, technical obsolescence and lower than anticipated product sales could lead to shorter useful lives or impairment.

Post-employment benefits. The Group operates a number of defined benefit plans and the fair values of the recognized plan assets and liabilities are based upon statistical and actuarial calculations. The measurement of the net defined benefit obligation is particularly sensitive to changes in the discount rate and expected mortality. The actuarial assumptions used may differ materially from actual results due to changes in market and economic conditions, longer or shorter life spans of participants, and other changes in the factors being assessed. These differences could impact on the defined benefit plan assets or liabilities recognized in the balance sheet in future periods.

Legal. The Group provides for anticipated legal settlement costs when there is a probable outflow of resources that can be reliably estimated. Where no reliable estimate can be made, no provision is recorded and contingent liabilities are disclosed where material. The status of significant legal cases is disclosed in Additional Information. These estimates consider the specific circumstances of each legal case and relevant legal advice, and are inherently judgmental due to the highly complex nature of legal cases. The estimates could change substantially over time as new facts emerge and each legal case progresses.

Environmental. The Group provides for anticipated environmental remediation costs when there is a probable outflow of resources that can be reasonably estimated. Environmental provisions consist primarily of costs to fully clean and refurbish contaminated sites, including landfills, and to treat and contain contamination at certain other sites. These estimates are inherently judgmental due to uncertainties related to the detection of previously unknown contaminated sites, the method and extent of remediation, the percentage of the problematic materials attributable to the Group at the remediation sites, and the financial capabilities of the other potentially responsible parties. The estimates could change substantially over time as new facts emerge and each environmental remediation progresses.

Income taxes. Significant estimates are required to determine the current and deferred tax assets and liabilities. Some of these estimates are based on interpretations of existing tax laws or regulations. Where tax positions are uncertain, accruals are recorded within income tax liabilities for management's best estimate of the ultimate liability that is expected to arise based on the specific circumstances and the Group's historical experience. Factors that may have an impact on current and deferred taxes include changes in tax laws, regulations or rates, changing interpretations of existing tax laws or regulations, future levels of research and development spending and changes in pre-tax earnings.

Leases.
Policy applicable from January 1, 2019
Where the Group is the lessee, key judgments include assessing whether arrangements contain a lease and determining the lease term. To assess whether a contract contains a lease requires judgment about whether it depends on a specified asset, whether the Group obtains substantially all the economic benefits from the use of that asset, and whether the Group has a right to direct the use of the asset. In order to determine the lease term judgment is required as extension and termination options have to be assessed along with all facts and circumstances that may create an economic incentive to exercise an extension option, or not exercise a termination option. Estimates include calculating the discount rate which is based on the incremental borrowing rate.

Policy applicable before January 1, 2019
The treatment of leasing transactions is mainly determined by whether the lease is considered to be an operating or finance lease. In making this assessment, management looks at the substance of the lease, as well as the legal form, and makes a judgment about whether substantially all of the risks and rewards of ownership are transferred. Arrangements which do not take the legal form of a lease but that nevertheless convey the right to use an asset are also covered by such assessments.

(3) Accounting policies

Consolidation policy

Subsidiaries are all companies over which the Group has control. Chugai controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Companies acquired during the year are consolidated from the date on which control is transferred to the Group, and subsidiaries to be divested are included up to the date on which control passes from the Group. Inter-company balances, transactions and resulting unrealized income are eliminated in full. Changes in ownership interests in subsidiaries are accounted for as equity transactions if they occur after control has already been obtained and if they do not result in a loss of control. Associates are companies over which the Group exercises, or has the power to exercise, significant influence, but which it does not control and they are accounted for using the equity method.

Foreign currency translation

Most foreign subsidiaries of the Group use their local currency as their functional currency. Certain foreign subsidiaries use other currencies (such as the euro) as their functional currency where this is the currency of the primary economic environment in which the entity operates. Local transactions in other currencies are initially reported using the exchange rate at the date of the transaction. Gains and losses from the settlement of such transactions and gains and losses on translation of monetary assets and liabilities denominated in other currencies are included in income, except when they are qualifying cash flow hedges. In such cases the gains and losses are deferred into other comprehensive income.

Upon consolidation, assets and liabilities of foreign subsidiaries using functional currencies other than Japanese yen are translated into Japanese yen using year-end rates of exchange. The income statement and statement of cash flows are translated at the average rates of exchange for the year. Translation differences due to the changes in exchange rates between the beginning and the end of the year and the difference between net income translated at the average and year-end exchange rates are taken directly to other comprehensive income.

Revenue

Sales. Revenue from the sale of goods supplied is recorded as 'Sales'.

Sales are recognized when a promise in a customer contract (performance obligation) has been satisfied by transferring control over the promised goods to the customer. Control over a promised good refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, those goods. Control is usually transferred upon shipment or delivery to or upon receipt of goods by the customer, in accordance with the delivery and acceptance terms agreed with the customers. The amount of sales to be recognized (transaction price) is based on the consideration the Group expects to receive in exchange for its goods, excluding amounts collected on behalf of third parties such as consumption tax or other taxes directly linked to sales. The Group recognizes deferred income (contract liability) if consideration has been received (or has become receivable) before the Group transfers the promised goods to the customer.

Royalty and other operating income. 'Royalty and other operating income' includes royalty income, income from out-licensing agreements and income from disposal of products and other items.

Revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property is recognized when the subsequent sale or usage occurs.

Income from out-licensing agreements typically arises from the receipt of upfront, milestone and other similar payments from third parties for granting a license to product or technology related intellectual property (IP). Out-licensing agreements may be entered into with no further obligation or may include commitments to conduct research, late-stage development, regulatory approval, co-marketing or manufacturing. Licenses granted are usually rights to use IP and are generally unique. Therefore, the basis of allocating revenue to performance obligations makes use of the residual approach. Upfront payments and other licensing fees are usually recognized upon granting the license unless some of the income shall be deferred for other performance obligations using the residual approach. Such deferred income is released and recognized as revenue when other performance obligations are satisfied. Milestone income is recognized at the point in time when it is highly probable that the respective milestone event criteria is achieved, and the risk of revenue reversal is considered remote.

Payments received for the disposal of product and similar rights are recognized as revenue upon transfer of control over such rights. To the extent that some of these payments relate to other performance obligations, a portion is deferred using the residual approach and recognized as revenue when performance obligations are satisfied.

Income from profit-sharing arrangements with collaboration partners is recognized as underlying sales and cost of sales are recorded by the collaboration partners.

Cost of sales
Cost of sales includes the corresponding direct production costs and related production overheads of goods sold and services rendered. Royalties, alliance and collaboration expenses, including all collaboration profit-sharing arrangements are also reported as part of cost of sales. Start-up costs between validation and the achievement of normal production capacity are expensed as incurred.

Research and development
Internal research and development activities are expensed as incurred for the following:
- Internal research costs incurred for the purpose of gaining new scientific or technical knowledge and understanding.
- Internal development costs incurred for the application of research findings or other knowledge to plan and develop new products for commercial production. The development projects undertaken by the Group are subject to technical, regulatory and other uncertainties, such that, in the opinion of management, the criteria for capitalization as intangible assets are not met prior to obtaining marketing approval by the regulatory authorities in major markets.
- Post-marketing studies after regulatory approval, such as phase IV costs in the pharmaceuticals business, generally involve safety surveillance and on-going technical support of a drug after it receives marketing approval to be sold. They may be required by regulatory authorities or may be undertaken for safety or commercial reasons. The costs of such post-marketing studies are not capitalized as intangible assets, as in the opinion of management, they do not generate separately identifiable incremental future economic benefits that can be reliably measured.

Acquired in-process research and development resources obtained through in-licensing arrangements, business combinations or separate asset purchases are capitalized as intangible assets. The acquired asset must be controlled by the Group, be separately identifiable and expected to generate future economic benefits, even if uncertainty exists as to whether the research and development will ultimately result in a marketable product. Consequently, upfront and milestone payments to third parties for pharmaceutical products or compounds before regulatory marketing approval are recognized as intangible assets. Assets acquired through such arrangements are measured on the basis set out in the "Intangible assets" policy. Subsequent internal research and development costs incurred post-acquisition are treated in the same way as other internal research and development costs. If research and development are embedded in contracts for strategic alliances, the Group carefully assesses whether upfront or milestone payments constitute funding of research and development work or acquisition of an asset.

Employee benefits
Short-term employee benefits include wages, salaries, social security contributions, paid annual leave and sick leave, profit sharing and bonuses, and non-monetary benefits for current employees. The costs are recognized within the operating results when the employee has rendered the associated service. The Group recognizes a liability for profit sharing and bonuses where contractually obliged or where there is a past practice that has created a constructive obligation.

Termination benefits are payable when employment is terminated by the Group before the normal retirement date, or whenever an employee accepts voluntary redundancy in exchange for these benefits. Termination costs are recognized at the earlier of when the Group can no longer withdraw the offer of the benefits or when the Group recognizes any related restructuring costs.

Post-employment benefits
For defined contribution plans, the Group contributions are recognized within the operating results when the employee has rendered the associated service.

For defined benefit plans the liability or asset recognized in the balance sheet is net amount of the present value of the defined benefit obligation and the fair value of the plan assets. All changes in the net defined benefit liability (asset) are recognized as they occur as follows:

Recognized in the income statement:
- Current service costs are charged to the appropriate income statement heading within the operating results.
- Past service costs, including curtailment gains or losses, are recognized immediately in general and administration within the operating results.
- Settlement gains or losses are recognized in general and administration within the operating results.
- Net interest on the net defined benefit liability (asset) is recognized in financing costs.

Recognized in other comprehensive income:
- Actuarial gains and losses arising from experience adjustments (the difference between previous assumptions and what has actually occurred) and changes in actuarial assumptions.
- The return on plan assets, excluding amounts included in net interest on the net defined benefit liability (asset).

Net interest on the net defined benefit liability (asset) comprises interest income on plan assets and interest costs on the defined benefit obligation. The net interest is calculated using the same discount rate that is used in calculating the defined benefit obligation, applied to the net defined benefit liability (asset) at the start of the period, taking account of any changes from contribution or benefit payments.

Pension assets and liabilities in different defined benefit plans are not offset unless the Group has a legally enforceable right to use the surplus in one plan to settle obligations in the other plan.

Equity compensation plans
The fair value of all equity compensation awards, including restricted stocks, granted to directors and certain employees is estimated at the grant date and recorded as an expense over the vesting period. The expense is charged to the appropriate income statement heading within the operating results. For equity-settled plans, an increase in equity is recorded for this expense and any subsequent cash flows from exercises of vested awards are recorded as changes in equity.

Property, plant and equipment
Property, plant and equipment are initially recorded at cost of purchase or construction, and include all costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. These include items such as costs of site preparation, installation and assembly costs and professional fees. The net costs of testing whether the asset is functioning properly, including validation costs, are also included in the initially recorded cost of construction. Property, plant and equipment are depreciated on a straight-line basis, except for land, which is not depreciated. The estimated useful lives of major classes of depreciable assets are as follows:
- Land improvements: 40 years
- Buildings: 10-50 years
- Machinery and equipment: 3-15 years

Where parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate components. The estimated useful lives of the assets are regularly reviewed, and, if necessary, the future depreciation charges are accelerated. Repairs and maintenance costs are expensed as incurred.

Leases
Policy applicable from January 1, 2019
At inception of a contract, the Group assesses whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Group recognizes a right-of-use asset and a corresponding lease liability for each contract that is, or contains, a lease at the lease commencement date, except for short-term leases and leases of low-value assets. Payments for short-term leases and leases of low-value assets are recognized as an expense on a straight-line basis over the term of the respective lease. The lease liability is initially measured at the present value of the future lease payments that are not paid at the lease commencement date. The lease payments are discounted using the interest rate implicit in the lease or, if not readily determinable, the Group's incremental borrowing rate in the respective markets. Lease payments include fixed payments, variable payments that depend on an index or rate known at the lease commencement date and payments from exercising purchase options if the Group is reasonably certain to exercise. The lease liability is subsequently measured at amortized costs using the effective interest method. It is remeasured, with a corresponding adjustment to the related right-of-use asset, when there is a change in future lease payments following a contract renegotiation, a change of an index or rate or a reassessment of options. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any payments made at or before the lease commencement date and which includes any initial direct costs incurred and expected costs of obligations to dismantle, remove or refurbish the underlying asset, less any incentives received. Right-of-use assets are depreciated on a straight-line basis from the commencement date to the end of the useful life of the underlying asset if the lease transfers ownership of the underlying asset to the lessee by the end of the lease term or if the cost of the right-of-use asset reflects that the lessee will exercise a purchase option. Otherwise, right-of-use assets are depreciated on a straight-line basis from the lease commencement date over the shorter of the lease term or the useful life of the underlying asset. Right-of-use assets are assessed for impairment whenever there is an indication for impairment.

Policy applicable before January 1, 2019
Where the Group is the lessee, finance leases exist when substantially all of the risks and rewards of ownership are transferred to the Group. Finance leases are capitalized at the start of the lease at fair value, or the present value of the minimum lease payments, if lower. The rental obligation, net of finance charges, is reported within debt. Finance lease assets are depreciated over the shorter of the lease term and its useful life. The interest element of the lease payment is charged against income over the lease term based on the effective interest rate method. Operating leases exist when substantially all of the risks and rewards of ownership are not transferred to the Group. Payments made under operating leases are charged against income on a straight-line basis over the period of the lease.

Intangible assets
Purchased patents, trademarks, licenses and other intangible assets are initially recorded at cost. Assets that have been acquired through a business combination are initially recorded at fair value. Once available for use, intangible assets are amortized on a straight-line basis over their useful lives. The estimated useful life is the lower of the legal duration and the economic useful life. The estimated useful lives of intangible assets are regularly reviewed. Estimated useful lives of major classes of amortizable intangible assets are as follows:

- Product intangibles in use: 1-17 years
- Marketing intangibles in use: 5 years
- Technology intangibles in use: 3-9 years

Impairment of property, plant and equipment, right-of-use assets and intangible assets
An impairment assessment is carried out at each reporting date when there is evidence that an asset may be impaired. In addition intangible assets that are not yet available for use are tested for impairment annually. When the recoverable amount of an asset, being the higher of its fair value less costs to sell and its value in use, is less than its carrying value, then the carrying value is reduced to its recoverable amount. This reduction is reported in the income statement as an impairment loss. Value in use is calculated using estimated cash flows. These are discounted using an appropriate long-term interest rate. When an impairment loss arises, the useful life of the asset is reviewed and, if necessary, the future depreciation/amortization charge is accelerated. If the amount of impairment loss subsequently decreases and the decrease can be related objectively to an event occurring after the impairment was recognized, then the previously recognized impairment loss is reversed through the income statement as an impairment reversal.

Inventories
Inventories are stated at the lower of cost and net realizable value. The cost of finished goods, work in process and intermediates includes raw materials, direct labour and other directly attributable costs and overheads based upon the normal capacity of production facilities. Cost is determined using the weighted average method. Net realizable value is the estimated selling price less cost to completion and selling expenses.

Accounts receivable
Accounts receivable are carried at the original invoice amount less allowances made for doubtful accounts, trade discounts, cash discounts, volume rebates and similar allowances. A receivable represents a right to consideration that is unconditional and excludes contract assets. The Group always measures an allowance for doubtful accounts that result from transactions that are within the scope of IFRS 15 equal to the credit losses expected over the lifetime of the trade receivables. These estimates are based on specific indicators, such as the ageing of customer balances, specific credit circumstances and the Group's historical loss rates for each category of customers, and adjusted for forward looking macroeconomic data. While the Group measures an allowance for doubtful accounts that result from transactions that are not within the scope of IFRS 15 equal to 12-months expected credit losses, when the credit risk for these accounts has not increased significantly since initial recognition.
Expenses for doubtful trade receivables are recognized within marketing and distribution expenses. Trade discounts, cash discounts, volume rebates and similar allowances are recorded on an accrual basis consistent with the recognition of the related sales, using estimates based on existing contractual obligations, historical trends and the Group's experience. Accounts receivable are written off (either partially or in full) when there is no reasonable expectation of recovery. Where receivables have been written off, the Group continues to engage in enforcement activities to attempt to recover the receivable due. Where recoveries are made, these are recognized in profit or loss.

Cash and cash equivalents
Cash and cash equivalents include cash on hand and time, call and current balances with banks and similar institutions. Such balances are only reported as cash equivalents if they are readily convertible to known amounts of cash, are subject to insignificant risk of changes in their fair value and have a maturity of three months or less from the date of acquisition.

Provisions and contingencies
Provisions are recognized where a legal or constructive obligation has been incurred which will probably lead to an outflow of resources that can be reliably estimated. In particular, restructuring provisions are recognized when the Group has a detailed formal plan that has either commenced implementation or has been announced. Provisions are recorded for the estimated ultimate liability that is expected to arise and are discounted when the time value of money is material. A contingent liability is disclosed where the existence of the obligation will only be confirmed by future events or where the amount of the obligation cannot be measured with reasonable reliability. Contingent assets are not recognized, but are disclosed where an inflow of economic benefits is probable.

Fair values
Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. It is determined by reference to quoted market prices or by the use of established valuation techniques such as option pricing models and the discounted cash flow method if quoted prices in an active market are not available.

Financial instruments
The Group classifies its financial assets, with the exception of derivatives, in the following measurement categories: amortized cost; fair value through OCI; and fair value through profit or loss.

The classification depends on the Group's business model for managing the financial assets and the contractual terms of the cash flows. The Group reclassifies debt securities and financial assets measured at amortized cost when and only when its business model for managing those assets changes.

At initial recognition, the Group measures a financial asset at its fair value excluding trade receivables at transaction price if it does not contain a significant financing component. In the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset are added to the fair value. Transaction costs of financial assets carried at fair value through profit or loss are expensed in profit or loss.

Financial assets measured at amortized cost: Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortized cost. A gain or loss on a debt security that is subsequently measured at amortized cost and is not part of a hedging relationship is recognized in profit or loss when the asset is derecognized or impaired. Interest income from these financial assets is included in other financial income using the effective interest rate method. Financial assets measured at amortized cost are mainly comprised of accounts receivable, cash and cash equivalents and time accounts over three months.

Financial assets measured at fair value through other comprehensive income (fair value through OCI): These are financial assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets' cash flows represent solely payments of principal and interest. These assets are initially recorded and subsequently carried at fair value. Changes in the fair value are recorded in other comprehensive income, except for the recognition of impairment gains or losses, interest revenue and foreign exchange gains and losses which are recognized in profit and loss. When the financial asset is derecognized, the cumulative gain or loss previously recognized in OCI is reclassified from equity to profit or loss. Interest income from these financial assets is included in other financial income using the effective interest rate method. Financial assets measured at fair value through other comprehensive income are mainly comprised of money market instruments.

Equity instruments measured at fair value through other comprehensive income (fair value through OCI): These are equity instruments measured at fair value through OCI for which an irrevocable election at initial recognition has been made, to present subsequent changes in fair value in other comprehensive income. Dividends are recognized as other financial income in profit or loss. Other net gains and losses are recognized in OCI and are never reclassified to profit or loss. When the instruments are derecognized, the cumulative amount of other comprehensive income is transferred to retained earnings.

Financial assets measured at fair value through profit or loss: These are financial assets whose performance is evaluated on a fair value basis. A gain or loss on a financial asset that is subsequently measured at fair value through profit or loss and is not part of a hedging relationship is recognized in profit or loss and presented within other financial income (expense) in the period in which it arises. Fair value through profit or loss assets are mainly comprised of debt instruments.

The Group classifies its financial liabilities as measured at amortized cost, except for derivatives. Financial liabilities are initially recorded at fair value, less transaction costs and subsequently carried at amortized cost using the effective interest rate method. Financial liabilities are mainly comprised of trade payables.

Derivative financial instruments that are used to manage the exposures to foreign currency exchange rate fluctuations are initially recorded and subsequently carried at fair value. Apart from those derivatives designated as qualifying cash flow hedging instruments, all changes in fair value are recorded as other financial income (expense).

Derecognition of financial instruments
A financial asset is derecognized when the contractual rights to the cash flows from the asset expire or when the Group transfers the rights to receive the contractual cash flows from the financial assets in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred. A financial liability is derecognized when the contractual obligations are discharged, cancelled or expire.

Impairment of financial assets
The Group recognizes loss allowances for expected credit losses ('ECL') for financial assets measured at amortized cost and debt securities measured at fair value through OCI.

The Group always measures loss allowances that result from transactions that are within the scope of IFRS 15 equal to the credit losses expected over the lifetime of the trade receivables.

The Group measures loss allowances at an amount equal to 12-month expected credit losses for its debt securities carried at fair value through OCI and at amortized cost when the credit risk for these accounts has not increased significantly since initial recognition at the reporting date. The Group considers a debt investment to have low credit risk when their credit risk rating is equivalent to the globally understood definition of 'investment grade'. The Group considers this to be at least Baa3 from Moody's and BBB-from S&P.

The Group measures the allowances for doubtful account at an amount equal to lifetime ECL for its debt investments at fair value through OCI and at amortized cost on which credit risk has increased significantly since their initial recognition. The Group assumes that the credit risk on a financial asset has increased significantly if it is more than 30 days past due.

The Group considers a financial asset to be in default when the counterparty is unlikely to pay its obligations to the Group in full. In assessing whether a counterparty is in default, the Group considers both qualitative and quantitative indicators that are based on data developed internally and for certain financial assets also obtained from external sources.

Financial assets are written off (either partially or in full) when there is no realistic prospect of recovery. This is generally the case when the Group determines that the customer does not have assets or sources of income that could generate sufficient cash flows to repay the amounts subject to the write-off. However, financial assets that are written off are still subject to enforcement activities in order to comply with the Group's policy for recovery of amounts due.

Hedge accounting
The Group uses derivatives to manage its exposures to foreign currency risk. The instruments used may include forwards contracts. The Group generally limits the use of hedge accounting to certain significant transactions. To qualify for hedge accounting the hedging relationship must meet several strict conditions on documentation, probability of occurrence, hedge effectiveness and reliability of measurement. While many of these transactions can be considered as hedges in economic terms, if the required conditions are not met, then the relationship does not qualify for hedge accounting. In this case the hedging instrument and the hedged item are reported independently as if there were no hedging relationship, which means that any derivatives are reported at fair value, with changes in fair value included in other financial income (expense).

As the Group may continue to apply the hedge accounting requirements of IAS 39 instead of those in IFRS 9 at the initial application of IFRS 9, the Group has chosen to continue to apply the hedge accounting requirements of IAS 39.

A cash flow hedge is a hedge of the exposure to variability in cash flows that is attributable to a particular risk associated with a recognized asset or liability or a highly probable forecast transaction and could affect profit or loss. The hedging instrument is recorded at fair value. The effective portion of the hedge is included in other comprehensive income and any ineffective portion is reported in other financial income (expense). If the hedging relationship is the hedge of the foreign currency risk of a firm commitment or highly probable transaction, when that transaction results in the recognition of a non-financial item, the cumulative changes in the fair value of the hedging instrument that have been recorded in other comprehensive income are included in the initial carrying value of the non-financial item at the date of recognition, or otherwise included in profit or loss when the hedged transaction affects net income.

For other hedged forecasted cash flows, the cumulative changes in the fair value of the hedging instrument that have been recorded in other comprehensive income are included in other financial income (expense) when the forecasted transaction affects net income.

Taxation
Income taxes include all taxes based upon the taxable profits of the Group. Other taxes not based on income, such as property and capital taxes, are included in the appropriate heading within the operating results.

Liabilities for income taxes, which could arise on the remittance of retained earnings, principally relating to subsidiaries, are only recognized where it is probable that such earnings will be remitted in the foreseeable future. Where the amount of tax liabilities is uncertain, accruals are recorded within income tax liabilities for management's best estimate of the ultimate liability that is expected to arise based on the specific circumstances and the Group's historical experience.

Deferred tax assets and liabilities are recognized on temporary differences between the tax bases of assets and liabilities and their carrying values. Deferred tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the unused tax losses can be utilized.

Current and deferred tax assets and liabilities are offset when the income taxes are levied by the same taxation authority and when there is a legally enforceable right to offset them. Deferred taxes are determined based on the currently enacted tax rates applicable in each tax jurisdiction where the Group operates.

Own equity instruments
The Group's holdings in its own equity instruments are recorded as a deduction from equity. The original purchase cost, consideration received for subsequent resale of these equity instruments and other movements are reported as changes in equity. The exercise of stock acquisition rights granted to directors and certain employees will result in the allotment from own equity instruments.

(4) Significant accounting policies
The Group applies the same significant accounting policies that are used for the previous fiscal year to the Consolidated Financial Statements, except for those stated in (5) Changes in accounting policies below.

(5) Changes in accounting policies
The Group has adopted IFRS 16 'Leases', including any consequential amendments to other standards, effective January 1, 2019. The nature and the effects of the changes from implementing IFRS 16 'Leases' most relevant to the Group's Consolidated Financial Statements are given below.

IFRS16 'Leases'
Effective January 1, 2019 the Group has implemented IFRS 16 'Leases'. IFRS 16 replaces existing leases guidance, including IAS 17 'Leases', and sets out the principles for recognition and measurement of leases. The new standard results in an increased volume of disclosure information in the consolidated financial statements. The main effect on the Group is that IFRS 16 introduces a single, on-balance sheet lease accounting model for lessees. It requires a lessee to recognize assets and liabilities for its leases unless practical expedients are applied for the recognition exemption. As a result, leased assets, including right-of-use assets, lease receivables and other assets totaling ¥ 15,203 million and lease liabilities totaling ¥ 14,553 million have been recorded on the balance sheet at January 1, 2019.

The application of the new standard results in the interest element of what was previously reported as operating lease costs being recorded as interest expenses. Given the leases involved and the current low interest rate environment, this effect is not material to the Group.

The main impact of the new standard on the statement of cash flows is that cash flows in respect of leases previously reported as operating leases are reported as part of cash flows from financing activities except for short-term lease payments, payments for leases of low-value assets and variable lease payments not included in the measurement of the lease liability from January 1, 2019. Previously these were included within cash flows from operating activities.

Transition approach
The Group has applied the cumulative catch-up method for the transition. Therefore, the cumulative effect of adopting IFRS 16 has been recognized as an adjustment to leased assets, including right-of-use assets, lease receivables and other assets totaling ¥ 15,203 million and lease liabilities totaling ¥ 14,553 million at January 1, 2019, with no restatement of comparative information. There is no impact on the opening balance of retained earnings at the date of initial application because the Group measures right-of-use assets at an amount equal to the lease liability. However, the Group has adjusted the lease liability by the amount of any prepaid or accrued lease payments relating to that lease recognized on the balance sheet immediately before the date of initial application. Except for this adjustment, there is no material impact on the Group's performance or financial position from the application of this standard.

Some practical expedients permitted by the standard are used, notably to not reassess upon transition whether an existing contract contains a lease, and the recognition exemptions for short-term leases and leases of low value assets.

Presentational changes
As a result of implementing IFRS 16, the Group has made a number of presentational changes in 2019, notably to present 'Right-of-use assets' as a separate line item in the balance sheet and to include lease liabilities in other current liabilities and other non-current liabilities.

(6) Future new and revised standards
The Group is currently assessing the potential impacts of new standards and interpretations that will be effective from January 1, 2020 and beyond. Based on the analysis to date, the Group does not anticipate that these will have a material impact on the Group's overall results and financial position.

2. Operating segment information

The Group has a single business of pharmaceuticals and does not have multiple operating segments. The Group's pharmaceuticals business consists of the research and development of new prescription medicines and the subsequent manufacturing, marketing and distribution activities. These functional activities are integrated and managed effectively.

Information on revenues by geographical area in millions of yen

	2019		2018	
	Sales	Royalties and other operating income	Sales	Royalties and other operating income
Japan	437,561	6,404	399,906	21,569
Overseas	151,335	90,884	127,939	30,374
of which Switzerland	134,330	87,731	109,938	24,250
Total	**588,896**	**97,288**	**527,844**	**51,943**

Information on revenues by major customers in millions of yen

	2019	2018
	Revenues	Revenues
F. Hoffmann-La Roche Ltd.	217,265	134,188
Alfresa Corporation	114,202	103,959
Mediceo Corporation	75,797	76,004

3. Revenue

Disaggregated revenue information in millions of yen

	2019			2018		
	Revenue from contracts with customers	Revenue from other sources	**Total**	Revenue from contracts with customers	Revenue from other sources	**Total**
Sales	585,320	3,576	**588,896**	525,643	2,202	**527,844**
Japan	437,561	-	**437,561**	399,906	-	**399,906**
Overseas	147,759	3,576	**151,335**	125,737	2,202	**127,939**
Royalties and other operating income	84,595	12,692	**97,288**	40,803	11,140	**51,943**
Royalty and profit-sharing income	63,862	12,645	**76,507**	12,942	11,140	**24,082**
Other operating income	20,733	47	**20,780**	27,861	-	**27,861**

The revenue from other sources primarily relates to collaboration income for which the counterparty is not considered a customer, such as income from profit-sharing arrangements and the gains or losses from hedging activities.

Contract balances in millions of yen

	December 31, 2019	January 1, 2019
Receivables-contracts with customers	170,837	162,879
Accounts receivable	139,649	150,804
Other current receivables	31,188	12,075
Contract assets	1,240	-
Contract liabilities	160	206

Contract assets generally increase when the Group transfers goods or services to a customer (excluding claims for which the right to remuneration is unconditional) before the customer pays the consideration or before the payment becomes due and decrease when the Group bills the customer.

Contract liabilities generally increase when the Group receives consideration from a customer prior to the transfer of goods or services to the customer and decrease when the Group meets its performance obligations.

Of the amount of revenue recognized for the year ended December 31, 2019, ¥41 million was included in the beginning balance of contract liabilities.

In 2019 there was revenue recognized of ¥80,846 million relating to performance obligations that were satisfied in previous periods, mainly in relation to royalty and milestone revenue.

Transaction price allocated to the remaining performance obligations

There are no material amounts of the total transaction price allocated to the remaining performance obligations which have an original expected duration of more than one year as of December 31, 2019. As a practical expedient, the Group does not disclose the information for remaining performance obligations which are part of contracts that have an original expected duration of one year or less.

There are no material amounts which are not included in the transaction price in the consideration from the contracts with customers.

4. Financing costs and other financial income (expense)

Financing costs in millions of yen

	2019	2018
Interest expense	-	(5)
Net interest cost of defined benefit plans	(88)	(53)
Interest expense on lease liabilities	(27)	-
Net other financing costs	(11)	(53)
Total financing costs	**(125)**	**(111)**

The implementation of IFRS 16 has resulted in part of what was previously reported as operating lease costs being recorded as interest expenses. Given the leases involved and the current low interest rate environment, this effect is not material to the Group.

Other financial income (expense) in millions of yen

	2019	2018
Dividend income from equity instruments measured at fair value through OCI	91	115
Net income from equity securities	**91**	**115**
Interest income from debt securities measured at fair value through OCI	20	9
Interest income from financial assets measured at amortized cost	89	74
Net interest income and income from debt securities	**109**	**83**
Foreign exchange gains (losses)	239	680
Gains (losses) on foreign currency derivatives	106	(429)
Net foreign exchange gains (losses)	**345**	**251**
Total other financial income (expense)	**545**	**449**

5. Other expense

Chugai filed an Advance Pricing Arrangement covering certain transactions with F. Hoffmann-La Roche Ltd. to the Japanese and Swiss tax authorities. In the first quarter of the year ended December 31, 2017, Chugai received a notice of agreement from both tax authorities which includes the instruction that the taxable income of Chugai shall be decreased by a certain amount and that of Roche shall be increased by the same amount in each fiscal year from 2016 to 2020, and if necessary, additional adjustments to the accounts shall be made in 2021.

As a result of this agreement, Chugai will transfer a part of the deducted amount of corporate and other taxes, to Roche as the estimated tax payable for Roche, in accordance with the license agreement between Chugai and Roche. The company has posted ¥3,124 million of adjustment from transfer pricing taxation.

6. Income taxes

Income tax expenses in millions of yen

	2019	2018
Current income taxes	(54,693)	(32,646)
Deferred taxes	4,360	4,276
Total income tax (expense)	**(50,333)**	**(28,370)**

Reconciliation of the Group's effective tax rate

	2019	2018
Weighted average expected tax rate	30.2%	30.3%
Tax effect of		
- Non-taxable income/non-deductible expenses	0.2%	0.4%
- Effect of changes in applicable tax rates on deferred tax balances	-%	0.0%
- Research and development tax credits	(5.3)%	(5.4)%
- Transfer pricing taxation related	(1.5)%	(2.2)%
- Other differences	0.6%	0.4%
Group's effective tax rate	**24.2%**	**23.4%**

Tax effects of other comprehensive income in millions of yen

	2019			2018		
	Pre-tax amount	Tax benefit	After-tax amount	Pre-tax amount	Tax benefit	After-tax Amount
Remeasurements of defined benefit plans	487	(158)	329	(3,566)	1,094	(2,472)
Financial assets measured at fair value through OCI	(578)	306	(272)	529	(166)	363
Cash flow hedges	(1,900)	583	(1,317)	(320)	95	(225)
Currency translation of foreign operations	(1,172)	-	(1,172)	(3,158)	-	(3,158)
Other comprehensive income	**(3,164)**	**731**	**(2,433)**	**(6,516)**	**1,024**	**(5,492)**

Income tax assets (liabilities) in millions of yen

	December 31, 2019	December 31, 2018
Current income taxes		
- Assets	0	3
- Liabilities	(41,047)	(19,567)
Net current income tax assets (liabilities)	**(41,046)**	**(19,564)**
Deferred taxes		
- Assets	42,680	35,568
- Liabilities	(9,304)	(9,031)
Net deferred tax assets (liabilities)	**33,376**	**26,537**

Current income taxes: movements in recognized net assets (liabilities) in millions of yen

	2019	2018
Net current income tax assets (liabilities) at January 1	(19,564)	(17,824)
Income taxes paid	34,782	31,565
(Charged) credited to the income statement	(54,693)	(32,646)
Currency translation effects and other	(1,571)	(659)
Net current income tax assets (liabilities) at December 31	**(41,046)**	**(19,564)**

Deferred taxes: movements in recognized net assets (liabilities) in millions of yen

	Property, plant and equipment and right-of-use assets	Intangible assets	Provisions	Employee benefits	Other temporary differences	Total
Year ended December 31, 2018						
At January 1, 2018	(19,002)	(3,155)	43	5,346	42,058	25,290
(Charged) credited to the income statement	(1,227)	32	2	253	5,216	4,276
(Charged) credited to other comprehensive income	-	-	-	1,094	595	1,690
(Charged) credited to Equity	-	-	-	-	(4,677)	(4,677)
Currency translation effects and other	9	(1)	(3)	(4)	(42)	(41)
At December 31, 2018	**(20,219)**	**(3,124)**	**42**	**6,689**	**43,149**	**26,537**
Year ended December 31, 2019						
At January 1, 2019	(20,219)	(3,124)	42	6,689	43,149	26,537
Impact of changes in accounting policies	(4,593)	-	-	-	4,593	-
At January 1, 2019 (revised)	(24,812)	(3,124)	42	6,689	47,742	26,537
(Charged) credited to the income statement	(1,960)	148	88	(1,331)	7,416	4,360
(Charged) credited to other comprehensive income	-	-	-	(158)	2,506	2,348
Currency translation effects and other	(1)	(0)	(1)	(1)	135	131
At December 31, 2019	**(26,773)**	**(2,976)**	**129**	**5,198**	**57,798**	**33,376**

Other temporary differences mainly relate to prepaid expenses, amortization of deferred assets and accrued expenses.

Deferred tax assets are not recognized for deductible temporary differences of ¥1,157 million (2018: ¥1,749 million). Deferred tax assets are recognized for tax losses carried forward only to the extent that realization of the related tax benefit is probable.

Unrecognized tax losses: expiry in millions of yen

	2019	2018
Less than one year	-	-
Over one year and less than five years	235	242
Over five years	61	0
Tax losses not recognized in deferred tax assets	**296**	**242**

Deferred tax assets for unused tax credits are recognized only to the extent that realization of the related tax benefit is probable.

Unrecognized unused tax credits: expiry in millions of yen

	2019	2018
Less than one year	-	-
Over one year and less than five years	-	-
Over five years	110	111
Unused tax credits not recognized in deferred tax assets	**110**	**111**

Deferred tax liabilities have not been established for the withholding tax and other taxes that would be payable on the unremitted earnings of wholly owned foreign subsidiaries of the Group, where such amounts are currently regarded as permanently reinvested. The temporary differences relating to the unremitted earnings were ¥2,473 million (2018: ¥2,107 million).

7. Property, plant and equipment

Property, plant and equipment: movements in carrying value of assets in millions of yen

	Land	Buildings and land improvements	Machinery and equipment	Construction in progress	Total
At January 1, 2018					
Cost	9,141	119,981	186,617	32,116	347,854
Accumulated depreciation and impairment	(28)	(62,044)	(114,212)	-	(176,285)
Net book value	**9,112**	**57,937**	**72,404**	**32,116**	**171,569**
Year ended December 31, 2018					
At January 1, 2018	9,112	57,937	72,404	32,116	171,569
Additions	-	13	633	71,197	71,843
Disposals	-	(94)	(299)	-	(394)
Transfers	43,040	16,506	38,938	(98,484)	-
Depreciation charge	-	(4,232)	(10,358)	-	(14,590)
Impairment charge	-	-	(59)	-	(59)
Other	-	-	(5,791)	-	(5,791)
Currency translation effects	-	(45)	(120)	(24)	(189)
At December 31, 2018	**52,152**	**70,085**	**95,347**	**4,804**	**222,388**
Cost	52,169	135,620	211,362	4,804	403,955
Accumulated depreciation and impairment	(16)	(65,535)	(116,015)	-	(181,566)
Net book value	**52,152**	**70,085**	**95,347**	**4,804**	**222,388**
Year ended December 31, 2019					
At January 1, 2019	52,152	70,085	95,347	4,804	222,388
Impact of changes in accounting policies	-	-	(279)	-	(279)
At January 1, 2019 (revised)	52,152	70,085	95,068	4,804	222,109
Additions	-	18	278	53,701	53,997
Disposals	(14)	(192)	(357)	-	(563)
Transfers	-	1,821	20,614	(22,435)	-
Depreciation charge	-	(6,387)	(11,391)	-	(17,778)
Impairment charge	-	-	(1,252)	-	(1,252)
Other	-	-	(917)	-	(917)
Currency translation effects	-	(23)	(11)	(2)	(37)
At December 31, 2019	**52,139**	**65,322**	**102,030**	**36,068**	**255,559**
Cost	52,155	136,642	224,929	36,068	449,794
Accumulated depreciation and impairment	(16)	(71,320)	(122,899)	-	(194,235)
Net book value	**52,139**	**65,322**	**102,030**	**36,068**	**255,559**

In 2019, no borrowing costs were capitalized as property, plant and equipment (2018: none).

Impairment charge

The carrying value was reduced to the value in use as the recoverable amount of certain assets was less than the carrying value.

Classification of impairment of property, plant and equipment in millions of yen

	2019	2018
Cost of sales	1,252	59
Marketing and distribution	-	-
Research and development	-	-
General and administration	-	-
Total impairment charge	**1,252**	**59**

Commitments
The Group has commitments for the purchase or construction of property, plant and equipment after the end of the year ended December 31, 2019 totaling ¥93,579 million (2018: ¥6,362 million).

8. Leases

The impact of IFRS 16 'Leases' on the Group consolidated financial statements is given in Note 1(5) "Changes in accounting policies" above. The comparative 2018 financial information has not been restated following the cumulative catch-up method for the transition applied by the Group. There is no significant difference between the amount calculated by discounting the sum of the future minimum lease payments under non-cancellable operating leases disclosed in the consolidated financial statements for the year ended December 31, 2018 by the incremental borrowing rate as of the date of initial application, and the lease liability recorded as adjustments at the beginning of the year ended December 31, 2019.

The Group enters into leasing transactions as a lessee mainly for reasons of convenience and flexibility. The Group has good cash generation ability and it enjoys strong long-term investment grade credit ratings. Therefore it typically does not enter into leasing arrangements for financing considerations. The main areas of leases that the Group has entered into are for offices and cars.

The right-of-use assets reported for the Group's leases are shown in the table below. Additions to the right-of-use assets during 2019 were ¥8,098 million.

Right-of-use assets: movements in carrying value of assets in millions of yen

	Buildings and land improvements	Machinery and equipment	Total
At January 1, 2019	-	-	-
Cumulative catch-up for previously reported operating leases on implementation of IFRS 16	13,301	1,902	15,203
At January 1, 2019 (revised)	**13,301**	**1,902**	**15,203**
Depreciation charge	(5,298)	(733)	(6,031)
At December 31, 2019	**8,481**	**1,267**	**9,749**

Lease liabilities are presented in other current liabilities and other non-current liabilities. The amount of current lease liabilities and non-current lease liabilities are given in Note 19 and 21 respectively. Interest expense on the lease liability during 2019 was ¥27 million. The maturity analysis of lease liabilities is shown in the table below.

Contractual maturities of lease liabilities in millions of yen

	Carrying value	Total	Less than 1 year	1-2 years	2-5 years	Over 5 years
At December 31, 2019						
Lease liabilities	12,751	12,792	7,278	4,007	1,377	130

Short-term leases and leases of low-value assets are accounted for using the recognition exemption permitted by IFRS 16. Expenses for short-term leases are recognized on a straight-line basis and mainly include short-term leases for parking lots. The total amount reported in 2019 was ¥792 million. Expenses for leases of low-value assets are recognized on a straight-line basis and mainly include IT equipment. The total amount reported in 2019 was ¥381 million. Expenses for variable lease payments not included in the measurement of lease liabilities reported in 2019 was ¥137 million. The Group did not enter into any sale and leaseback transactions.

The major cash flows in respect of leases where the Group is the lessee are shown in the table below.

Leases: cash flows in millions of yen

	2019
Included in cash flows from operating activities	(1,310)
Included in cash flows from financing activities	(8,888)
Total lease payments	**(10,197)**

Cash flows from operating activities include cash flows from short-term leases, leases of low-value assets and variable lease payments. Cash flows from financing activities include the payment of interest and the principal portion of lease liabilities as well as prepayments made before the lease commencement date.

9. Intangible assets

Intangible assets: movements in carrying value of assets in millions of yen

	Product intangibles: in use	Product intangibles: not available for use	Marketing intangibles: in use	Technology intangibles: in use	Total
At January 1, 2018					
Cost	19,916	21,241	4,382	103	45,641
Accumulated amortization and impairment	(14,604)	(8,631)	(1,259)	(69)	(24,564)
Net book value	**5,312**	**12,609**	**3,123**	**33**	**21,078**
Year ended December 31, 2018					
At January 1, 2018	5,312	12,609	3,123	33	21,078
Additions	148	5,178	2,577	564	8,468
Disposals	-	-	-	-	-
Transfers	1,562	(1,562)	-	-	-
Amortization charge	(916)	-	(818)	(254)	(1,988)
Impairment charge	(78)	(4,765)	-	-	(4,844)
Currency translation effects	(13)	(2)	-	-	(15)
At December 31, 2018	**6,015**	**11,457**	**4,883**	**344**	**22,699**
Cost	21,409	20,662	6,887	667	49,625
Accumulated amortization and impairment	(15,394)	(9,205)	(2,004)	(323)	(26,927)
Net book value	**6,015**	**11,457**	**4,883**	**344**	**22,699**
Year ended December 31, 2019					
At January 1, 2019	6,015	11,457	4,883	344	22,699
Additions	190	3,187	2,727	-	6,104
Disposals	-	-	-	-	-
Transfers	2,182	(2,182)	-	-	-
Amortization charge	(964)	-	(1,377)	(251)	(2,592)
Impairment charge	-	(2,577)	(87)	-	(2,664)
Currency translation effects	(4)	(2)	-	-	(6)
At December 31, 2019	**7,418**	**9,883**	**6,146**	**92**	**23,540**
Cost	23,677	21,592	9,614	667	55,550
Accumulated amortization and impairment	(16,259)	(11,708)	(3,468)	(575)	(32,010)
Net book value	**7,418**	**9,883**	**6,146**	**92**	**23,540**

Significant intangible assets

The product intangibles in use and not available for use are mainly acquired through in-licensing agreements of products with related parties. The remaining amortization periods for product intangibles in use are from 1 to 15 years.

Impairment charge

Impairment charge in each year was mainly related to the cessation of R&D projects and the uncertainty regarding expected profits.

Classification of amortization and impairment expenses in millions of yen

	2019		2018	
	Amortization	Impairment	Amortization	Impairment
Cost of sales	1,062	87	1,014	-
Marketing and distribution	256	-	133	-
Research and development	632	2,577	428	4,844
General and administration	642	-	413	-
Total	**2,592**	**2,664**	**1,988**	**4,844**

Internally generated intangible assets
The Group currently has no internally generated intangible assets from development as the criteria for the recognition as an asset are not met.

Intangible assets with indefinite useful lives
The Group currently has no intangible assets with indefinite useful lives.

Product intangibles not available for use
These mostly represent in-process research and development assets acquired either through in-licensing arrangements or separate purchases. Due to the inherent uncertainties in the research and development processes, intangible assets not available for use are particularly at risk of impairment if the project is not expected to result in a commercialized product.

Impairment of intangible assets
Impairment charges arise from changes in the estimates of the future cash flows expected to result from the use of the asset and its eventual disposal. Factors such as the presence or absence of competition, technical obsolescence or lower than anticipated sales for products with capitalized rights could result in shortened useful lives or impairment.

Potential commitments from alliance collaborations
The Group is party to in-licensing and similar arrangements with its alliance partners. These arrangements may require the Group to make certain milestone or other similar payments dependent upon the achievement of agreed objectives or performance targets as defined in the collaboration agreements.

The Group's current estimate of future commitments for such payments is set out in the table below. These figures are undiscounted and are not risk adjusted, meaning that they include all such potential payments that can arise assuming all projects currently in development are successful. The timing is based on the Group's current best estimate.

Potential future collaboration payments at December 31, 2019 in millions of yen

	Third party	Related party	Total
Within one year	522	3,117	3,639
Between one and two years	400	4,785	5,185
Between two and three years	1,736	2,180	3,916
Total	**2,658**	**10,082**	**12,740**

10. Financial non-current assets

Financial non-current assets in millions of yen

	December 31, 2019	December 31, 2018
Financial assets measured at fair value through OCI	2,958	9,723
Total financial non-current assets	**2,958**	**9,723**

Financial non-current assets are equity instruments held not for pure investment purposes, but for the Group's business purposes to maintain and strengthen the relationship with business partners. Therefore, the Group has designated all equity instruments as measured at fair value through OCI.

11. Other non-current assets

Other non-current assets in millions of yen

	December 31, 2019	December 31, 2018
Long-term prepaid expenses	18,926	23,654
Other assets	5,824	5,422
Total other non-current assets	**24,750**	**29,077**

Long-term prepaid expenses are mainly payments to related parties for start-up and validation costs at plants used for outsourcing to the related parties.

12. Inventories

Inventories in millions of yen

	December 31, 2019	December 31, 2018
Raw materials and supplies	57,390	42,199
Work in process	165	118
Intermediates	45,870	53,682
Finished goods	66,570	65,037
Provision for slow-moving and obsolete inventory	(1,873)	(1,676)
Total inventories	**168,122**	**159,360**

Inventories expensed through cost of sales totaled ¥250,924 million (2018: ¥245,919 million). Inventory write-downs during the year resulted in an expense of ¥1,053 million (2018: ¥1,051 million).

13. Accounts receivable

Accounts receivable in millions of yen

	December 31, 2019	December 31, 2018
Trade receivables – third party	106,789	125,478
Trade receivables – related party	32,848	25,307
Notes receivables	12	19
Other receivables – third party (Contracts with customers)	319	1,105
Other receivables – related party (Contracts with customers)	30,869	10,970
Other receivables – third party	4,070	6,717
Other receivables – related party	6,743	9,967
Allowances for doubtful accounts	(10)	(7)
Total accounts receivable	**181,641**	**179,556**

14. Marketable securities

Marketable securities in millions of yen

	December 31, 2019	December 31, 2018
Financial assets measured at fair value through OCI		
Money market instruments	119,994	94,000
Debt securities	8,751	8,001
Financial assets measured at amortized cost		
Time accounts over three months	373	532
Total marketable securities	**129,117**	**102,533**

Marketable securities are held for fund management purposes. Money market instruments are mainly certificates of deposit, cash in trust and commercial paper. Debt securities are mainly corporate bonds.

15. Cash and cash equivalents

Cash and cash equivalents in millions of yen

	December 31, 2019	December 31, 2018
Cash - cash in hand and in current or call accounts	195,514	140,912
Cash equivalents - time accounts with a maturity of three months or less	8,427	5,948
Total cash and cash equivalents	**203,941**	**146,860**

16. Other current assets

Other current assets in millions of yen

	December 31, 2019	December 31, 2018
Derivative financial instruments	5,052	2,204
Total financial current assets	**5,052**	**2,204**
Prepaid expenses	11,807	9,577
Total non-financial current assets	**11,807**	**9,577**
Total other current assets	**16,858**	**11,781**

17. Debt

Debt: movements in carrying value of recognized liabilities in millions of yen

	2019	2018
At January 1	214	336
Increase in debt	-	12
Decrease in debt	(214)	(134)
At December 31	**-**	**214**
Finance lease obligations	-	214
Total debt	**-**	**214**
Long-term debt	-	82
Short-term debt	-	133
Total debt	**-**	**214**

Lease liabilities are presented in other current liabilities and other non-current liabilities following the implementation of IFRS 16.

18. Provisions and contingent liabilities

Provisions: movements in recognized liabilities in millions of yen

	Environmental provisions	Other provisions	Total
Year ended December 31, 2018			
At January 1, 2018	311	1,808	2,120
Additional provisions created	-	36	36
Unused amounts reversed	-	-	-
Utilized	(29)	(51)	(80)
Other	-	(3)	(3)
At December 31, 2018	**282**	**1,791**	**2,073**
Long-term provisions	281	1,791	2,072
Short-term provisions	1	-	1
At December 31, 2018	**282**	**1,791**	**2,073**
Year ended December 31, 2019			
At January 1, 2019	282	1,791	2,073
Additional provisions created	-	374	374
Unused amounts reversed	(0)	-	(0)
Utilized	(2)	(109)	(110)
Other	-	16	16
At December 31, 2019	**280**	**2,073**	**2,353**
Long-term provisions	280	2,068	2,348
Short-term provisions	-	4	4
At December 31, 2019	**280**	**2,073**	**2,353**
Expected outflow of resources			
Within one year	-	4	4
Between one to two years	-	327	327
Between two to three years	-	211	211
More than three years	280	1,531	1,811
At December 31, 2019	**280**	**2,073**	**2,353**

Environmental provisions

Provisions for environmental matters include various separate environmental issues. By their nature the amounts and timings of any outflows are difficult to predict. Significant provisions are discounted where the time value of money is material.

Other provisions

Other provisions arise mainly from expected decommissioning and removal costs with respect to property, plant and equipment. The timings of cash outflows are by their nature uncertain. Significant provisions are discounted where the time value of money is material.

Contingent liabilities

The operations and earnings of the Group continue, from time to time and in varying degrees, to be affected by political, legislative, fiscal and regulatory developments, including those relating to environmental protection. The industries in which the Group operates are also subject to other risks of various kinds. The nature and frequency of these developments and events, not all of which are covered by insurance, as well as their effect on future operations and earnings, are not predictable.

The Group has entered into strategic alliances with various companies in order to gain access to potential new products or to utilize other companies to help develop the Group's own potential new products. Potential future payments may become due to certain collaboration partners achieving certain milestones as defined in the collaboration agreements. The Group's best estimates for future commitment payments are given in Note 9.

19. Other non-current liabilities

Other non-current liabilities in millions of yen

	December 31, 2019	December 31, 2018
Deferred income	643	727
Lease liabilities	5,489	-
Other long-term liabilities	783	1,219
Total other non-current liabilities	**6,914**	**1,946**

Lease liabilities are presented in other current liabilities and other non-current liabilities following the implementation of IFRS 16.

20. Accounts payable

Accounts payable in millions of yen

	December 31, 2019	December 31, 2018
Trade payables – third party	7,403	5,991
Trade payables – related party	40,323	29,943
Other taxes payable	8,612	6,600
Accounts payable purchase of property, plant and equipment	6,625	5,637
Other payables – third party	4,998	4,909
Other payables – related party	9,674	18,626
Total accounts payable	**77,635**	**71,706**

21. Other current liabilities

Other current liabilities in millions of yen

	December 31, 2019	December 31, 2018
Deferred income	252	239
Lease liabilities	7,263	-
Accrued bonus and related items	17,529	14,024
Derivative financial instruments	6,848	2,096
Other accrued liabilities	28,690	27,451
Total other current liabilities	**60,582**	**43,810**

Lease liabilities are presented in other current liabilities and other non-current liabilities following the implementation of IFRS 16.

22. Equity attributable to Chugai shareholders

Changes in equity attributable to Chugai shareholders in millions of yen

	Share capital	Capital surplus	Retained earnings	Other reserves			Total
				Fair value reserve	Hedging reserve	Translation reserve	
Year ended December 31, 2018							
At January 1, 2018	72,970	64,815	550,974	6,068	281	(3,183)	691,924
Impact of changes in accounting policies	-	-	10,606	-	-	-	10,606
At January 1, 2018 (revised)	72,970	64,815	561,580	6,068	281	(3,183)	702,530
Net income attributable to Chugai shareholders	-	-	92,488	-	-	-	92,488
Financial assets measured at fair value through OCI							
- Equity instruments measured at fair value through OCI	-	-	-	528	-	-	528
- Debt securities at fair value through OCI	-	-	-	1	-	-	1
- Income taxes	-	-	-	(166)	-	-	(166)
Cash flow hedges							
- Effective portion of fair value gains (losses) taken to equity	-	-	-	-	(441)	-	(441)
- Transferred to income statement	-	-	-	-	42	-	42
- Transferred to initial carrying amount of hedged items	-	-	-	-	79	-	79
- Income taxes	-	-	-	-	95	-	95
Currency translation of foreign operations							
- Exchange differences	-	-	-	-	-	(3,158)	(3,158)
- Non-controlling interests	-	-	-	-	-	82	82
Defined benefit plans							
- Remeasurement gains (losses)	-	-	(3,566)	-	-	-	(3,566)
- Income taxes	-	-	1,094	-	-	-	1,094
Other comprehensive income, net of tax	**-**	**-**	**(2,472)**	**363**	**(225)**	**(3,077)**	**(5,410)**
Total comprehensive income	**-**	**-**	**90,016**	**363**	**(225)**	**(3,077)**	**87,078**
Dividends	-	-	(35,003)	-	-	-	(35,003)
Equity compensation plans	31	(97)	-	-	-	-	(66)
Own equity instruments	-	1,325	-	-	-	-	1,325
Transfer from other reserves to retained earnings	-	-	1,498	(1,498)	-	-	-
At December 31, 2018	**73,000**	**66,043**	**618,091**	**4,933**	**57**	**(6,260)**	**755,864**

Changes in equity attributable to Chugai shareholders in millions of yen

	Share capital	Capital surplus	Retained earnings	Other reserves			Total
				Fair value reserve	Hedging reserve	Translation reserve	
Year ended December 31, 2019							
At January 1, 2019	73,000	66,043	618,091	4,933	57	(6,260)	755,864
Net income attributable to Chugai shareholders	-	-	157,560	-	-	-	157,560
Financial assets measured at fair value through OCI							
- Equity instruments measured at fair value through OCI	-	-	-	(554)	-	-	(554)
- Debt securities at fair value through OCI	-	-	-	(24)	-	-	(24)
- Income taxes	-	-	-	306	-	-	306
Cash flow hedges							
- Effective portion of fair value gains (losses) taken to equity	-	-	-	-	(1,482)	-	(1,482)
- Transferred to income statement	-	-	-	-	(2)	-	(2)
- Transferred to initial carrying amount of hedged items	-	-	-	-	(416)	-	(416)
- Income taxes	-	-	-	-	583	-	583
Currency translation of foreign operations							
- Exchange differences	-	-	-	-	-	(1,172)	(1,172)
- Non-controlling interests	-	-	-	-	-	-	-
Defined benefit plans							
- Remeasurement gains (losses)	-	-	487	-	-	-	487
- Income taxes	-	-	(158)	-	-	-	(158)
Other comprehensive income, net of tax	**-**	**-**	**329**	**(272)**	**(1,317)**	**(1,172)**	**(2,433)**
Total comprehensive income	**-**	**-**	**157,889**	**(272)**	**(1,317)**	**(1,172)**	**155,127**
Dividends	-	-	(56,373)	-	-	-	(56,373)
Equity compensation plans	16	52	-	-	-	-	68
Own equity instruments	-	941	-	-	-	-	941
Changes in non-controlling interests	-	-	(1,662)	-	-	19	(1,643)
Transfer from other reserves to retained earnings	-	-	4,131	(4,131)	-	-	-
At December 31, 2019	**73,016**	**67,037**	**722,076**	**530**	**(1,260)**	**(7,413)**	**853,985**

Share capital (Number of shares)

	December 31, 2019	December 31, 2018
Authorized shares	799,805,050	799,805,050
Issued shares (Non-par value common stock)	559,685,889	559,685,889

Dividends

Date of resolution	Type of shares	Total dividends (millions of yen)	Dividend per share (yen)	Record date	Effective date
March 22, 2018 (Resolution of the Annual General Meeting of shareholders)	Common stock	18,044	33	December 31, 2017	March 23, 2018
July 26, 2018 (Board resolution)	Common stock	16,960	31	June 30, 2018	August 31, 2018
March 28, 2019 (Resolution of the Annual General Meeting of shareholders)	Common stock	30,097	55	December 31, 2018	March 29, 2019
July 25, 2019 (Board resolution)	Common stock	26,275	48	June 30, 2019	August 30, 2019
March 30, 2020 (Resolution of the Annual General Meeting of shareholders)	Common stock	50,372	92	December 31, 2019	March 31, 2020

Own equity instruments

	Number of shares	
	2019	2018
At January 1	12,459,413	12,909,947
Issue of common stocks	-	-
Exercises of equity compensation plans	(259,500)	(393,800)
Purchase/Disposal of own equity instruments	5,341	3,566
Grant of restricted stock	(42,900)	(60,300)
At December 31	**12,162,354**	**12,459,413**
Book value (millions of yen)	**28,506**	**29,190**

Other reserves

Fair value reserve: The fair value reserve represents the cumulative net change in the fair value of financial assets measured at fair value through OCI until the asset is sold, impaired or otherwise disposed of.

Hedging reserve: The hedging reserve represents the effective portion of the cumulative net change in the fair value of cash flow hedging instruments related to hedged transactions that have not yet occurred.

Translation reserve: The translation reserve represents the cumulative currency translation differences relating to the consolidation of foreign subsidiaries of the Group that use functional currencies other than the Japanese yen.

23. Non-controlling interests

Changes in equity attributable to non-controlling interests in millions of yen

	2019	2018
At January 1	664	973
Net income attributable to non-controlling interests	-	591
Currency translation of foreign operations	-	(82)
Other comprehensive income, net of tax	**-**	**(82)**
Total comprehensive income	**-**	**509**
Changes in non-controlling interests	(664)	-
Dividends to non-controlling shareholders	-	(817)
At December 31	**-**	**664**

Chugai sanofi-aventis S.N.C. became a wholly owned subsidiary of Chugai Pharma Europe Ltd. in January 2019. As a result, non-controlling interests decreased by ¥664 million in 2019, reducing the balance to zero.

24. Employee benefits

Employee benefits expense in millions of yen

	2019	2018
Wages and salaries	77,496	74,551
Social security costs	9,201	9,064
Defined contribution plans	992	973
Operating expenses for defined benefit plans	4,369	4,427
Equity compensation plans	309	286
Other employee benefits	9,374	4,235
Employee benefits expense included in operating results	**101,742**	**93,535**
Net interest cost of defined benefit plans	88	53
Total employee benefits expense	**101,830**	**93,588**

Other employee benefits consist mainly of welfare costs and expenses related to an early retirement incentive program.

25. Post-employment benefits plans

Post-employment benefits plans are classified as “defined contribution plans” if the Group pays fixed contributions into third-party financial institutions and will have no further legal or constructive obligation to pay further contributions. All other plans are classified as “defined benefit plans”, even if Chugai’s potential obligation is relatively minor or has a relatively remote possibility of arising.

Employees are covered by defined contribution and defined benefit plans sponsored by Group companies, most of which are classified as defined benefit plans.

A resolution was passed in the 98th Annual General Meeting of shareholders held in March 2009 to abolish the retirement benefits system for directors. In addition, a resolution was passed in the 95th Annual General Meeting of shareholders held in March 2006 to abolish the retirement benefits system for outside directors and audit & supervisory board members (including outside audit & supervisory board members).

Defined contribution plans

Defined contribution plans are funded through payments by the Group to funds administered by third parties. The Group’s expenses for these plans were ¥992 million (2018: ¥973 million).

Defined benefit plans
The Group has defined benefit plans mainly comprising a corporate pension fund and a lump-sum retirement benefit plan. Under the corporate pension fund, employees can receive a lump-sum payment based on the number of accumulated points received during their years of service. Employees with over a certain period of service can receive part of or all of the payment as certain annuity or life annuity. Under the lump-sum retirement benefit plan, employees can receive a lump-sum payment based on the number of accumulated points received during their years of service. A retirement benefit trust has been established for the lump-sum retirement benefit plan. Certain employees may be entitled to additional special retirement benefits apart from the defined benefit plans based on the conditions under which termination occurs.

The corporate pension fund and retirement benefit plan trust are independent of the Group and are funded only by payments from the Group.

A pension asset management strategy is developed to optimize expected returns and to manage risks through adopting investment strategies from a long-term perspective. For this purpose, the Group focusses on long-term objectives which are not influenced by fluctuations in short-term yields, and maintains a well-diversified portfolio.

The funding status is closely monitored at the corporate level and valuations at the balance sheet date are carried out annually. Although the financial position of the Group's pension fund is assessed to be sound, the Group has introduced risk-based contributions to prepare for risks that may arise in the future.

The defined benefit obligation is calculated using the projected unit credit method. If potential assets arise since defined benefit plans are over-funded, the recognition of pension assets is limited to the present value of any economic benefits available from refunds from the plans or reductions in future contributions to the plan.

Defined benefit plans: income statement in millions of yen

	2019	2018
Current service cost	4,369	4,427
Total operating expenses	**4,369**	**4,427**
Net interest cost of defined benefit plans	88	53
Total expense recognized in income statement	**4,457**	**4,479**

Defined benefit plans: funding status in millions of yen

	December 31, 2019	December 31, 2018
Fair value of plan assets	88,264	76,157
Defined benefit obligation	(95,359)	(90,829)
Over (under) funding	**(7,094)**	**(14,671)**
Defined benefit plan assets	-	-
Defined benefit plan liabilities	(7,094)	(14,671)
Net recognized asset (liability)	**(7,094)**	**(14,671)**

Defined benefit plans: fair value of plan assets in millions of yen

	2019	2018
At January 1	76,157	78,516
Interest income on plan assets	525	545
Remeasurements on plan assets	4,453	(2,227)
Currency translation effects	(3)	(8)
Employer contributions	11,223	2,442
Benefits paid – funded plans	(4,092)	(3,112)
At December 31	**88,264**	**76,157**
Composition of plan assets		
- Equity securities	13,188	10,640
- Debt securities	54,109	49,035
- Cash and cash equivalents	9,573	7,114
- Other investments	11,394	9,368
Total plan assets	**88,264**	**76,157**

Equity securities and debt securities have quoted market prices (Level 1 of fair value hierarchy).

In 2019, a contribution of ¥8,967 million was made, comprising additional contributions to the retirement benefit trust under the lump-sum retirement benefit plan and risk-based contributions to the corporate pension fund under the corporate pension fund plan, in addition to the provision of standard contributions.

Defined benefit plans: present value of defined benefit obligation in millions of yen

	2019	2018
At January 1	90,829	87,809
Current service cost	4,369	4,427
Interest cost	612	597
Remeasurements – demographic assumption	908	991
Remeasurements – financial assumptions	2,701	153
Remeasurements – experience adjustments	359	197
Currency translation effects	(11)	(23)
Benefits paid – funded plans	(4,408)	(3,322)
At December 31	**95,359**	**90,829**
Duration in years	15.6	15

Actuarial assumptions

Actuarial assumptions are unbiased and mutually compatible estimates of variables that determine the ultimate cost of providing post-employment benefits. They are set on an annual basis by the responsible departments of the Group based on advice from actuaries. Actuarial assumptions consist of demographic assumptions on matters such as mortality and employee turnover, and financial assumptions on matters such as interest rates.

Demographic assumptions: Demographic assumptions relate to mortality and employee turnover rates. Mortality rates are based on the standard mortality rate stated in the Ordinance for Enforcement of the Defined-Benefit Corporate Pension Act. Rates of employee turnover are based on historical behavior within the Group companies.

Financial assumptions: Discount rates are determined mainly with reference to interest rates on high-quality corporate bonds and reflect the period over which the obligations are to be settled.

	December 31, 2019	December 31, 2018
Discount rates (%)	0.51	0.69

Defined benefit plans: sensitivity of defined benefit obligation to actuarial assumption in millions of yen
The impact resulting from changes of actuarial assumption on the defined benefit obligation is shown in the table below. It is based on the assumption that variables other than the stated assumption used for the calculation are held constant.

	2019
Discount rates	
- 0.25% increase	(3,696)
- 0.25% decrease	3,942
Life expectancy	
- 1 year increase	2,186

Future cash flows
Based on the most recent actuarial valuations, the Group expects that employer contributions for defined benefit plans in 2020, including risk-based contributions, will be approximately ¥4,600 million.

26. Equity compensation plans

The Group operates equity-settled equity compensation plans for directors and certain employees. IFRS 2 "Share-based Payment" requires that the value of share-based payments be estimated based on the fair value at grant date and recorded as an expense over the vesting period. Effective since 2017, for the purpose of further promoting shared value with shareholders and providing an incentive to sustainably increase the Group's corporate value, strengthening linkage between compensation and mid- to long-term business performance, a restricted stock compensation plan (the "Compensation Plan") was introduced in place of the existing stock option compensation plans.

Expenses for equity compensation plans in millions of yen

	2019	2018
Cost of sales	1	1
Marketing and distribution	25	29
Research and development	59	60
General and administration	215	192
Total	**300**	**282**
Equity-settled plans		
- Chugai common stock options	-	52
- Chugai stock options as stock-based compensation	-	-
- Tenure-based restricted stock	224	158
- Performance-based restricted stock	76	72

Cash inflow from equity compensation plans in millions of yen

	2019	2018
Equity-settled plans		
- Exercises of Chugai common stock options	735	996
- Exercises of Chugai stock options as stock-based compensation	-	0

(1) Stock options

Chugai common stock options

The Group has issued stock acquisition rights to directors and certain employees as common stock options since 2003. Each right entitles the holder to purchase 100 Chugai shares at a specified exercise price. The rights are non-tradable and have an exercise period of around ten years after receiving the rights under the condition of approximately two years of continuous service of the holder after the grant date.

Chugai common stock options – movement in number of rights outstanding

	2019		2018	
	Number of rights	Weighted average exercise price (yen)	Number of rights	Weighted average exercise price (yen)
Outstanding at January 1	7,991	298,489	11,727	288,337
Granted	-	-	-	-
Forfeited	-	-	-	-
Exercised	(2,595)	283,054	(3,736)	266,623
Expired	(10)	169,600	-	-
Outstanding at December 31	**5,386**	**306,166**	**7,991**	**298,489**
- of which exercisable	5,386	306,166	7,991	298,489

Chugai common stock options – terms of rights outstanding at December 31, 2019

	Rights outstanding			Rights exercisable	
Year of grant	Number outstanding	Weighted average years remaining contractual life	Weighted average exercise price (yen)	Number exercisable	Weighted average exercise price (yen)
2010	76	0.31	188,100	76	188,100
2011	30	1.40	139,700	30	139,700
2012	778	2.31	152,800	778	152,800
2013	764	3.32	250,000	764	250,000
2014	1,065	4.31	267,400	1,065	267,400
2015	1,324	5.31	400,700	1,324	400,700
2016	1,349	6.31	374,600	1,349	374,600
Total	**5,386**	**4.55**	**306,166**	**5,386**	**306,166**

Chugai stock options as stock-based compensation

The Group has issued stock acquisition rights to directors as stock options as stock-based compensation since 2009 in lieu of the retirement benefit system for directors which was abolished. Each right entitles the holder to purchase 100 Chugai shares at an exercise price of ¥100. The rights are non-tradable and have an exercise period of 30 years after receiving the rights, which may be vested upon the holder's retirement as a director of Chugai.

Chugai stock options as stock-based compensation – movement in number of rights outstanding

	2019		2018	
	Number of rights	Weighted average exercise price (yen)	Number of rights	Weighted average exercise price (yen)
Outstanding at January 1	3,783	100	3,985	100
Granted	-	-	-	-
Forfeited	-	-	-	-
Exercised	-	-	(202)	100
Expired	-	-	-	-
Outstanding at December 31	**3,783**	**100**	**3,783**	**100**
- of which exercisable	-	-	-	-

Chugai stock options as stock-based compensation – terms of rights outstanding at December 31, 2019

Year of grant	Rights outstanding			Rights exercisable	
	Number outstanding	Weighted average years remaining contractual life	Weighted average exercise price (yen)	Number exercisable	Weighted average exercise price (yen)
2009	519	19.31	100	-	-
2010	579	20.31	100	-	-
2011	672	21.40	100	-	-
2012	659	22.31	100	-	-
2013	414	23.32	100	-	-
2014	383	24.31	100	-	-
2015	261	25.31	100	-	-
2016	296	26.31	100	-	-
Total	**3,783**	**22.27**	**100**	**-**	**-**

Exercise of stock acquisition rights

	2019		2018	
	Number of rights	Weighted average share price (yen)	Number of rights	Weighted average share price (yen)
Chugai common stock options	2,595	8,006	3,736	6,158
Chugai stock options as stock-based compensation	-	-	202	5,380

(2) Restricted stock compensation plan

Under the Compensation Plan, the restricted stocks to be provided consist of "tenure-based restricted stock" for Eligible Directors, as well as certain employees, which requires continuous service for a certain period for Chugai, and "performance-based restricted stock" for only Eligible Directors which requires the attainment of Chugai's mid- to long-term business performance target in addition to the aforementioned continuous service. The Eligible Directors and employees, shall make in–kind contribution of all monetary compensation claims or monetary claims to be provided by Chugai according to the Compensation Plan, and shall, in return, receive shares of common stock of Chugai that will be issued or disposed of by Chugai.

For the disposal of shares of common stocks of Chugai under the Compensation Plan, Chugai and each Eligible Directors and employees, shall make an agreement on allotment of restricted stocks including that (1) The Eligible Directors and employees, shall not transfer, create a security interest on, or otherwise dispose of the allotted shares during a certain restriction period, and (2) Chugai shall take back all or part of the allotted shares without cost in case where certain events happen.

Number of shares allotted and fair value at the grant date by year

Year		Tenure-based restricted stock	Performance-based restricted stock
2017	Number of shares allotted	74,900 shares	48,100 shares
	Fair value at the grant date	3,820 yen	2,910 yen
2018	Number of shares allotted	40,600 shares	19,700 shares
	Fair value at the grant date	5,400 yen	*3,859 yen
2019	Number of shares allotted	29,500 shares	13,400 shares
	Fair value at the grant date	7,700 yen	5,305 yen

*Revised from ¥5,788 to ¥3,859 from 2019
The impact of the aforementioned revision for 2018 was insignificant, and therefore the revised amount has been reflected in the consolidated financial statements for 2019.

Overview of the Compensation Plan

	Tenure-based restricted stock	Performance-based restricted stock
Evaluation method	Market price	Monte Carlo simulation
Allottees	Directors of Chugai Employees of Chugai Directors of Chugai's subsidiaries Employees of Chugai's subsidiaries	Directors of Chugai
Settlement method	Equity settlement	
Transfer restriction period	3 years	
Conditions for releasing transfer restriction	On the condition that the Eligible Directors, vice presidents and employees maintain their positions continuously during the transfer restriction period, Chugai shall release the transfer restriction for all of the allotted shares at the expiration of the transfer restriction period.	On the condition that the Eligible Directors maintain their positions continuously during the transfer restriction period, Chugai shall release the transfer restriction for the number of allotted shares, which is calculated by multiplying the number of shares that the Eligible Directors obtain at the expiration of the transfer restriction period by the release rate that is determined by the growth rate on the three-year (the "Evaluation Period") Total Shareholders Return (TSR) for a peer group as a performance goal decided by the Board of Directors in advance. The release rate is applied against the number of shares that is provided at the beginning of the restriction period by multiplying the maximum coefficient of 150%, ranging from 0% to 150% separately set by Chugai's Board, and is set from 0% to 100%.

The TSR calculation formula is as follows:

TSR = (Increase in the stock price during the Evaluation Period (B-A) + Dividends during the Evaluation Period) ÷ Initial stock price (A)

A: Initial stock price (Average closing price for the three months prior to the start of the Evaluation Period)

B: Final stock price (Average closing price for the three months prior to the end of the Evaluation Period)

27. Earnings per share

Basic earnings per share

	2019	2018
Net income attributable to Chugai shareholders (millions of yen)	**157,560**	**92,488**
Weighted average number of common stock	559,685,889	559,685,889
Weighted average number of own equity instruments	(12,305,837)	(12,662,197)
Weighted average number of shares in issue	**547,380,052**	**547,023,692**
Basic earnings per share (yen)	**287.84**	**169.08**

Diluted earnings per share

	2019	2018
Net income attributable to Chugai shareholders (millions of yen)	**157,560**	**92,488**
Weighted average number of shares in issue	547,380,052	547,023,692
Adjustment for assumed exercise of equity compensation plans, where dilutive	790,042	892,227
Weighted average number of shares in issue used to calculate diluted earnings per share	**548,170,094**	**547,915,919**
Diluted earnings per share (yen)	**287.43**	**168.80**

There were no rights in equity compensation plans, which are anti-dilutive, and therefore excluded from the calculation of diluted earnings per share (2018: none).

28. Statement of cash flows

Cash flows from operating activities

Cash flows from operating activities arise from the Group's primary activities including research and development, manufacturing and sales in the Pharmaceuticals business. These are calculated by the indirect method by adjusting the Group's operating profit for any operating income and expenses that are not cash flows (for example depreciation, amortization and impairment) in order to derive the cash generated from operations. Operating cash flows also include income taxes paid on all activities.

Cash generated from operations in millions of yen

	2019	2018
Net income	157,560	93,079
Financing costs	125	111
Other financial income (expense)	(545)	(449)
Other expense	3,124	3,212
Income taxes	50,333	28,370
Operating profit	**210,597**	**124,323**
Depreciation of property, plant and equipment	17,778	14,590
Depreciation of right-of-use assets	6,031	-
Amortization of intangible assets	2,592	1,988
Impairment of property, plant and equipment	1,252	59
Impairment of intangible assets	2,664	4,844
Operating expense for defined benefit plans	4,369	4,427
Operating expense for equity-settled equity compensation plans	300	282
Net (income) expense for provisions	287	-
Inventory write-downs	1,053	1,051
Other adjustments	2,577	294
Cash generated from operations	**249,500**	**151,857**

Cash flows from investing activities
Cash flows from investing activities are principally those arising from the Group's investments in property, plant and equipment and intangible assets. Cash flows connected with the Group's portfolio of marketable securities and other investments are also included, as are any interest and dividend payments received in respect of these securities and investments.

Interest and dividends received in millions of yen

	2019	2018
Interest received	106	85
Dividends received	91	115
Total	**197**	**200**

Cash flows from financing activities
Cash flows from financing activities are primarily dividend payments to Chugai shareholders and lease liabilities paid.

Significant non-cash transactions
There were no significant non-cash transactions (2018: none).

29. Risk management

(1) Financial risk management
The Group is exposed to various financial risks arising from its underlying operations and corporate finance activities. The Group's financial risk exposures are predominantly related to changes in foreign exchange rates, interest rates and equity prices as well as the creditworthiness and the solvency of the Group's counterparties.

Financial risk management within the Group is governed by policies approved by the Board of Directors of Chugai. These policies cover credit risk, liquidity risk and market risk. The policies provide guidance on risk limits, type of authorized financial instruments and monitoring procedures. Policy implementation and day-to-day risk management are carried out by the relevant functions and regular reporting on these risks is performed by the relevant finance & accounting and controlling functions within Chugai.

1) Credit risk
Accounts receivable are exposed to customer credit risk. The main accounts receivable are trade receivables. The management of trade receivables is focused on the assessment of country risk, setting of credit limits, ongoing credit evaluation and account monitoring procedures. As part of the credit risk management, sales administration departments regularly monitor the financial position of major customers by checking payment term and balances of trade receivables for each customer according to the accounting manuals to ensure early identification and mitigation of overdue balances and potential bad debts associated with the deterioration of customers' financial position.

The objective of the management of trade receivables is to sustain the growth and profitability of the Group by optimizing asset utilization while maintaining risks at an acceptable level. The Group obtains credit insurance and similar enhancements when appropriate to protect the collection of trade receivables. No material collateral was held for trade receivables (2018: none).

Of the Group's accounts receivable, trade receivables from third parties are mainly to Japanese customers, of which major customers account for 66% as of December 31, 2019.

Trade receivables: major customers in millions of yen

	December 31, 2019	December 31, 2018
Alfresa Corporation	22,070	32,483
Suzuken Co., Ltd.	21,346	19,998
Mediceo Corporation	14,806	22,585
Toho Pharmaceutical Co., Ltd.	11,816	13,171
Total	**70,038**	**88,237**

Customer credit risk exposure based on accounts receivable days overdue that are within the scope of IFRS 15 in millions of yen

	Current	Overdue 1-3 months	Overdue 4-12 months	Overdue more than 1 year	Credit impaired	Total
At December 31, 2019						
Gross carrying amount	170,474	360	4	-	-	170,838
- Expected credit loss rate (%)	0	0	5	-	-	0
Allowance for doubtful accounts	(10)	(0)	(0)	-	-	(10)

	Current	Overdue 1-3 months	Overdue 4-12 months	Overdue more than 1 year	Credit impaired	Total
At December 31, 2018						
Gross carrying amount	162,742	137	-	0	-	162,879
- Expected credit loss rate (%)	0	0	-	100	-	0
Allowance for doubtful accounts	(7)	(0)	-	(0)	-	(7)

The expected credit loss ('ECL') rate is based on the Group's historical experience and the Group's expectation of economic conditions over the period until receivables are expected to be paid.

Derivative transactions and money market instruments are restricted to financial institutions with high credit ratings in an effort to mitigate the counterparty risks.

The maximum exposure to credit risk resulting from financial activities, without taking into account any collateral held or other credit enhancements, is equal to the carrying value of the Group's financial assets.

Financial assets with credit risks (excluding accounts receivables that result from transactions that are within the scope of IFRS 15)
Cash and cash equivalents are held with banks and financial institutions, which are predominantly rated investment grade, based on Moody's and S&P Ratings. Cash and short-term time deposits are subject to rules which limit the Group's exposure to individual financial institutions.

Investments in marketable securities (excluding equity securities) are entered into on the basis of guidelines with regard to liquidity, quality and maximum amount. As a general rule, the Group invests only in high-quality securities with adequate liquidity and with counterparties that have a credit rating of at least Baa3 from Moody's and BBB- from S&P.

Credit risk on accounts receivables that result from transactions that are not within the scope of IFRS 15 are managed based on data obtained from external sources and historical experience.

The credit risk of the counterparties with external ratings below investment grade or non-rated is closely monitored and reviewed on an individual basis.

Rating analysis (excluding accounts receivables that result from transactions that are within the scope of IFRS 15) in millions of yen

	2019		
	Total	Fair value through OCI (12-month ECL)	Amortized costs (12-month ECL)
AAA~BBB- range	340,196	127,991	212,205
Total investment grade	**340,196**	**127,991**	**212,205**
Below BBB- range (below investment grade)	754	754	-
Unrated	1,595	-	1,595
Total gross carrying amounts	**342,545**	**128,745**	**213,800**
Loss allowance	**-**	**-**	**-**

	2018		
	Total	Fair value through OCI (12-month ECL)	Amortized costs (12-month ECL)
AAA~BBB- range	263,010	102,001	161,009
Total investment grade	**263,010**	**102,001**	**161,009**
Below BBB- range (below investment grade)	-	-	-
Unrated	3,067	-	3,067
Total gross carrying amounts	**266,076**	**102,001**	**164,076**
Loss allowance	**-**	**-**	**-**

Financial assets measured at amortized cost and those at fair value through OCI (excluding equity securities) are investment grade and therefore considered to be low risk, and thus the impairment allowance is determined at 12 months expected credit losses ('ECL') with a reference to external credit ratings of the counterparties. There were no financial assets for which the Group observed a significant increase in the credit risk which would require the application of the lifetime expected credit losses impairment model. There was no material impact resulting from the revised impairment approach under IFRS 9. In addition, there were no material movements in the loss allowance in 2019.

2) Liquidity risk

Liquidity risk arises through a surplus of financial obligations over available financial assets due at any point in time. The Group's approach to liquidity risk is to maintain sufficient readily available reserves in order to meet its liquidity requirements at any point in time. The Group manages liquidity risks based on a cash management plan prepared and updated as appropriate by finance and accounting departments based on the reporting from each department.

Chugai is rated as highly creditable by more than one major credit rating agency. The ratings will permit efficient access to the international capital markets in the event of major financing requirements.

Contractual maturities of financial liabilities in millions of yen

	Total	0-3 months	4-6 months	7-12 months	Over 1 year
At December 31, 2019					
Accounts payable	77,635	71,228	6,371	33	3
Other current liabilities					
- Derivative financial instruments*	6,848	598	1,461	3,038	1,751
Total financial liabilities	**84,483**	**71,826**	**7,832**	**3,071**	**1,754**
At December 31, 2018					
Accounts payable	71,706	68,178	3,340	28	160
Other current liabilities					
- Derivative financial instruments*	2,096	531	302	890	372
Total financial liabilities	**73,802**	**68,709**	**3,642**	**919**	**532**

*Derivative financial instruments are held for risk management purposes and for which there is no intention to cancel before the maturity date.

The maturity analysis of lease liabilities is shown in Note 8.

3) Market risk

Market risk arises from changing market prices, mainly due to foreign exchange rates and interest rates, of the Group's financial assets or financial liabilities which affect the Group's net income and equity.

Foreign exchange risk: Accounts receivable and accounts payable denominated in foreign currencies are exposed to foreign exchange risk. The objective of the Group's foreign exchange risk management activities is to preserve the economic value of its current and future assets and to minimize the volatility of the Group's financial result. The Group enters into derivative transactions such as foreign exchange forward contracts to reduce the risk of foreign currency exchange fluctuations related to both assets and liabilities denominated in foreign currencies. Some of these transactions qualify as cash flow hedges at the point that the forecast transaction is expected.

When making use of derivatives for hedging foreign exchange risk on assets and liabilities denominated in foreign currencies, Chugai conducts such operations in accordance with its internal regulations and monthly reports are prepared on the balance of such transactions, valuation gains and losses, and other related matters at fair value. Consolidated subsidiaries do not utilize derivative transactions.

Sensitivity analysis: Chugai has financial instruments denominated in currencies other than its functional currency. The table below shows the impact on profit before taxes resulting from a 1% decrease of the Swiss franc, euro and US dollar against the Japanese yen, which is Chugai's functional currency. The effective portion of derivative financial instruments for which hedge accounting is applied is excluded from the calculation. All calculations are based on the assumption that exchange rates for other currencies are constant and there are no changes in other variables such as interest rates.

Foreign currency sensitivity analysis

	2019	2018
Year-end exchange rate (yen per each currency)		
CHF	112.31	112.03
EUR	121.93	126.13
USD	108.88	110.28
Profit before taxes (millions of yen)		
CHF	1,191	12
EUR	22	32
USD	(462)	(289)

(Note) Positive numbers are the amount of positive impact on profit before taxes resulting from a 1% decrease of each currency against the Japanese yen. The amounts above do not reflect the impact on Chugai's cash flows or forecast result.

The impact resulting from a 1% decrease of each currency against the Japanese yen on the financial instruments denominated in foreign currency is shown in the tables below.

	2019			2018		
	Exposure (m CHF)	Exposure (m YEN)	Impact (m YEN)	Exposure (m CHF)	Exposure (m YEN)	Impact (m YEN)
CHF						
Accounts receivable	567	63,706	(637)	324	36,278	(363)
Accounts payable	(386)	(43,346)	433	(344)	(38,513)	385
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	14	1,614	(16)	15	1,667	(17)
Notional amounts of derivative financial instruments						
- Effective portion of hedge	(1,277)	(141,057)	1,411	(5)	(637)	6
- Other than above	-	-	-	-	-	-
Total	**(1,081)**	**(119,083)**	**1,191**	**(10)**	**(1,204)**	**12**
	Exposure (m EUR)	Exposure (m YEN)	Impact (m YEN)	Exposure (m EUR)	Exposure (m YEN)	Impact (m YEN)
EUR						
Accounts receivable	86	1,239	(12)	2	265	(3)
Accounts payable	(28)	(3,470)	35	(27)	(3,435)	34
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	-	-	-	-	-	-
Notional amounts of derivative financial instruments						
- Effective portion of hedge	-	-	-	-	-	-
- Other than above	-	-	-	-	-	-
Total	**58**	**(2,230)**	**22**	**(25)**	**(3,170)**	**32**
	Exposure (m USD)	Exposure (m YEN)	Impact (m YEN)	Exposure (m USD)	Exposure (m YEN)	Impact (m YEN)
USD						
Accounts receivable	11	1,210	(12)	35	3,850	(38)
Accounts payable	(73)	(7,984)	80	(100)	(11,034)	110
Financial non-current assets	-	-	-	-	-	-
Cash and cash equivalents	-	-	-	-	-	-
Notional amounts of derivative financial instruments						
- Effective portion of hedge	499	52,942	(529)	333	36,061	(361)
- Other than above	-	-	-	-	-	-
Total	**437**	**46,168**	**(462)**	**267**	**28,877**	**(289)**

Interest rate risk: There were no debt and loans at December 31, 2019 and given the nature of leases and the current low interest rate environment, the Group is not exposed to material interest rate risk.

(2) Financial instruments

Carrying value and fair value of financial instruments

The Group's financial instruments are mainly comprised of financial non-current assets, debt instruments included in other non-current assets, accounts receivable, marketable securities, cash and cash equivalents, derivative financial instruments included in other current assets, accounts payable, derivative financial instruments included in other current liabilities, debt and lease liabilities included in other non-current liabilities and other current liabilities. The carrying values of these financial instruments are equal to or reasonable approximates of fair values. Disclosure of the fair value of lease liabilities are not required.

Accounting classifications and fair values in millions of yen

	Financial assets measured at fair value through OCI	Fair value -hedging instruments	Fair value through profit or loss	Financial assets at amortized cost	Financial liabilities at amortized cost	Total
At December 31, 2019						
Non-current financial assets						
- Equity instrument	2,958	-	-	-	-	2,958
Other non-current assets						
- Debt instrument	-	-	113	-	-	113
Accounts receivable	-	-	-	181,641	-	181,641
Marketable securities						
- Debt instrument	8,751	-	-	-	-	8,751
- Money market instruments	119,994	-	-	-	-	119,994
- Time accounts over 3 months	-	-	-	373	-	373
Cash and cash equivalents	-	-	-	203,941	-	203,941
Other current assets						
- Derivative financial instruments	-	5,052	-	-	-	5,052
Total financial assets	**131,703**	**5,052**	**113**	**385,954**	**-**	**522,821**
Accounts payable	-	-	-	-	77,635	77,635
Other current liabilities						
- Derivative financial instruments	-	6,848	-	-	-	6,848
Total financial liabilities	**-**	**6,848**	**-**	**-**	**77,635**	**84,483**

	Financial assets measured at fair value through OCI	Fair value -hedging instruments	Fair value through profit or loss	Financial assets at amortized cost	Financial liabilities at amortized cost	Total
At December 31, 2018						
Non-current financial assets						
- Equity instrument	9,723	-	-	-	-	9,723
Other non-current assets						
- Debt instrument	-	-	-	-	-	-
Accounts receivable	-	-	-	179,556	-	179,556
Marketable securities						
- Debt instrument	8,001	-	-	-	-	8,001
- Money market instruments	94,000	-	-	-	-	94,000
- Time accounts over 3 months	-	-	-	532	-	532
Cash and cash equivalents	-	-	-	146,860	-	146,860
Other current assets						
- Derivative financial instruments	-	2,204	-	-	-	2,204
Total financial assets	**111,724**	**2,204**	**-**	**326,948**	**-**	**440,876**
Accounts payable	-	-	-	-	71,706	71,706
Other current liabilities						
- Derivative financial instruments	-	2,096	-	-	-	2,096
Total financial liabilities	**-**	**2,096**	**-**	**-**	**71,706**	**73,801**

Fair value hierarchy

The table below analyses financial instruments carried at fair value, by valuation method. The different levels have been defined as follows:

- Level 1 – quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2 – observable inputs directly or indirectly other than quoted prices in active markets for identical assets and liabilities.
- Level 3 – fair value determined using valuation method which includes unobservable inputs.

Fair value hierarchy of financial instruments in millions of yen

	Level 1	Level 2	Level 3	Total
At December 31, 2019				
Marketable securities:				
- Money market instruments	-	119,994	-	119,994
- Debt securities	8,751	-	-	8,751
Other current assets				
- Derivative financial instruments	-	5,052	-	5,052
Financial non-current assets				
- Equity instruments measured at fair value through OCI	878	-	2,080	2,958
Other non-current assets				
- Debt instrument	-	-	113	113
Financial assets recognized at fair value	**9,629**	**125,045**	**2,192**	**136,867**
Other current liabilities				
- Derivative financial instruments	-	(6,848)	-	(6,848)
Financial liabilities recognized at fair value	**-**	**(6,848)**	**-**	**(6,848)**

	Level 1	Level 2	Level 3	Total
At December 31, 2018				
Marketable securities:				
- Money market instruments and time accounts over 3 months	-	94,000	-	94,000
- Debt securities	8,001	-	-	8,001
Other current assets				
- Derivative financial instruments	-	2,204	-	2,204
Financial non-current assets				
- Available-for-sale financial assets	7,330	-	2,394	9,723
Financial assets recognized at fair value	**15,331**	**96,204**	**2,394**	**113,928**
Other current liabilities				
- Derivative financial instruments	-	(2,096)	-	(2,096)
Financial liabilities recognized at fair value	**-**	**(2,096)**	**-**	**(2,096)**

Level 1 financial assets consist of corporate bonds and quoted shares. Level 2 financial assets consist primarily of certificates of deposit, cash in trust, commercial paper and derivative financial instruments.

Fair values Level 2 financial assets are determined as follows:
• Marketable securities and derivative financial instruments are based on valuation models that use observable market data for interest rates, yield curves, foreign exchange rates and implied volatilities for similar instruments at the measurement date.

The Group recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period during which the transfer has occurred. There were no significant transfers between Level 1 and Level 2 and vice versa.

Level 3 financial assets mainly consist of unquoted shares. Valuation is based on valuation method which includes unobservable inputs.

Reconciliation of financial instruments classified into level 3 in millions of yen

	Fair value through other comprehensive income	Fair value through profit or loss	Total
At January 1, 2018	1,616	-	1,616
Gains or losses	72	-	72
Purchases	706	-	706
Disposals	-	-	-
Transfers	-	-	-
Currency translation effects	(1)	-	(1)
At December 31, 2018	**2,394**	**-**	**2,394**
At January 1, 2019	2,394	-	2,394
Gains or losses	(8)	-	(8)
Purchases	100	113	213
Disposals	(406)	-	(406)
Transfers	-	-	-
Currency translation effects	-	-	-
At December 31, 2019	**2,080**	**113**	**2,192**

Derecognition of FVTOCI equity investments

The fair value at the date of derecognition, cumulative gain or loss on disposal, and dividends recognized related to investments derecognized as a result of disposal of FVTOCI equity investments during the year, are as follows;

	December 31, 2019	December 31, 2018
Fair value at the date of derecognition	7,111	2,863
Cumulative gain or loss	5,748	2,163
Dividends	88	-

These are mainly stock divestments as a result of examination by the Board of Directors, the suitability of shareholding by assessing matters such as whether the purpose is appropriate, the capital efficiency in relation to the shareholding, and the rationale of the relevant transactions.

The cumulative gain or loss on disposal is before tax effect, and amounts transferred from other reserves to retained earnings is ¥4,131 million (2018: ¥1,498 million).

(3) Derivative financial instruments

Derivative financial instruments in millions of yen

Assets	December 31, 2019	December 31, 2018
Forward exchange contracts	5,052	2,204
Total	**5,052**	**2,204**

Liabilities	December 31, 2019	December 31, 2018
Forward exchange contracts	(6,848)	(2,096)
Total	**(6,848)**	**(2,096)**

Hedge accounting

Hedge effectiveness is determined at the inception of the hedge relationship, and through periodic prospective effectiveness assessments at each reporting date to ensure that an economic relationship exists between the hedged item and hedging instrument. The Group performs a qualitative assessment of the hedge effectiveness, and the Group concludes that risks being hedged for the hedged items and the hedging instruments are sufficiently aligned.

The Group manages foreign exchange rate fluctuation risks by applying cash flow hedge, and an ineffective portion may occur when the volume of hedged items is lower than the hedged amount. The ineffective portion of the hedge accounting is recognized in the income statement and included in other financial income (expense). It is measured using the hypothetical derivative method for cash flow hedges. In 2019 there were no actual ineffectiveness being reported for any hedge accounting relationships, or hedging relationships for which hedge accounting is no longer applied (2018: None).

The table below shows fair values and nominal amounts of derivative financial instruments, including a range of the timing of the nominal amounts of the hedging instruments, which are designated as hedging instruments in a cash flow hedge. At December 31, 2019, the Group has the following cash flow hedges which are designated in a qualifying hedge relationship.

Cash flow hedges

	Nominal amount	Fair value in million yen		Maturity range
		Asset	Liability	
Risk hedged:				
Foreign exchange rate fluctuations				
- Forward exchange contracts	CHF 3,890 million	3,885	(6,848)	2020-2021
	USD 499 million	1,166	-	2020-2021
Total		**5,052**	**(6,848)**	

The Group is exposed to foreign exchange risk from transactions for inventories and others in foreign currencies with foreign related parties. The Group has entered into foreign exchange forward contracts to hedge a part of foreign exchange risk. Such instruments are recorded as fair value assets of ¥(1,796) million (2018: fair value assets of ¥109 million).

Reconciliation of hedging reserves in equity in millions of yen

	Forward exchange contracts
At January 1, 2019	57
Effective portion of fair value gains (losses) taken to equity	(1,482)
Transferred to income statement	(2)
Transferred to initial carrying amount of hedged items	(416)
Income taxes	583
At December 31, 2019	**(1,317)**

The present value of expected cash flows from qualifying cash flow hedges is shown in the table below.

Present value of expected cash flows of qualifying cash flow hedges in millions of yen

	Total	0-6 months	7-12 months	Over 1 Year
Year ended December 31, 2019				
Cash inflows	486,322	179,436	212,439	94,447
Cash outflows	(488,118)	(179,359)	(213,291)	(95,468)
Total cash inflow (outflow)	**(1,796)**	**77**	**(852)**	**(1,021)**
Year ended December 31, 2018				
Cash inflows	275,004	102,316	119,583	53,105
Cash outflows	(274,895)	(102,221)	(119,610)	(53,065)
Total cash inflow (outflow)	**109**	**95**	**(27)**	**41**

(4) Capital management

The Group defines the capital that it manages as the Group's total capitalization, being the equity including non-controlling interests. The Group's objectives when managing capital are:

- To safeguard the Group's ability to continue as a going concern, so that it can continue to provide benefits for patients and returns to investors.
- To provide an adequate return to investors based on the level of risk undertaken.
- To have available the necessary financial resources to allow the Group to invest in areas that may deliver future benefits for patients and returns to investors.
- To maintain sufficient financial resources to mitigate against risks and unforeseen events.

Capitalization is monitored and reported to the CFO as part of the Group's regular internal management reporting.

The Group is not subject to regulatory capital adequacy requirements.

Capital in millions of yen

	December 31, 2019	December 31, 2018
Capital and reserves attributable to Chugai shareholders	853,985	755,864
Equity attributable to non-controlling interests	-	664
Capitalization	**853,985**	**756,529**

30. Related parties

(1) Controlling shareholder

Effective October 1, 2002, the Roche Group and Chugai completed an alliance to create a leading research-driven Japanese pharmaceutical company, which was formed by the merger of Chugai and Roche's Japanese pharmaceuticals subsidiary, Nippon Roche. Through the merger, Chugai became a member of the Roche Group as the surviving company.

Chugai has entered into certain agreements with Roche, which are discussed below:

Basic Alliance Agreement: As part of the Basic Alliance Agreement signed in December 2001, Roche and Chugai entered into certain arrangements covering the future operation and governance of Chugai. Amongst other matters these cover the following areas:

- The structuring of the alliance.
- Roche's rights as a shareholder.
- Roche's rights to nominate members of Chugai's Board of Directors.
- Certain limitations to Roche's ability to buy or sell Chugai's common stock.

Chugai issues additional shares of common stock in connection with its convertible debt and equity compensation plans, and may issue additional shares for other purposes, which affects Roche's percentage ownership interest. The Basic Alliance Agreement provides, amongst other matters, that Chugai will guarantee Roche's right to maintain its shareholding percentage in Chugai at not less than 50.1%.

Licensing Agreements: Under the Japan Umbrella Rights Agreement signed in December 2001, Chugai has exclusive rights to market Roche's pharmaceutical products in Japan. Chugai also has right of first refusal on the development and marketing in Japan of all development compounds advanced by Roche.

The Rest of the World Umbrella Rights Agreement (excluding Japan and South Korea) signed in May 2002 was revised and the Amended and Restated Rest of the World Umbrella Rights Agreement (excluding Japan, South Korea and Taiwan) was signed in August 2014. Under this Agreement, Roche has the right of first refusal on the development and marketing of Chugai's development compounds in markets outside Japan, excluding South Korea and Taiwan.

Further to these agreements, Roche and Chugai have signed a series of separate agreements for certain specific products. Depending on the specific circumstances and the terms of the agreement, this may result in payments on an arm's length basis between Roche and Chugai, for any or all of the following matters:

- Upfront payments, if a right of first refusal to license a product is exercised.
- Milestone payments, dependent upon the achievement of agreed performance targets.
- Royalties on future product sales.

These specific product agreements may also cover the manufacture and supply etc. of the respective products to meet the other party's clinical and/or commercial requirements on an arm's length basis.

Research Collaboration Agreements: Roche and Chugai have entered into research collaboration agreements in the areas of small-molecule synthetic drug research and biotechnology-based drug discovery.

Dividends: The dividends distributed to Roche by Chugai in respect to its holdings of Chugai shares totaled ¥34,528 million (2018: ¥21,454 million).

(2) Material transactions and balances with related parties

Transactions with F. Hoffmann-La Roche in millions of yen

	2019	2018
Revenues	217,265	134,188
Purchases	145,336	125,657

From the year ended December 31, 2019, revenues include royalties and other operating income in addition to sales due to the increased significance of royalties and other operating income.

Balances with F. Hoffmann-La Roche in millions of yen

	December 31, 2019	December 31, 2018
Accounts receivable	69,152	46,078
Trade accounts payable	38,006	29,567

From December 31, 2019, accounts receivable also includes other receivables due to the increased significance of other receivables.

(3) Remuneration of key management personnel

Remuneration of members of the Board and audit & supervisory board members in millions of yen

	2019	2018
Board of directors		
- Regular remuneration	298	304
- Bonuses	120	120
- Tenure-based restricted stock compensation plan	86	57
- Performance-based restricted stock compensation plan	76	72
- Chugai common stock options	—	21
Total	**580**	**573**
Audit & supervisory board members		
- Regular remuneration	96	87
Total	**96**	**87**

31. Subsidiaries

Subsidiaries	Country of incorporation	Equity interest %	
		2019	2018
Consolidated subsidiaries			
Chugai Research Institute for Medical Science, Inc.	Japan	100	100 %
Chugai Clinical Research Center Co., Ltd.	Japan	100	100 %
Chugai Business Support Co., Ltd.	Japan	100	100 %
Medical Culture, Inc.	Japan	100	100 %
Chugai Distribution Co., Ltd.	Japan	100	100 %
Chugai Pharma Manufacturing Co., Ltd.	Japan	100	100 %
Forerunner Pharma Research Co., Ltd.	Japan	100	100 %
Chugai Pharma USA, Inc.	United States	100	100 %
Chugai Pharma Europe Ltd.	United Kingdom	100	100 %
Chugai Pharma U.K. Ltd.	United Kingdom	100	100 %
Chugai Pharma Germany GmbH	Germany	100	-
Chugai Pharma France S.A.S.	France	100	100 %
Chugai Pharma Europe Logistics S.A.S.	France	100	55 %
Chugai Pharma Taiwan Ltd.	Taiwan	100	100 %
Chugai Pharma Science (Beijing) Co., Ltd.	China	100	100 %
Chugai Pharma China Co., Ltd.	China	100	100 %
Chugai Pharma Technology Taizhou Co., Ltd.	China	100	100 %
Chugai Pharmabody Research Pte. Ltd.	Singapore	100	100 %

(Note) Chugai sanofi-aventis S.N.C. became a wholly owned subsidiary of Chugai Pharma Europe Ltd., through the additional acquisition of its shares in January 2019, and changed its name to Chugai Pharma Europe Logistics S.A.S. In addition, Chugai Pharma Germany GmbH was established as a subsidiary of Chugai Pharma Europe Ltd. in February 2019.

32. Subsequent events

At the meeting of the Board of Directors held on January 21, 2020, a stock split and partial amendment to the articles of incorporation was resolved.

a. Purpose of the stock split

The stock split aims to reduce the investment unit price for the Company's stock, increase the liquidity of the stocks, and to further expand the investor base.

b. Outline of the stock split

(a) Method

Fixing Tuesday, June 30, 2020 as a record date, the Company will split its ordinary shares owned by shareholders listed or recorded in the shareholder registry three-for-one.

(b) Number of shares to be increased by the stock split

(i) Total number of shares issued before the stock split	559,685,889
(ii) Increase in the number of shares upon the stock split	1,119,371,778
(iii) Total number of shares issued after the stock split	1,679,057,667
(iv) Total number of shares issuable after the stock split	2,399,415,150

(c) Schedule

(i) Announcement of record date	Monday, June 15, 2020
(ii) Record date	Tuesday, June 30, 2020
(iii) Effective date	Wednesday, July 1, 2020

c. Effect of these changes on per share information

Per-share information calculated as if this stock split had taken place at the beginning of the year ended December 31, 2018 is as follows:

	2019	2018
Basic earnings per share (yen)	95.95	56.36
Diluted earnings per share (yen)	95.81	56.27

d. Partial amendment to the articles of incorporation

(a) Reasons for the amendment

In line with the stock split, pursuant to the Article 184.2 of the Companies Act of Japan, the Company will amend as of Wednesday, July 1, 2020, the total number of shares issuable set by Article 6 in the Articles of Incorporation of the Company.

(b) Details of the amendment

Details are as follows.

Before the amendment	After the amendment
Article 6. (Total Number of Shares Issuable) The total number of shares issuable of the Company shall be 799,805,050 shares.	Article 6. (Total Number of Shares Issuable) The total number of shares issuable of the Company shall be 2,399,415,150 shares.

(c) Schedule

Effective date of the amendment to the articles of incorporation: Wednesday, July 1, 2020

e. Others

(a) Change in the amount of stated capital

The stock split will not change the amount of stated capital.

Additional information

This additional information is provided for the benefit of readers and does not form part of the consolidated financial statements.

1. Significant legal cases

At December 31, 2019, the Group is involved in the following significant legal cases for which the outcome cannot be determined at this time, but for which the Group assesses that the possibility of any settlement to be remote:

(1) Arbitration in England regarding Actemra
In May 2017 Medical Research Council and LifeArc (formerly Medical Research Council Technology) requested arbitration against Chugai Pharmaceutical Co., Ltd. ('Chugai') with an arbitrator being appointed on 9 August 2017. In April 2018 United Kingdom Research and Innovation ('UKRI') was established and became the successor in title to the Medical Research Council, and the final claimants in the arbitration were LifeArc and UKRI (collectively, the 'Claimants'). Sums were sought from Chugai for alleged breach of obligations under a collaboration agreement dated 15 August 1990 in connection with the development of the humanized anti-human IL-6 receptor monoclonal antibody Actemra/ RoActemra. It was claimed that Chugai is obliged to pay royalties to the Claimants pursuant to the collaboration agreement. In January 2020 Chugai executed a formal settlement agreement with the Claimants to end this arbitration. Under the settlement agreement Chugai made a lump-sum payment to the Claimants as a sole settlement payment. The terms and conditions of this settlement agreement, including the amount of the settlement payment, are confidential. The matter is now concluded.

(2) Patent infringement lawsuit (in Japan) regarding Emicizumab
Baxalta (Baxalta Incorporated and Baxalta GmbH) filed a lawsuit against Chugai at the Tokyo District Court on May 6, 2016 (service of the complaint), for an injunction against manufacture, usage, transfer, exportation and offer of any transfer regarding emicizumab (development code name: ACE910) alleging emicizumab is infringing one of its Japanese patents (patent number 4313531). With regard to this action, the Tokyo District Court rendered a decision in favor of Chugai's claim. Given this ruling, Baxalta appealed to the Intellectual Property High Court on May 10, 2018 (service of appeal) and a decision in favour of Chugai's claim was rendered by the High Court on October 3, 2019. Baxalta has filed a petition for the acceptance of a final appeal to the Supreme Court.

(3) Patent infringement lawsuit (in US) regarding Emicizumab
Baxalta (Baxalta Incorporated and Baxalta GmbH) filed a lawsuit against Chugai and Genentech Inc., at the United States District Court for the District of Delaware on May 4, 2017 (the date of the complaint) requesting a relief including an injunction enjoining manufacturing, using, offering to sell, or selling emicizumab within the United States, or importing emicizumab into the United States. Baxalta filed a stipulation of dismissal with prejudice regarding Baxalta's claims against Chugai with the Court on September 13, 2018, and the Court issued an Order Dismissing Chugai from this lawsuit on September 19, 2018 (local time). The Court also entered a judgment in favour of Genentech on February 1, 2019. Given this, Baxalta appealed to the United States Court of Appeals for the Federal Circuit on February 8, 2019.

(4) A patent infringement lawsuit (in US) against Alexion
Chugai alleges that the anti-C5 antibody ALXN1210 (ravulizumab) product, an investigational drug developed by Alexion Pharmaceuticals, Inc., infringes one of its U.S. patents (U.S. Patent No. 9,890,377) relating to its proprietary antibody engineering technology. Thus, Chugai filed a patent infringement lawsuit against Alexion at the United States District Court for the District of Delaware on November 15, 2018 (the date of the complaint) requesting a judgment that the ALXN1210 product infringes Chugai's U.S. patent and injunctive relief precluding manufacturing and selling of the ALXN1210 product within the U.S. Chugai filed another patent infringement lawsuit against Alexion at the United States District Court for the District of Delaware on November 12, 2019 (the date of the complaint) requesting a judgment that the ALXN1210 product infringes Chugai's U.S. patent (U.S. Patent No. 10,472,623) and injunctive relief precluding manufacturing and selling of the ALXN1210 product within the U.S.

(5) A patent infringement lawsuit (in Japan) against Alexion
Chugai alleges that the anti-C5 antibody ALXN1210 (ravulizumab) product, an investigational drug developed by Alexion Pharma Godo Kaisha (Japan Regional Headquarters), infringes some of its Japan patents (Patent No. 4954326 and No. 6417431) relating to its proprietary antibody engineering technology. Thus, Chugai filed a patent infringement lawsuit against Alexion at the Tokyo District Court on December 5, 2018 (the date of the complaint) requesting a judgment that the ALXN1210 product infringes Chugai's Japan patent and injunctive relief precluding manufacturing and selling of the ALXN1210 product in Japan.

(6) A patent infringement lawsuit (in US) against Fresenius Kabi

Fresenius Kabi USA, LLC, in concert with Fresenius Kabi Oncology Limited and Fresenius SE & Co. KGaA (collectively "Fresenius"), filed an Abbreviated New Drug Application ("ANDA") for approval of a generic version of Alecensa to the U.S. Food and Drug Administration. Under the framework of the Drug Price Competition and Patent Term Restoration Act (known as Hatch-Waxman Act), Chugai, Roche and Genentech filed a patent infringement lawsuit against Fresenius at the United States District Court for the District of Delaware on March 19, 2020 (the date of the complaint) alleging submission of ANDA infringed Chugai's U.S. Patents (Nos. 9,126,931; 9,440,922; 9,365,514 and 10,350,214).

Independent Auditor's Report

Independent Auditor's Report

To the Board of Directors of Chugai Pharmaceutical Co., Ltd.:

We have audited the accompanying consolidated financial statements of Chugai Pharamaceutical Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheet as at December 31, 2019, and the consolidated income statement, statement of comprehensive income ,statement of changes in equity and statement of cash flows for the year then ended, and notes, comprising a summary of significant accounting policies and other explanatory information.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgement, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, while the objective of the financial statement audit is not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries as at December 31, 2019, and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards.

KPMG AZSA LLC

March 30, 2020
Tokyo, Japan

Glossary

Terms Related to Chugai's Business

Unmet medical need
Medical need that is not adequately met due to a lack of effective treatments.

First-in-class
An original drug that is highly novel and useful, and will significantly change the therapeutic system.

Best-in-class
A drug that offers clear advantages over other existing drugs in the same category, such as those with the same molecular target.

Development pipeline
At pharmaceutical companies, refers to drug candidates that are being developed.

Proof of Concept (PoC)/Early PoC
Proof of concept (PoC) is confirmation that the therapeutic effect conceived in the research stage is effective in humans. Early PoC means that in addition to safety, signs of efficacy or pharmacological effect have been confirmed in a limited number of cases.

Clinical trial
A study to verify the safety, efficacy and other characteristics of a drug in human subjects. Studies conducted for the purpose of filing an application for approval are called clinical trials.

Phase I: Performed on a small number of healthy volunteers (or, for certain disease areas and diseases, on patients) to assess the drug's safety and the process by which it is absorbed, distributed, metabolized and eliminated by the body.

Phase II: Performed on a small number of consenting patients to determine the safest and most effective dosage and the dosing regimen.

Phase III: Performed on a large number of consenting patients to verify the efficacy and safety of the new drug in comparison with existing drugs or placebo.

Phase IV: Post-marketing clinical surveillance. Performed on a larger number of consenting patients than in phase III studies to verify the drug's safety and efficacy for its approved indication(s).

Application for approval
An application submitted by a pharmaceutical company to a regulatory agency to obtain approval for manufacturing and marketing of a new drug after its efficacy and safety have been verified in clinical trials. In Japan, the Minister of Health, Labour and Welfare (MHLW) grants manufacturing and marketing approval to substances deemed appropriate as pharmaceuticals based on reviews by the Pharmaceutical Affairs and Medical Devices Agency as well as academic and other experts in the Pharmaceutical Affairs and Food Sanitation Council.

Additional indication
A new indication for a previously approved drug.

Lifecycle management
The various measures taken to maximize the potential value of a drug, including shortening development time, expanding sales, extending the product's life, and conducting appropriate cost control.

Personalized Healthcare
Even when a particular disease is treated with the same drug, there may be differences in the efficacy and side effects of that drug depending on the patient. One of the causes is thought to be that the genetic information related to the disease is different in each patient. Personalized healthcare (PHC) is an approach that focuses on these genetic-level differences to provide treatment tailored to the characteristics of each patient's disease. It therefore brings significant benefits in term of efficiency, safety and cost effectiveness.

Cancer Genomic Medicine
One example of PHC. Medical treatment that measures multiple cancer-related genes in a single test using gene panel examination and performs optimal treatment according to each patient's genomic profile.

Biopharmaceuticals
Drugs created by applying biotechnology such as genetic recombination. In the 1980s, when rapid advances were made in genetic engineering, Chugai decided to shift to research and development of biopharmaceuticals and made related large-scale capital investments.

Therapeutic antibody
A type of biopharmaceutical, it is an artificially created antibody used as a medicine to prevent or treat diseases. Therapeutic antibodies are designed to act only on the specific molecule (antigen) that causes the disease, and therefore can be expected to provide high therapeutic efficacy and reduce side effects. Chugai launched the first therapeutic antibody created in Japan in 2005, and is leading the world with its proprietary antibody engineering technologies.

Modality
In the pharmaceutical industry, refers to the material classification of a medicine. Until the 1990s, small molecule drugs were virtually the only modality, but the options are now increasing. New modalities enable new approaches to diseases that have no effective treatment methods. Chugai is focusing on establishing middle molecules as a third modality, in addition to its biologics and small molecules.

Open innovation
Generating innovative value by utilizing the technologies and development capabilities of external research networks such as with universities, research institutions and other organizations.

Translational Research
Research that builds a bridge between the findings of basic research by academia and the development of new medicines by pharmaceutical companies.

Terms Related to Human Resources

Work-life synergy (Work-life balance)
Chugai's work-life synergy aims to generate a synergistic effect that brings forth motivation, vitality and innovation by enhancing both work and the lives of individuals. Work-life synergy, an advancement of the concept of work-life balance, is necessary for a fulfilling personal life, as well as for becoming the top innovator in the healthcare industry.

Diversity and Inclusion
At Chugai, diversity refers to a diversity of attributes such as gender, age and nationality, as well as ways of thinking, values and experience. Inclusion refers to the state of respecting each other's differences and the ability of everyone to contribute and perform at his or her full potential. When people with various backgrounds work together, they become aware of diverse perspectives and ideas. Companies promote diversity to create new value, which leads to innovation. Using this awareness for business innovation, companies promote diversity to create better-quality products and services. Also called "diversity and inclusion (D&I)," which refers to receptivity to diversity and incorporating diverse opinions and ideas rather than the simple pursuit of variety, and also encompasses the concept of raising organizational value.

Talent management
Talent management is the human resource strategy by which we identify and develop leaders and highly skilled specialists at an early stage. It is also the means by which we improve the skills and enhance the motivation of employees throughout the Company, with the aim of realizing our corporate strategy and catalyzing the creation of innovation. Each organization at Chugai has formulated a long-term human resource development plan and is building a talent pool of leaders.

Terms Related to the Roche Group

Roche
A pharmaceutical company established in 1896 and headquartered in Basel, Switzerland. With business operations in more than 100 countries, the Roche Group contributes to medicine in a wide range of fields through its two business segments: pharmaceuticals and diagnostics. Central to the Roche Group's strategy is PHC, the approach of selecting the most appropriate treatment by using biomarkers and diagnostic/genetic tests including genomic profiling to identify patients most likely to show a significant response to a particular drug. The Roche Group's sales in 2019 were 61.5 billion Swiss francs.

Roche Diagnostics K.K.
The Japanese subsidiary of the Roche Group's diagnostics division. Established in 1998, Roche Diagnostics K.K. provides a wide range of innovative diagnostic solutions, including in-vitro diagnostics and diagnostic equipment and research reagents and related equipment.

Genentech Inc.
A leading biotechnology company headquartered in South San Francisco, California. Genentech has been a member of the Roche Group since 1990.

Foundation Medicine Inc. (FMI)
FMI was established in Massachusetts, U.S.A. in 2010. In 2015, Roche took a majority stake, and then acquired the remaining outstanding shares in 2018 to make FMI a wholly-owned subsidiary. Chugai established the FMI business as a specialized unit in October 2018 to promote uptake and product value maximization of FMI's "Comprehensive Genomic Profiling Service" in Japan.

Network (As of April 1, 2020)

Chugai Pharmaceutical

Head Office
Nihonbashi Mitsui Tower (Reception 15F)
2-1-1 Nihonbashi-Muromachi,
Chuo-ku, Tokyo 103-8324 Japan
Tel +81-(0)3-3281-6611 (main switchboard)
URL: https://www.chugai-pharm.co.jp/english/

Research Laboratories

Fuji Gotemba Research Laboratories
1-135 Komakado, Gotemba City,
Shizuoka Pref. 412-8513 Japan
Tel +81-(0)550-87-3411

Kamakura Research Laboratories
200 Kajiwara, Kamakura City,
Kanagawa Pref. 247-8530 Japan
Tel +81-(0)467-47-2260

Ukima Research Laboratories
5-5-1 Ukima, Kita-ku,
Tokyo 115-8543 Japan
Tel +81-(0)3-3968-6111

Plants (Chugai Pharma Manufacturing Co., Ltd.)

Ukima Plant
5-5-1 Ukima, Kita-ku, Tokyo 115-8543 Japan
Tel +81-(0)3-3968-6200

Fujieda Plant
2500 Takayanagi, Fujieda City,
Shizuoka Pref. 426-0041 Japan
Tel +81-(0)54-635-2311

Utsunomiya Plant
16-3 Kiyohara-Kogyodanchi, Utsunomiya City,
Tochigi Pref. 321-3231 Japan
Tel +81-(0)28-667-7611

Branches

Hokkaido Branch
8F Nihon Seimei Sapporo Bldg., 4-1-1
Kita-sanjo-Nishi, Chuo-ku, Sapporo City,
Hokkaido 060-0003 Japan
Tel +81-(0)11-271-5311

Miyagi and Yamagata Branch
3F Sankyo Sendai Bldg., 1-12-7 Honcho,
Aoba-ku, Sendai City,
Miyagi Pref. 980-0014 Japan
Tel +81-(0)22-225-8551

Kita-Tohoku Branch
(Iwate/Aomori/Akita)
5F Higashi-nihon Fudousan Morioka Ekimae
Bldg., 15-20 Morioka-ekimae-dori, Morioka City,
Iwate Pref. 020-0034 Japan
Tel +81-(0)19-625-2811

Fukushima Branch
17F Big-i, 2-11-1 Kouriyamashi Ekimae,
Fukushima Pref. 963-8002 Japan
Tel +81-(0)24-933-6303

Saitama Branch
8F Omiya Center Bldg., 1-9-6 Sakuragicho,
Omiya-ku, Saitama City,
Saitama Pref. 330-0854 Japan
Tel +81-(0)48-642-4771

Ibaraki Branch
8F Nissei Mito Bldg., 2-2-27 Izumi-cho,
Mito City, Ibaraki Pref. 310-0026 Japan
Tel +81-(0)29-227-1951

Gunma and Tochigi Branch
9F East Tower, 16-11 Sakae-cho,
Takasaki City, Gunma Pref. 370-0841 Japan
Tel +81-(0)27-321-6511

Niigata Branch
9F Niigata Ekimae Bldg., 3-2-3 Benten,
Chuo-ku, Niigata City,
Niigata Pref. 950-0901 Japan
Tel +81-(0)25-247-7331

Nagano and Yamanashi Branch
8F Kenshin Matsumoto Fukashi Bldg.,
2-5-2 Fukashi, Matsumoto City,
Nagano Pref. 390-0815 Japan
Tel +81-(0)263-34-1373

Tokyo Branch 1
Tokyo Branch 2
Tokyo Branch 3
17F Osaki Bright Core Bldg.,
5-5-15 Kita-shinagawa, Shinagawa-ku,
Tokyo 141-0001 Japan
Tel +81-(0)3-5449-6760

Tokyo Tama Branch
6F Tachikawa Nishiki-cho Bldg.,
1-8-7 Nishiki-cho, Tachikawa City,
Tokyo 190-0022 Japan
Tel +81-(0)42-523-6661

Chiba Branch
5F Fujimi Hainesu Bldg., 2-7-5 Fujimi, Chuo-ku,
Chiba City, Chiba Pref. 260-0015 Japan
Tel +81-(0)43-224-1511

Yokohama Branch
3F Yokohama East Square, 1-4 Kinkou-cho,
Kanagawa-ku, Yokohama City,
Kanagawa Pref. 221-0056 Japan
Tel +81-(0)45-450-7670

Atsugi Branch
8F Nihon Seimei Hon-atsugi Bldg,
1-2-1 Asahi-cho, Atsugi City,
Kanagawa Pref., 243-0014 Japan
Tel +81-(0)46-229-2700

Aichi Branch
KDX Sakura-dori Bldg., 3-20-17
Marunouchi, Naka-ku, Nagoya City,
Aichi Pref. 460-0002 Japan
Tel +81-(0)52-961-8511

Gifu and Mie Branch
11F Nouhi Nissei Bldg., 2-8 Hashimoto-cho,
Gifu City, Gifu Pref. 500-8856 Japan
Tel +81-(0)58-252-7400

Shizuoka Branch
4F Nissei Shizuoka Ekimae Bldg.,
59-7 Kurogane-cho, Aoi-ku, Shizuoka City,
Shizuoka Pref. 420-0851 Japan
Tel +81-(0)54-252-5125

Kyoto and Shiga Branch
7F Karasuma Chuo Bldg., 659 Tearaimizu-cho,
Nishikikoji-agaru, Karasuma-dori, Nakagyo-ku,
Kyoto City, Kyoto 604-8152 Japan
Tel +81-(0)75-212-6090

Hokuriku Branch
(Ishikawa/Toyama/Fukui)
13F Visage, 16-1 Showa-cho, Kanazawa City,
Ishikawa Pref. 920-0856 Japan
Tel +81-(0)76-232-6766

Osaka-Kita Branch
13F Uemura Nissei Bldg.,
3-3-31 Miyahara, Yodogawa-ku,
Osaka City, Osaka 532-0003 Japan
Tel +81-(0)6-6350-6355

Osaka-Minami Branch
14F Portas Center Bldg.,
4-45-1 Ebisujima-cho, Sakae-ku,
Sakae City, Osaka 590-0985 Japan
Tel +81-(0)72-223-1575

Nara and Wakayama Branch
5F Nara Center Bldg., 7-1-33 Omiya-cho,
Nara City, Nara Pref. 630-8115 Japan
Tel +81-(0)742-33-6011

Hyogo Branch
9F Meiji Yasuda Seimei Kobe Bldg.,
8-3-5 Isogami-dori, Chuo-ku, Kobe City,
Hyogo Pref. 651-0086 Japan
Tel +81-(0)78-241-6851

Hiroshima Branch
6F Nissei Hiroshima Bldg.,
7-32 Nakamachi, Naka-ku, Hiroshima City,
Hiroshima Pref. 730-0037 Japan
Tel +81-(0)82-543-6100

Yamaguchi Branch
10F Square Shin-yamaguchi,
2-21 Ogori-kogane-machi, Yamaguchi City,
Yamaguchi Pref. 754-0021 Japan
Tel +81-(0)83-972-1666

Tottori and Shimane Branch
6F Yonago Shoko Kaigisho Kaikan,
2-204 Kamo-cho, Yonago City,
Tottori Pref. 683-0823 Japan
Tel +81-(0)859-34-3521

Okayama Branch
4F Lit City Bldg., 15-1 Ekimoto-machi, Kita-ku,
Okayama City, Okayama Pref. 700-0024 Japan
Tel +81-(0)86-214-3760

Kagawa and Tokushima Branch
7F Ichigo Takamatsu Bldg.,
2-2-7 Kotobuki-cho, Takamatsu City,
Kagawa Pref. 760-0023 Japan
Tel +81-(0)87-811-6988

Ehime and Kouchi Branch
8F Taiju Seimei Matsuyama Bldg.,
4-1-1 Ichiban-cho, Matsuyama City,
Ehime Pref. 790-0001 Japan
Tel +81-(0)89-945-3600

Fukuoka Branch
8F Echo Bldg., 2-13-34 Hakataeki-higashi,
Hakata-ku, Fukuoka City,
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Tel +81-(0)92-451-8181

Nagasaki and Saga Branch
Nagasaki Ekimae Daiichi Seimei Bldg.,
2-3 Nishizaka-machi, Nagasaki City,
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Tel +81-(0)95-825-4772

Kumamoto and Oita Branch
2F Ichigo Kumamoto Bldg., 6-7 Karashima-cho,
Chuo-ku, Kumamoto City,
Kumamoto Pref. 860-0804 Japan
Tel +81-(0)96-359-6311

Kagoshima and Miyazaki Branch
7F KSC Kamoike Bldg., 2-4-35 Yojiro,
Kagoshima City,
Kagoshima Pref. 890-0062 Japan
Tel +81-(0)99-251-1600

Okinawa Branch
11F JPR Naha Bldg.,
1-1-19 Matsuyama, Naha City,
Okinawa Pref. 900-0032 Japan
Tel +81-(0)98-861-1211

Regional Management Offices (RMO)

Domestic

Hokkaido and Tohoku RMO
3F Sankyo Sendai Bldg., 1-12-7 Honcho,
Aoba-ku, Sendai City,
Miyagi Pref. 980-0014 Japan
Tel +81-(0)22-225-8551

Kanto-Kita and Koshinetsu RMO
8F Omiya Center Bldg., 1-9-6 Sakuragicho,
Omiya-ku, Saitama City,
Saitama Pref. 330-0854 Japan
Tel +81-(0)48-642-4771

Kanto-Minami RMO
17F Osaki Bright Core Bldg.,
5-5-15 Kita-shinagawa, Shinagawa-ku,
Tokyo 141-0001 Japan
Tel +81-(0)3-5449-6760

Tokai and Hokuriku RMO
KDX Sakura-dori Bldg., 3-20-17 Marunouchi,
Naka-ku, Nagoya City,
Aichi Pref. 460-0002 Japan
Tel +81-(0)52-961-8511

Kansai RMO
13F Uemura Nissei Bldg., 3-3-31 Miyahara,
Yodogawa-ku, Osaka City,
Osaka 532-0003 Japan
Tel +81-(0)6-6350-6355

Chugoku and Shikoku RMO
6F Nissei Hiroshima Bldg., 7-32 Nakamachi,
Naka-ku, Hiroshima City,
Hiroshima Pref. 730-0037 Japan
Tel +81-(0)82-543-6100

Kyushu RMO
8F Echo Bldg., 2-13-34 Hakataeki-higashi,
Hakata-ku, Fukuoka City,
Fukuoka Pref. 812-0013 Japan
Tel +81-(0)92-451-8181

Domestic Subsidiaries

Chugai Clinical Research Center Co., Ltd.
Nihonbashi-Honcho-2-Chome Bldg.
(Reception 3F)
2-2-5 Nihonbashi-Muromachi,
Chuo-ku, Tokyo 103-0023 Japan
Tel +81-(0)3-3273-1173

Chugai Research Institute
for Medical Science, Inc.
1-135 Komakado, Gotemba City,
Shizuoka Pref. 412-8513 Japan
(within the Fuji Gotemba Research Laboratories)
Tel +81-(0)550-87-5425

Chugai Business Support Co., Ltd.
5-5-1 Ukima, Kita-ku,
Tokyo 115-8543 Japan
(within the Ukima Representative Office)
Tel +81-(0)3-3968-8760

Medical Culture Inc.
Muromachi CS Bldg.,
4-6-5 Nihonbashi-Muromachi,
Chuo-ku, Tokyo 103-0022 Japan
Tel +81-(0)3-5202-8270

Chugai Distribution Co., Ltd.
1-20 Okuwa, Kazo City,
Saitama Pref. 347-0010 Japan
(within the Kazo Distribution Center)
Tel +81-(0)480-76-0381

Chugai Pharma Manufacturing Co., Ltd.
5-5-1 Ukima, Kita-ku,
Tokyo 115-8543 Japan
(within the Ukima Representative Office)
Tel +81-(0)3-3968-6200

Forerunner Pharma Research Co., Ltd.
Komaba Open Laboratory, The University
of Tokyo, 4-6-1 Komaba, Meguro-ku,
Tokyo 153-8904 Japan
Tel +81-(0)3-5452-5726

Overseas Subsidiaries, Affiliates and R&D Partners

Europe

Chugai Pharma Europe Ltd.
Mulliner House, Flanders Road,
Turnham Green, London W4 1NN U.K.
Tel +44-(0)20-8987-5600

Chugai Pharma U.K. Ltd.
Mulliner House, Flanders Road,
Turnham Green, London W4 1NN U.K.
Tel +44-(0)20-8987-5680

Chugai Pharma France SAS
Tour Franklin, Arche Sud,
100/101 Quartier Boieldieu,
92042 Paris La Défense cedex, France
Tel +33-(0)1-56-37-05-20

Chugai Pharma Europe Logistics S.A.S.
Tour Franklin, Arche Sud,
100/101 Quartier Boieldieu,
92042 Paris La Défense cedex, France
Tel +33-(0)1-56-37-05-20

Chugai Pharma Germany GmbH
Lyoner Straße 15, 60528
Frankfurt am Main, Germany
Tel +49-(0)69-663000-0

United States

Chugai Pharma USA, Inc.
300 Connell Drive, Suite 3100
Berkeley Heights, NJ 07922 U.S.A.
Tel +1-(0)908-516-1350

Asia

Chugai Pharma Science (Beijing) Co., Ltd.
1108 Beijing Fortune Bldg.
No. 5, Dong San Huan Bei Lu,
Chao Yang District, Beijing 100004, China
Tel +86-(0)10-6590-9556

Chugai Pharma China Co., Ltd.
Building G31, No. 801 Jiankang Dadao,
Medical City, Taizhou, Jiangsu 225300 China
Tel +86-(0)523-8681-9823

Shanghai Branch
Unit 2901, Central Plaza,
No. 381 Central Huaihai Road,
Shanghai 200020 China
Tel +86-(0)21-6319-0388

Beijing Branch
1118 Beijing Fortune Bldg.
No. 5, Dong San Huan Bei Lu,
Chao Yang District,
Beijing 100004 China
Tel +86-(0)10-6590-8066

Guangzhou Branch
Unit 1508, Pearl River Tower, No. 15,
Zhujiang West Road,
Guangzhou 510623 China
Tel +86-(0)20-8363-3468

Chugai Pharma Technology Taizhou Co., Ltd.
East of the Building G31,
No. 801 Jiankang Avenue,
Medical City Taizhou, Jiangsu 225300 China
Tel +86-(0)523-8681-9822

Chugai Pharma Taiwan Ltd.
3F., No. 260, Dunhua N. Rd., Songshan District,
Taipei 10548 Taiwan, R.O.C.
Tel +886-(0)2-2715-2000

Chugai Pharmabody Research Pte. Ltd.
3 Biopolis Drive, #07-11 to 16 Synapse,
Singapore 138623
Tel +65-(0)6933-4888

Shareholder Information (As of December 31, 2019)

Major Shareholders

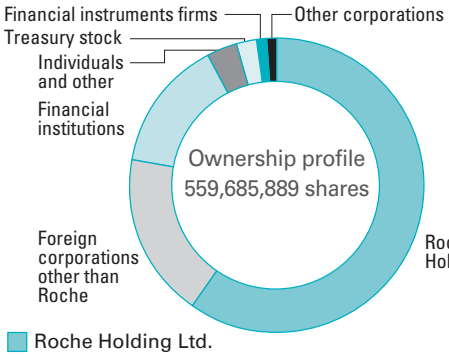
Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
Roche Holding Ltd	335,223	61.24
The Master Trust Bank of Japan, Ltd. (Trust Account)	30,258	5.52
JP MORGAN CHASE BANK 380055	16,388	2.99
Japan Trustee Services Bank, Ltd. (Trust Account)	16,075	2.93
STATE STREET BANK AND TRUST COMPANY 505001	10,537	1.92
Japan Trustee Services Bank, Ltd. (Trust Account 7)	4,756	0.86
Japan Trustee Services Bank, Ltd. (Trust Account 5)	4,230	0.77
STATE STREET BANK WEST CLIENT - TREATY 505234	3,998	0.73
SSBTC CLIENT OMNIBUS ACCOUNT	3,795	0.69
NORTHERN TRUST CO. (AVFC) SUB A/C AMERICAN CLIENTS	3,528	0.64

Note: 12,162,354 shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

Stock Price Information (From January 1, 2019 to December 31, 2019)

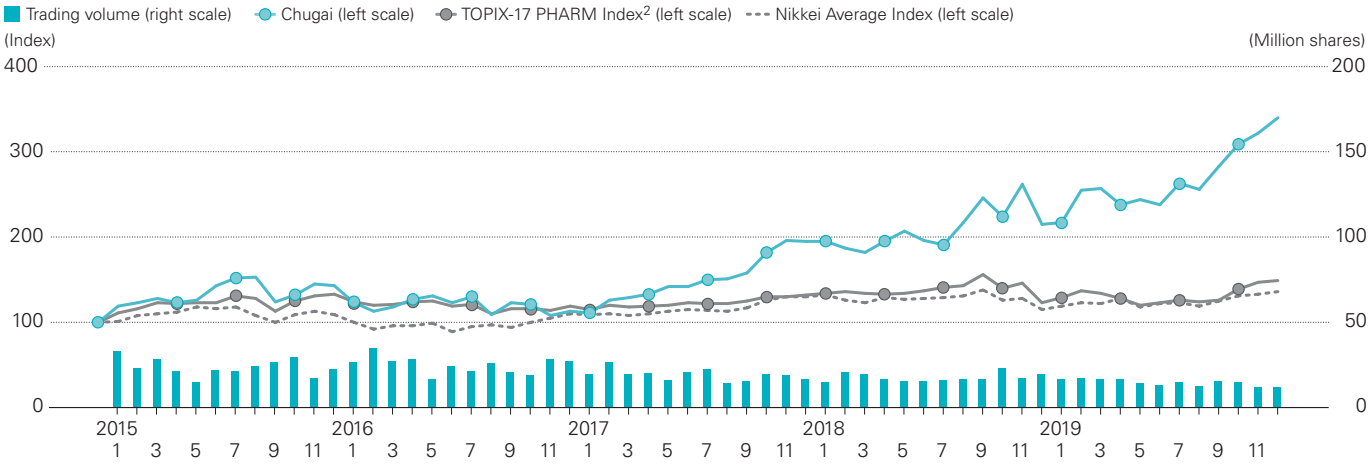
	Stock Price	
	Low	High
First Quarter	¥6,270	¥ 7,800
Second Quarter	6,750	7,640
Third Quarter	7,090	8,410
Fourth Quarter	8,090	10,160

Classification of Shareholders



- Roche Holding Ltd.
  Shares: 335,223,645 59.89% (Shareholder: 1)
- Foreign corporations other than Roche
  Shares: 101,135,449 18.07% (Shareholder: 792)
- Financial institutions
  Shares: 80,649,192 14.40% (Shareholder: 68)
- Individuals and other
  Shares: 18,971,024 3.38% (Shareholder: 18,704)
- Treasury stock
  Shares: 12,162,354 2.17% (Shareholder: 1)
- Financial instruments firms
  Shares: 6,713,622 1.19% (Shareholder: 36)
- Other corporations
  Shares: 4,830,603 0.86% (Shareholder: 150)

Share Performance[1] with Stock Indices

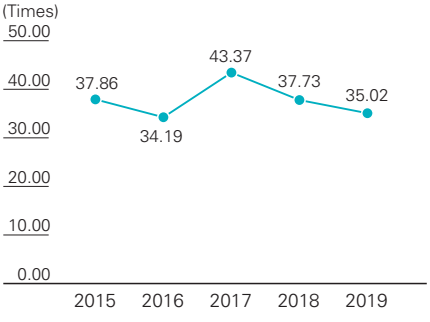


1. Closing price on December 30, 2014 = 100
2. A capitalization-weighted index that consists of pharmaceutical companies on the Tokyo Stock Exchange, First Section.

Share Price Indicators

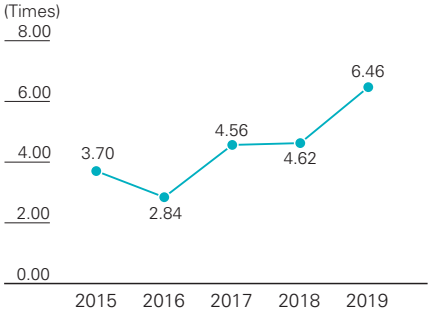
Price/Earnings Ratio

Year-end share price/Basic net income per share



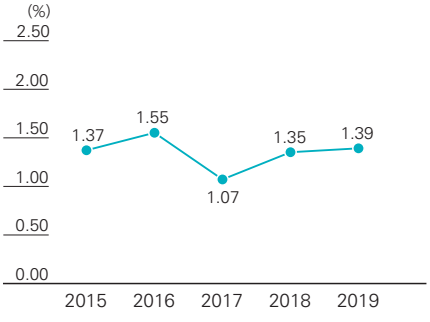
Price/Book Ratio

Year-end share price/Equity per share attributable to Chugai shareholders



Dividend Yield

Dividends per share/Year-end share price



Corporate Overview

(As of December 31, 2019)

Company Name	Chugai Pharmaceutical Co., Ltd.
Year of Foundation	1925
Year of Establishment	1943
Address	2-1-1, Nihonbashi-Muromachi, Chuo-ku, Tokyo 103-8324 Japan
Stated Capital	¥73,202 million
Number of Employees	7,394 (Consolidated)
Number of Shares Issued of Common Stock	559,685,889
Number of Shareholders	19,752
Stock Listing	Tokyo Stock Exchange, First Section
Fiscal Year-End	December 31
General Meeting of Shareholders	March
Transfer Agent	Mitsubishi UFJ Trust and Banking Corporation
For further information, please contact:	Corporate Communications Dept. Tel: +81-(0) 3-3273-3313 Fax: +81-(0) 3-3281-6607 E-mail: ir@chugai-pharm.co.jp

Editorial Policy

This integrated report is structured to encourage dialogue with shareholders, investors and other stakeholders. We hope it will be useful in sharing value with you.

Scope of This Report

This report presents information on Chugai Pharmaceutical Co., Ltd. and its consolidated subsidiaries. In some places, however, it gives data specifically pertaining to Chugai Pharmaceutical Co., Ltd.

Timeframe

The basic timeframe for this report is the financial reporting period of January to December 2019. However, in view of the importance of providing the latest information available, some information relating to activities that occurred in 2020 is included, mainly in research and clinical development data.

Information in This Report

This report presents information that Chugai believes to be important given its significance in building Chugai's corporate value over the short, medium and long term, and its degree of impact on stakeholders.

Reference Guidelines

The content of this report is focused on value creation, using as reference The International Integrated Reporting Framework issued by the International Integrated Reporting Council (IIRC) and Guidance for Integrated Corporate Disclosure and Company-Investor Dialogue for Collaborative Value Creation compiled by the Ministry of Economy, Trade and Industry of Japan. Sustainability information was prepared with reference to Environmental Reporting Guidelines 2018 issued by the Ministry of the Environment of Japan, the GRI Sustainability Reporting Standards of the Global Reporting Initiative (GRI), and the Final Report on Recommendations of the Task Force on Climate-related Financial Disclosures (TCFD).

External Evaluation of Chugai's ESG Initiatives

FTSE4Good

MEMBER OF Dow Jones Sustainability Indices
In Collaboration with RobecoSAM

MSCI 2019 Constituent MSCI ESG Leaders Indexes

Listed for All Four ESG Indices used by the Government Pension Investment Fund of Japan

FTSE Blossom Japan

S&P/JPX カーボン エフィシェント 指数

MSCI MSCI Japan ESG Select Leaders Index

MSCI MSCI Japan Empowering Women Index (WIN)

As the result of a third-party audit, FTSE Russell (a registered trademark of FTSE International Limited and Frank Russell Company) hereby attests that Chugai satisfies the conditions of listing on the FTSE Blossom Japan Index and has been made a constituent stock of such index. The FTSE Blossom Japan Index was created by FTSE Russell, a global index provider, and has been designed to measure the performance of Japanese companies demonstrating excellent environmental, social, and governance (ESG) practices. The FTSE Blossom Japan Index is widely used in the creation and evaluation of sustainable investment funds and other financial products.

Preparation and Internal Use of This Report

Management Participation in Planning

We consider this report to be an important tool for dialogue on Chugai's value creation. In producing it, Representative Director and Deputy Chairman Moto Ueno (left photo) and Chief Financial Officer (CFO) Toshiaki Itagaki (right photo) engaged in discussions on its concept, structure, content and design at a number of meetings and took responsibility up to its completion. Interviews and confirmation of the content were conducted with Representative Director, Chairman & CEO Tatsuro Kosaka and Representative Director, President & Chief Operating Officer (COO) Osamu Okuda, in addition the two aforementioned officers.

Positioning of the Report within the Company

The level of awareness of this report is high within the Company, and in addition to discussions held among persons in charge in each division during its production process, it is used in a wide range of applications including introduction at strategy briefings for employees and use in new graduate recruiting.

Innovation all for the patients

CHUGAI PHARMACEUTICAL CO., LTD.

A member of the Roche group

2-1-1 Nihonbashi-Muromachi, Chuo-ku, Tokyo 103-8324 Japan URL: https://www.chugai-pharm.co.jp/english/