

## Annual Report 2020

Fiscal year ended December 31, 2020



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(This document)

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## Chugai in Action

Outline of Functions / Response to the COVID-19 Pandemic / Research / Development / Pharmaceutical Technology and Production / Marketing / Medical Affairs / Drug Safety / Quality and Regulatory Compliance / Intellectual Property / Human Resources / Human Rights / Environment, Health, and Safety (EHS) / Social Contribution / Global Health

#### Basic Information

Basic Information on the Pharmaceutical Industry / Oncology / Bone and Joint Diseases/

Autoimmune Diseases / Renal Diseases / Neurology / Other Diseases

## Financial Information

Consolidated Financial Indicators / Management's Discussion and Analysis / Business Risks /

Consolidated Financial Statements

#### **Forward-Looking Statements**

This report may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the "Company"). These statements reflect the Company's current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company's businesses.

### Disclaimer

In this report, information on pharmaceutical products or drug candidates under development may be included, but such information is not intended for promotional or advertising purposes, or as medical advice, etc. The trademarks appearing in the report are protected by trademark rights, copyright, and other intellectual property (IP) rights.

#### About the Cover

The cover design represents innovation by Chugai—driven by various drug discovery technologies, science, and digital technologies—that brings new hope for better global healthcare and individual patient wellbeing.



### **Editorial Policy**

### This report is positioned to encourage dialogue.

This integrated report is structured to encourage dialogue with shareholders, investors, and other stakeholders. The 2020 report is being released in two parts: this annual report that provides a comprehensive outline of value creation over the medium-to-long term plus a separate activity report that provides more detailed information. The report structure is aimed at clarifying how information is organized and arranged into chapters, and at providing more detailed information for the reader that is easily accessible. 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 2020. However, in view of the importance of providing the latest information available, some information relating to activities that occurred in 2021 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 Dialogues for Collaborative Value Creation compiled by the Ministry of Economy, Trade and Industry (METI) 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).

#### **Production Process and In-House Use**

August-September	October-November	December-January	February-March	April-May
Secretariat Planning and Design	Draft Plan Review and Verification	Content Production  • Content confirmation,	Specific Page Layout  • Develop messaging,	Finalization • Final sign off by main
Set up production systems	Review and verification     by management team	approval by main executives responsible	structure composition, data	executives responsible (Ueno, Itagaki)
Design concept	Interview with relevant	(Ueno, Itagaki)	Create messaging based	Overall checks,
Create outline of planned structure     Environmental, social, and governance (ESG) meeting, review interviews     Interview with investors	parties  • Verify Material Issues  • Review structure content, required messaging  • Liaison with internal divisions	Verify risks     Progress update on short-, medium-, and long-term plans	on interviews with management team and external directors  Page layout verification by relevant executives	fine-tuning by production department  Third-party review

### **Management Participation in Planning**

The underlined stages in the production processes listed above show the steps that involve the management team. In particular, Representative Director and Deputy Chairman Motoo 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 and Chairman Tatsuro Kosaka, and Representative Director, President & Chief Executive Officer (CEO) Dr. Osamu Okuda.





### **Departments Responsible within the Company**

The Secretariat mostly comprises the Corporate Communications Department with the addition of the Sustainability Department. Additional members participated from the Corporate Planning Department, General Affairs Department, and Human Resources Management Department, and representatives were appointed from each division and department to build a company-wide production organization.

### Positioning of This 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.



### 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
   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

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's Business Processes

Core Source of Innovation

Our unique science and technologies

Strategic alliance with Roche

### Medium- to Long-Term Perspective

Research



### World-class drug discovery technologies

16

In-house projects in the development pipeline (As of February 4, 2021)

 $67^{1}$ 

Publications in academic papers and presentations at scientific conferences regarding Chugai's research findings (2020) 5,366

Patents held (including pending applications) (As of December 31, 2020)

Human resources



### Our greatest asset to achieve our Mission

Environment, health, and safety (EHS), investments



Cohesive management from a medium- and long-term perspective

Zero

2022

CO<sub>2</sub> emissions target for 2050

Scheduled completion of next-generation research facilities at the Chugai Life Science Park Yokohama



### Medium-Term Perspective

### Clinical Development and Pharmaceutical Technology

### Rich development pipeline

## Total of 8

Breakthrough therapy designations<sup>2</sup> (Cumulative total as of February 4, 2021)

Pipeline projects (As of February 4, 2021)

### 30

New products launched and new indications (2016-2020)

## 14.6%

Ratio of female managers<sup>3</sup> (Non-consolidated employee basis)4 (2020)

## ¥109,580

Education and training expenditures per employee (Non-consolidated employee basis)4 (2020)

## 194

Roche Human Resource Exchange Program (2004 - 2020)

## ¥254.7 billion

Total capital investment over past five years (2016–2020)

## 17% lower<sup>5</sup>

Energy consumption per employee, compared with 2010 (2020)



- Total of drug discovery and pharmaceutical technology
   A system introduced in July 2012 by the U.S. Food and Drug Administration (FDA) aimed at expediting the developm or life-threatening diseases or symptoms
   Number of female managers as a percentage of the total number of managers
   Calculated based on Chugai (non-consolidated) employees
   Chugai Group domestic operations and overseas research and production sites

### **Short-Term Perspective**



### Solutions (Marketing, Medical Affairs, Drug Safety)

### **Defined presence**

### No. 1 in Japan

Share of sales in the Japanese therapeutic antibody market (22.5%)<sup>6</sup>

### No.1 in Japan

Satisfaction ranking based on healthcare professionals' assessments (Oncology; hospitals with 100 or more beds)7 (Hemophilia)8

## No.1 in Japan

Share of sales in the Japanese oncology market (15.2%)6

## No.1 in Japan

Adequacy ranking for provision of safety information (Hospitals with 100 or more beds)9

### Products, information, etc.

We provide healthcare professionals and medical institutions with various kinds of information through our initiatives to deliver solutions. Products themselves are provided via pharmaceutical wholesalers.

Financial Performance



### Recognized for growth potential and profitability

 $$^{4}786.9$  billion

Revenues (No. 5 in Japan)10

38.3%

Ratio of operating profit to revenues (IFRS) (No. 2 in Japan)<sup>10</sup> (2020)

 $\pm 7.5$  trillion

Market capitalization (No. 1 among pharmaceutical companies in Japan)10 (As of the end of March 2021)

- Copyright © 2021 IQVIA. Source: JPM 2020 (calendar year), Reprinted with permission. The scope of the market is defined by Chugai.
- Source: INTAGE Healthcare Inc., CS Survey of Oncology, 2020. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
- Source: INTAGE Healthcare Inc, CS Survey of Hemophilia, 2020. Based on a survey of overall assessments of companies by physicians, as defined by Chuga
- 9. Source: INTAGE Healthcare Inc., 2020 questionnaire about safety information needs.
- 10. Financial results of pharmaceutical companies: (Chugai) Fiscal year ended December 31, 2020; (Other companies in the same industry) Fiscal year ended

December 31, 2020 or March 31, 2020

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 Sumitomo Dainippon Pharma Co., Ltd., Shionogi & Co., Ltd., Kyowa Kirin Co., Ltd., and ONO PHARMACEUTICAL CO., LTD.)

#### Value Provided

### Healthcare professionals and medical institutions

Better disease control
 More treatment options

Chugai provides better disease control and more treatment options through its innovative pharmaceuticals and advanced solutions. Patients in territories other than those managed by Chugai (Japan, South Korea, and Taiwan) have access to Chugai products through Roche and other global companies.

#### **Patients**

- Better drug efficacy and safety
   Better QoL
- Treatment choices that fit each patient

As well as direct improvements in drug efficacy and safety, Chugai also helps to improve QoL through early diagnosis and improved prognoses, and delivers the best treatment through personalized healthcare (PHC).



### Themes over the Past Year



## Six projects added to the pipeline, including the world's first switch antibody

In 2020, six projects were added to the pipeline, including STA551 that uses Chugai's proprietary switch antibody technology designed to bind to a target antigen only in the presence of a molecule (switch molecule) that becomes highly concentrated at the disease site.



# Japanese approval filing for nemolizumab for atopic dermatitis and development of additional indications

An approval filing was submitted in Japan by domestic licensing partner Maruho Co., Ltd. (in Q3 of fiscal 2020). Overseas licensing partner Galderma S.A. started phase III clinical studies on prurigo nodularis. The U.S. FDA granted breakthrough therapy designation for nemolizumab for the treatment of pruritus associated with prurigo nodularis.



## Launch of Enspryng that uses recycling antibody technology

Enspryng was launched in Japan and the United States in August 2020 as a drug with a new mechanism of action to treat neuromyelitis optica spectrum disorder (NMOSD). Chugai's proprietary technology means





Enspryng can be administered subcutaneously once every four weeks, providing improved patient convenience.



## Approval granted for blood-based test for cancer genomic profiling

In March 2021, Chugai obtained approval for FoundationOne Liquid CDx Cancer Genomic Profile as the liquid biopsy test that provides comprehensive genomic profiling (CGP), making it useful in cancers where tissue-based biopsy is difficult. The goal is to support the evolution of genomic cancer medicine.



FOUNDATIONONE®LIQUID CDx



### Research and development for COVID-19

As well as conducting clinical studies on the use of Actemra to treat COVID-19, Chugai has been involved in other COVID-19 initiatives including joint research between Chugai Pharmabody Research Pte. Ltd. and A\*STAR¹ and out-licensing of antibody engineering technologies to Eli Lily and Company for drug development purposes. Chugai has also in-licensed development and exclusive marketing rights in Japan from Roche for an antibody cocktail development program from Regeneron Pharmaceuticals, Inc. and an orally administered antiviral developmental agent from Atea Pharmaceuticals, Inc.

1. Agency for Science, Technology and Research in Singapore



## Announces CHUGAI DIGITAL VISION 2030 to accelerate DX

Chugai is moving ahead with a range of DX initiatives and also stepping up collaborations with external partners. Chugai was the only company selected as a Digital Transformation Stock (DX Stock)





Transformation Stock (DX Stock) 2020 in the pharmaceutical sector by the METI and the Tokyo Stock Exchange (TSE).



## Progressing global health initiatives with NGO<sup>2</sup> partners

Chugai organized a workshop to promote multidisciplinary team healthcare in Cambodia in February 2020 and began a project focused on improving the quality of patient-centric cancer treatment in Yangon, Myanmar in July.

Chugai is collaborating with the NPO Japan Heart on the Cambodia program and the NGO City Cancer Challenge Foundation (C/Can) on the Myanmar program.



## Selected for the first time in DJSI World, a global ESG investment Index

In November 2020, Chugai was recognized as a highly sustainable company when it was selected for the first time in the DJSI World<sup>3</sup> comprised of the top eight pharmaceutical companies in the world.

3. The World Index of the Dow Jones Sustainability Indices (DJSI) that includes top global companies in terms of ESG investment.

Member

#### Dow Jones Sustainability Indices

Powered by the S&P Global CSA



## New personnel systems designed and introduced

Chugai introduced new personnel systems in April 2020 to allow personnel treatment to be matched with the role and performance outcomes of the right person in the right place. The new systems will promote and support employees for self-directed career development and taking on challenges for further growth.



## New management system of business administration

Chugai announced a new management system effective March 23, 2021, comprising Dr. Osamu Okuda as President & CEO, Tatsuro Kosaka as Chairman, and Motoo Ueno as Deputy Chairman, with the goal of pursuing new growth strategies under a new system of business administration.



## Formulation of new value creation strategy toward 2030

In February 2021, Chugai announced a new 10-year growth strategy aimed at becoming a top innovator in the healthcare industry in 2030.





### The pursuit of innovation remains the key concept underpinning value creation at Chugai. We aim to support patients and society by genuinely addressing their hopes and expectations and delivering solutions to specific unmet medical needs.

### Renewed Determination to Pursue Innovation in **Line with Our Mission Statement**

The COVID-19 pandemic has had a serious and unprecedented impact around the world. Chugai's operations have been affected to some degree, but as a healthcare-related company, our first priority has been to ensure a stable supply of medicines to patients.

This pandemic is transforming economic and social structures, and has focused attention on a range of social issues, including such environmental risks as population growth, demographic aging, and climate change. Issues such as workstyles, digitalization, and risk management are becoming increasingly important from a business perspective.

Looking at the business environment for healthcare, our assumptions for the future seem to be transpiring right now. All around the world, we are seeing new measures to curb drug costs, and the trend toward value-based healthcare (VBHC), in which only medicines and solutions that offer true value are chosen due to limited resources, is becoming even more pronounced. As the competitive landscape heats up, it will be important to flexibly incorporate advances in life sciences and digital technology.

Against this backdrop, Chugai has renewed determination to

pursue innovation for becoming a top innovator in the healthcare industry, in line with our unwavering mission to dedicate ourselves to the medical community and human health around the world. Our duty is to solve unmet medical needs one by one through pharmaceuticals and solutions with true value. This also provides our Company with opportunities for growth. Through innovation only possible at Chugai, we will contribute to patients and society by creating shared value with stakeholders.

### Mid-Term Business Plan IBI 21 Achieved and **Completed One Year Ahead of Schedule**

Having realized the "top pharmaceutical company" target set for ourselves in 2009, we updated our Mission Statement in 2019 and formulated mid-term business plan IBI 21 toward achieving this goal.

Against the target of an average annual growth rate of around 30 percent\* for Core EPS over the three-year period to 2021, we achieved an average growth rate of 49.5 percent over the years of 2019 and 2020, far exceeding our expectations. Even in the servere business environment, the Company demonstrated its strong growth trajectory by posting record high profits for four consecutive years.

We also made steady progress in all five of our priority strategies. In the pipeline, four new in-house projects moved

### IBI 21: General Overview of Five Priority Strategies (2019–2020)

1. Value Creation	Steady progress in drug discovery, including progress of in-house projects	Mid-size molecule project: Progressed as planned toward P1 start in 2021     Antibody project: Phase I started for next-generation switch antibody STA551     Start of global phase III for crovalimab/SKY59, approval of Enspryng and start of sales
2. Value Delivery	Expanded market penetration of growth drivers and accelerated value maximization	Hemlibra: Significant increase in overseas revenues, expansion in the number of countries with approval     Tecentriq: Progress in expanding indications including first-in-class
Promote Advances in 3. Personalized Healthcare (PHC)	Formulation of CHUGAI DIGITAL VISION 2030 and promotion of cancer genomic medicine	<ul> <li>Digital: Progress of company-wide digital strategy and acceleration of Al drug discovery, etc.</li> <li>Successful expansion of FoundationOne CDx indications, FoundationOne Liquid CDx filed for approval</li> <li>Filed for ROS1 indication of Rozlytrek using real-world data (RWD) as reference data</li> </ul>
Strengthen Human Capital 4. and Conduct Fundamental Structural Reform	Progress in transforming systems to support innovation	Started operation of a new HR system     Progress with structural reforms in corporate and prioritized divisions
5. Strengthen Sustainable Platforms	Enhancing platforms to support efforts for innovation	Selected for first time as a constituent of DJSI World     Enhanced stakeholder communication

into clinical development during the past two years, including the next-generation antibody STA551 that uses our switch antibody engineering technology. We have achieved strong growth in the global market with Hemlibra, Actemra, and Alecensa, all of which were discovered at Chugai, and in 2020 another in-house product, Enspryng, was approved in many countries around the world. In the Japanese market, Tecentriq was approved as a first-in-class (FIC) treatment for various types of cancer and is now penetrating the market. Development of mid-size molecule drugs, which we are focusing on as our third modality, has proceeded steadily, and we plan to start clinical studies during 2021. In terms of human capital, we are accelerating our diversity and inclusion (D&I) programs, and in April 2020 we introduced a new HR system centered on the promotion of talent management and role-based performance. In addition, we formulated CHUGAI DIGITAL VISION 2030, strongly promoted the Company's digital transformation (DX), and made significant progress with a range of initiatives to strengthen our platforms for sustainability. Through these measures, we achieved both our initial qualitative and quantitative targets and made significant strides forward in developing a foundation for innovation. For these reasons, we completed IBI 21 one year ahead of schedule.

\* Increased in January 2020 from the initial outlook of high single digits (7–9%)

### **Pursuit of Innovation Remains Key** for Future Value Creation

Chugai is now implementing a new growth strategy, TOP I 2030, in order to become a top innovator in 2030. The pursuit of innovation remains the key concept underpinning this strategy.

I have long said that to create innovation, it is important to carefully refine and continuously evolve: science, which is the source of value and the basis for decision-making; technologies, which are indispensable for Chugai's business; and human capital and corporate culture, which are the main drivers of innovation.

The results of employee awareness surveys show that Chugai's human capital and corporate culture now reflect an in-depth understanding of the patient-centric concept described in our Core Values. We have run a number of programs, including manager workshops and dialogues with the management team, as well as dialogues between our employees and representatives from patient organizations. As a result, we are starting to see the patient-centric concept used in decision-making for our business activities and in initiatives to measure true value for patients. I myself have received many valuable suggestions from discussions with six cancer patient groups in 2020.

### **Creating Shared Value under** the New Management Structure

Dr. Osamu Okuda was appointed President & CEO in March 2021. Although I have stepped down as CEO, I will continue to serve as Chairman of the Board of Directors. This change of CEO was based on succession planning by the Appointment Committee and a report on CEO succession by the same committee. A smooth transition to the new leadership team has been a key theme in corporate management, and I believe we have made the right decisions in terms of succession planning. The TOP I 2030 strategy also reflects the ambitions of the new management team, with Dr. Okuda playing a core role in its development.

Looking ahead, it will become increasingly important for corporate management to genuinely address the needs and expectations of society and apply them to managing the business in a rapidly changing environment. Sustainability is becoming even more important, and we will work to incorporate the perspective of strengthening platforms for sustainability into the evaluation criteria for executive remuneration, with the aim of sharing this perspective among the management team toward the creation of shared value.

Look forward to even more value creation from us.



By 2030, we aim to have global first-class drug discovery capabilities and be a top innovator in the healthcare industry, an innovator that patients around the world can count on. To achieve this, we will create shared value with society and deliver advanced and sustainable patient-centric healthcare.

# As Chugai's new CEO, how will you approach the changing business environment?

Having performed environmental scenario analysis from the perspective of markets, science and technology, and customers, we have reaffirmed our determination to realize patient-centric healthcare by continuing to focus on value creation through innovative drugs from a medium- to long-term perspective through to 2030.

I was appointed President & CEO in March 2021. It is a great honor to be entrusted with Chugai's future, and I am firmly resolved to take on this tremendous responsibility.

Looking back over the past year, the COVID-19 pandemic has triggered rapid changes across economies and society in general. Chugai has implemented a range of measures to ensure a stable supply of medicines and to halt the spread of infection. Surveying the healthcare field, it seems that the changes we had expected to occur over a decade, such as progress in digitalization, have transpired in only a year. It is more important than ever to ensure that our medium- to long-term outlook reflects such sudden structural changes in markets, science and technology, and customers. This is why we have conducted environmental scenario analysis for our

medium- to long-term outlook in order to develop a roadmap for future value creation.

The first market change of note is that governments around the world have responded to the COVID-19 pandemic by implementing large-scale fiscal stimulus measures that may result in greater pressure to rein in healthcare expenditures and drug costs in the future. In particular, we need to keep a close eye on drug pricing policy in the United States, the largest pharmaceutical market in the world, including policies introduced by the new presidential administration.

Changes in science and technology present both risks and opportunities. With increasing diversity in new modalities such as gene therapies, cell therapies, and digital therapeutics, we

had assumed that these modalities might erode existing pharmaceutical markets such as small molecule drugs and antibodies. At this stage, however, the new modalities appear to complement or add to existing modalities. In the evolving field of digital technologies, we believe that making full use of these technologies will become key to determining our competitive edge in the future.

From the perspective of customers, such as patients and healthcare professionals, patients are becoming more informed about diseases and treatment methods, and have more opinions about their own treatment than ever before. We also anticipate a greater acceptance of digital technologies in the so-called "new normal" society.

As such, it appears that the future healthcare environment will converge on value-based healthcare (VBHC). This will

accelerate the trend to only select those pharmaceuticals or solutions that deliver true value, with low-value options falling by the wayside. Against this backdrop, Chugai remains committed to creating innovative pharmaceuticals as its core business from a medium- to long-term perspective until 2030. This means we will continue to create value with a focus on:

- Pursuing innovation for patient-centric healthcare
- Creating and delivering innovative pharmaceuticals as our core business
- Maximizing the use of the strategic alliance with Roche in our business model
- ▶ P22 Value Creation Model
- P24 Vision of Chugai as a Top Innovator in 2030: Outlook for Chugai's Business Environment in 2030
- Activity Report, P4 Response to the COVID-19 Pandemic

# Q What is Chugai's strategy aiming to achieve?

# The goal is for all of our employees to work together toward the vision of making Chugai a top innovator in the healthcare industry by 2030.

Chugai was very successful under IBI 21, reaching the targets one year ahead of schedule (see Message from the Chairman for an overview of IBI 21). Based on these results and the outlook for the business environment, the first step in formulating our new growth strategy was to set a vision of what we want to achieve. Chugai's Envisioned Future is to become a top innovator in the healthcare industry, as described in our Mission Statement. Once we knew the direction Chugai is headed in the next 10 years and how we can realize sustained growth, we set a specific picture of where we should be by 2030, and I would like to see all of our employees come together as a driving force for value creation.

We have also developed three perspectives on what it will mean to be a top innovator in 2030. The first is defined as "expectation from patients all over the world," reflecting our desire to pursue innovation for patients. With world-class drug discovery capabilities, patients around the world will be able to count on Chugai to create new treatments.

At the same time, we aim to attract talent and players from around the world. In the healthcare field, where diverse players are engaged in friendly rivalry, we want to become an exciting company that passionate talent and players

### Realizing the Vision of Chugai as a Top Innovator in 2030

## Expectation from patients all over the world



With world-class drug discovery capabilities, patients around the world expect that "Chugai will surely create new treatments."

## Attracting talent and players from around the world



Attract passionate talent from all over the world and inspire players globally to think they can create something new by partnering with Chugai.

#### Role model for the world



Recognized for ESG initiatives through its business activities, Chugai will become a global role model as a leader in resolving social issues. throughout the world want to participate and collaborate with to create something new.

Finally, we want to be a "role model for the world" by creating social value. As ESG initiatives increasingly come under the spotlight in the future, Chugai, which has declared its support for the United Nations Sustainable Development Goals (SDGs) in line with our basic policy of creating shared value with society, is determined to focus more on unique

initiatives and become a company that society can count on, and be recognized by companies around the world as a leader in resolving social issues.

- P10 Message from the Chairman
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- ▶ P56 Background to Growth Strategy Development
- ▶ P72 Message from the CFO

## Q. Please tell us about the new growth strategy.

TOP I 2030 sets out three key drivers for achieving global first-class drug discovery and a futuristic business model.

We formulated TOP I 2030 as a 10-year value creation strategy in order to realize our vision of becoming a top innovator in the healthcare industry. The strategy, based on our basic management policy of creating shared value with society, is the approach that Chugai is taking to contribute to the sustainability of society.

TOP I 2030 is based on the two pillars of "global first-class drug discovery" and a "futuristic business model." We have established three key drivers to achieve this: Research & Early Development (RED) Shift, digital transformation (DX), and Open Innovation.

### New Growth Strategy TOP I 2030



To develop global first-class drug discovery capabilities, we have defined RED functions (which correspond to the initial development stages of research, early clinical development, and pharmaceutical technology functions) as our value creation engine. We aim to increase R&D output by focusing our investment of business resources in these RED functions. Although we have emphasized R&D investment in the past, we have not always been able to concentrate our resources on RED functions. In terms of clinical development costs, spending in late-stage development has tended to be higher than in the early stages. In addition, new opportunities are opening up in, for example, new mid-size molecule technologies and the development and adoption of new modalities, so we will strengthen our RED functions through an unprecedented shift in resource allocation. The resources for this investment will be freed up by building a futuristic business model that significantly improves productivity across all value chains. This will strengthen the cycle of investment and re-investment and further enhance Chugai's value creation engine.

In order to strengthen this drug discovery capability and build a futuristic business model, DX and Open Innovation are also essential. We aim to transform the drug discovery process and take new approaches using artificial intelligence (AI) in drug discovery. At the same time, we will promote the transformation of our operating model through the use of digital technologies in all functions. In the rapidly advancing fields of drug discovery, science, and digital technology, it is becoming more difficult for innovation to be forged by one company alone. We need to be much more proactive in forming external partnerships; new value will be created through synergies with our strengths, rather than through independent efforts.

Based on TOP I 2030, we aim to double R&D output and be in a position to launch in-house global products every year.

- ▶ P26 Vision of Chugai as a Top Innovator in 2030: Value Shared by a Top Innovator
- ▶ P28 Vision of Chugai as a Top Innovator in 2030: Key Drivers to Becoming a Top Innovator
- ▶ P50 Targets and Progress in Material Issues
- ▶ P54 Main Risks and Countermeasures
- ▶ P58 New Growth Strategy TOP I 2030

## Can you give more detail on each strategy under TOP I 2030?

We are pursuing five reforms, namely Drug Discovery, Development, Pharmaceutical Technology, Value Delivery, and Foundation for Growth.

Five reforms are being promoted under TOP I 2030.

For Drug Discovery, we will strengthen drug discovery technologies by leveraging digital technologies and enhancing collaboration with external players. Mid-size molecules will be developed as our third modality alongside small molecule drugs and antibodies. We will also develop other new modalities by leveraging our strengths in protein engineering technologies. Moreover, we will flexibly incorporate Roche technologies to evolve to a world-class level of multi-modality drug discovery. From among these, we will select the optimal modality to take forward each innovative drug discovery idea and generate lead candidates for clinical development. As for mid-size molecules, which are expected to drive future growth, we will prioritize the investment of business resources there because of their potential to provide new value to patients by reaching "tough" intracellular targets (proteins) that cannot be targeted by conventional drug discovery technologies, and because of their oral absorption properties.

For Development, we will pursue initiatives in both early-stage and late-stage clinical development. In the early stages, we will focus on improving predictability in humans through an intricate understanding of biological responses and the utilization of innovative technologies such as modeling & simulation (M&S) and human organoid\* construction. The aim is to achieve a dramatic improvement in development success rates. We will also promote accelerated development of additional indications from an earlier stage. In late-stage clinical development, we will achieve significant improvements in our operating model by using digital technologies to increase the efficiency of clinical trial operations and reform management processes.

For Pharmaceutical Technology, we will build pharmaceutical technology platforms suited to the mid-size molecules and new modalities in early-stage development, and focus on improving the speed of technology development and investigational drug manufacturing. In commercial production, we will pursue world-class cost competitiveness and stable supply by reducing costs and restructuring manufacturing systems as well as developing next-generation plants that use digital robotics.

For Value Delivery, we will develop a system for generating evidence that enables the delivery of personalized healthcare (PHC); establish a new customer engagement model that

combines in-person, remote, and digital technologies; and build platforms to deliver the optimal information to each customer. At the same time, we will concentrate resources in growth areas through the optimal allocation of human resources in line with our product portfolio and reforms to back-office functions. Our goal with these reforms is to achieve high-level value delivery for patient-centric healthcare.

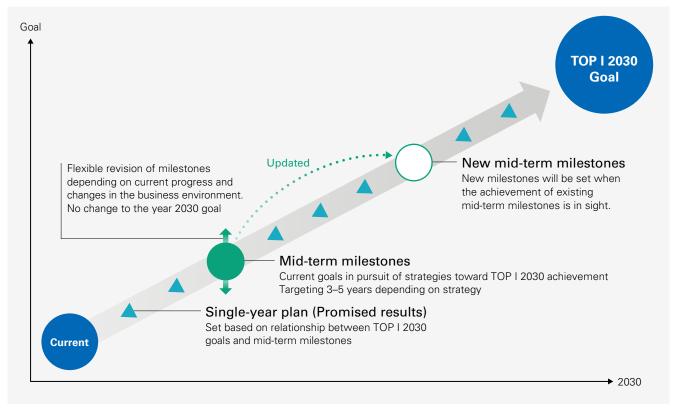
For Foundation for Growth, which underlies these reforms, we have designated five areas where changes are particularly important, including areas relevant to Material Issues and key themes. In the area of People and Organization, we will thoroughly implement our new personnel system, acquire the highly specialized talent we require, promote new ways of working, and strengthen our corporate culture to encourage bold challenges. In the Digital area, we will strengthen our digital infrastructure and improve efficiencies across all value chains, as well as create innovative new drugs using digital technology in line with CHUGAI DIGITAL VISION 2030. In the area of Environment, we will focus on achieving our mid-term environmental goals for 2030, which include high targets such as zero CO2 emissions by 2050. In the area of Quality, we aim to establish next-generation quality management systems suited to new modalities and new businesses. Finally, for Insight Business, where internal

and external data are analyzed to extract valuable insights and deliver solutions, we will investigate technologies through our pharmaceutical business, build the necessary capabilities, and consider commercialization.

As for our method of formulating business plans, we have decided to discontinue issuing mid-term plans every three years, given the rapidly changing business environment at present. Instead, we will confirm the validity of the TOP I 2030 goals with mid-term milestones and single-year plans. We have made this change because we need to be more agile than ever before when reviewing and updating strategies and plans in response to changes in the business environment. Fixed three-year activity plans may limit the range of decision-making for resource allocation or hinder sound risk-taking, including investment for growth. We have also decided to stop releasing quantitative guidance on financial results in our business strategies. However, we will continue to disclose single-year plans as before and will share information with stakeholders in a conscientious and timely manner, including the progress of TOP I 2030 and updates on the R&D pipeline.

- \* Tissue structures designed to have similarities to organs in the human body
- ▶ P60 New Growth Strategy TOP I 2030 (Drug Discovery, Development, Pharmaceutical Technology, Value Delivery, and Foundation for Growth)

### New Growth Strategy through 2030: Changes in the Planning Process





## • What will be the most important issue for value creation in the future?

Pursuit of innovation remains the most important issue, but without question, the source of innovation is our people.

Under TOP I 2030, the realization of advanced and sustainable patient-centric healthcare is the goal of our value creation, and our top priority will remain the pursuit of innovation.

That said, where does this innovation come from? I firmly believe that our people are the source of innovation. Employee motivation is a critical factor here, and the management team is responsible for providing our employees with the opportunities, working environment, and colleagues that give them a sense of fulfillment. I want Chugai to be an organization that fosters a culture of innovation, a company where employees can grow and play an active role regardless of their background or attributes, a company where employees can design their own career paths and tackle new challenges of their own choosing. The results of the employee awareness survey conducted in 2020 were better than the previous survey in 2018, particularly for the key theme of "employee engagement," where Chugai ranked highly compared with other global corporations with positive results. The challenges facing Chugai, however, have not changed. The survey highlighted issues with company-wide optimization of resources, divisional and departmental collaboration, and appropriate employment conditions for challenging roles. Under TOP I 2030, we will execute a plan for resource allocation and business process development to resolve these issues.

Another indispensable factor for creating innovation is diversity and inclusion (D&I). Chugai has regarded diversity as a key management issue since 2010, and has been working to design systems and create an environment to promote D&I. We are establishing a culture where female employees and non-Japanese employees can make the most of their skills. The number of female managers has been increasing, but I believe we need to accelerate such initiatives even more. We have two female executive officers and one foreign national executive officer, but I would like to increase the diversity of our executive team as well.

In 2021, the first year of TOP I 2030, it is essential that all Chugai employees fully understand and share this strategy, and that each and every employee across all value chains play a leading role in promoting the reforms. Execution is key. I am resolute in my determination to implement TOP I 2030 and realize our vision of Chugai as a top innovator.

Finally, I would like to engage in ongoing dialogues with our stakeholders in order to share this vision of value creation and our progress to achieve it. I look forward to your continued support.

Activity Report, P17 Human Resources



Chugai aims to become a top innovator for advanced and sustainable patient-centric healthcare through its focus on innovation. This means the value we provide for patients will encompass more than just greater drug efficacy. Our goal is to provide pharmaceuticals and solutions that have been proven to have true value for each patient.

### Case Study

### The Value of Treating Hemophilia

Hemophilia is a rare disease characterized by a deficiency or dysfunction in the factors needed for blood clotting, which impairs the body's ability to stop bleeding after some kind of injury. Nowadays, with the advancement of treatment methods, people with hemophilia can lead normal lives and are even advised to exercise regularly. The main treatment for hemophilia A is replacement therapy, where blood clotting factor VIII is administered intravenously between one and three times a week. This treatment places a fairly substantial burden on the patient, particularly for pediatric patients, and can also result in the development of inhibitors against the replacement clotting factor. Chugai's in-house product Hemlibra is expected to transform current treatment systems, as the drug can be administered subcutaneously once every one or two weeks, or even once every four weeks, to prevent bleeding regardless of inhibitor status. Hemlibra is one major outcome of our goal of realizing advanced and sustainable patient-centric healthcare.

### Hemlibra

Total of more than 11,000 patients treated Approved in over 100 countries (As of April 2021)



### Our History and Shared Value

Chugai was founded in 1925 in response to the shortage of medicine after the Great Kanto Earthquake. The business environment has changed significantly over the years, but Chugai has continued to operate even as it implemented changes in business areas, research fields, and business models, all the while sharing value with patients and society. Looking back, there have been six major turning points when important decisions were made that allowed us to change and evolve our shared value. This section presents an overview of Chugai's history and the shared value it provides.

1925 1970 Manufacturing and In-house Import and sales of drugs **Business** sales of prescription development and areas Manufacturing and sales of OTC drugs drugs 1 sales of new drugs · Built strengths in Small-molecule Embarked on research certain fields of drug research Research into pharmaceutical research (basic and applied fields technology and (e.g., immunology, research using formulation bone and joint existing technologies) diseases) In-licensing of products from overseas Shifted business **Business**  Focused on application, industrialization, resources to in-house models drug development and sales of existing technologies

#### 1960s

### Shift to Prescription **Pharmaceuticals**

After Japan's National Health Insurance (NHI) system was established in 1961, advances in healthcare necessitated a broader range of pharmaceuticals to provide more treatment options. In response, Chugai shifted its core business from manufacturing and sales of over-the-counter (OTC) drugs to prescription drugs, also increasing the Company's focus on research and development. As a result, our stagnating business performance began to recover.

#### Main Shared Value

Patients: Access to comprehensive medical

Society: Expansion of treatment options; a stable healthcare system; further advances in the healthcare and pharmaceutical industries

#### 1980s

### 2 Commitment to Development of Biopharmaceuticals

In the 1980s, Chugai decided to invest business resources into the research and development of biopharmaceuticals, which offered new approaches to diseases and promising therapies with high efficacy and safety, because the Company believed that unmet medical needs could not be fully addressed with the chemically synthesized small-molecule drugs that were the mainstream at the time. We also worked to establish mass-production technologies, which laid the foundations for the subsequent development of our 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

### Since 2000s

### Strategic Alliance with Roche

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, a unique business model emerged, which 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 value contribution.

#### 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

2000 2010 2020 Increased focus on Promotion of PHC 4 creation of innovative drugs 5 Accelerated development Realization of Embarked on of proprietary research Accelerated research advanced and research into technologies 5 into therapeutic sustainable biopharmaceuticals antibodies 5 patient-centric Research into mid-size 2 healthcare 6 molecule drugs Strategic alliance with Roche Continuous global (In-licensing of Roche products, utilization of development of research infrastructure) in-house products 5 Development of in-house products in the (Out-licensing to global market (Utilizing Roche's global network) Roche and other Focused on novel targets and new companies) technology development

#### Since 2000s

### Promotion of PHC

Personalized healthcare (PHC), in which the optimal treatment is provided based on the patient's genetic profile and other diagnostic information, is a trend in healthcare that offers significant benefits to all stakeholders. Ever since the launch of Herceptin (in-licensed from Roche), Chugai has played a pioneering role that has driven the uptake of PHC, 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 OoL; reduced burden

**Society:** Optimal treatments for each patient stratum; avoidance of unnecessary administration

#### Since 2000s

### 5 Launch of Therapeutic Antibody and Continuous Creation of Innovative Drugs

In 2005, Chugai launched Actemra, the first therapeutic antibody created in Japan, to further address unmet medical needs. 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.

#### Main Shared Value

Patients: Superior efficacy and safety; groundbreaking outcomes

Society: Evolution of treatment paradigms; enhanced treatment adherence and diagnosis; response to rare diseases

### Since 2019

### 6 Commitment to Realizing Advanced and Sustainable Patient-Centric Healthcare

Given the challenges facing the healthcare industry in terms of patient trends, systems for the provision of medical care, and healthcare finances, Chugai declared in 2019 that it would work toward becoming a top innovator for advanced and sustainable patientcentric healthcare based on the creation of shared value. Our commitment to contribute to all patients, healthcare, and society has remained unchanged since our founding.

#### Main Shared Value

At Chugai, we have defined shared value with each group of stakeholders that goes beyond simple cooperation, as we work to achieve advanced and sustainable patient-centric healthcare.

P26 Value Shared by a Top Innovator

### Value Creation Model

Our growth and development through increase in corporate value

Creation of shared value for Chugai and society

Realization of advanced and sustainable patient-centric healthcare

Social growth and development by resolving social issues

**Envisioned Future for 2030** 

## Top innovator in the healthcare industry

### Chugai business model

### Focus on innovation

Creation of innovative drugs and services

Chugai's unique science and technologies

Strategic alliance with Roche

### Two Revenue Bases

**Strategic Alliance with Roche** 

### **Products from Chugai research**

Able to specialize in highly innovative drug discovery

Revenue base that drives growth (Out-licensing to Roche and global market development)

### **Products in-licensed from Roche**

Exclusive domestic sales of breakthrough therapies

Stable revenue base (Efficient product launches through collaboration with Roche)

▶ P32 Collaboration with Roche

### Commitment to "Creating Shared Value"

Chugai has adopted "creating shared value" as its basic management policy, in line with its philosophy of growing together with its various stakeholders by resolving social issues through business activities. The goal (outcome) of this shared value, which is also part of our Envisioned Future, is to realize advanced and sustainable patient-centric healthcare.

Sustainable healthcare systems are needed around the world, as expectations and needs for pharmaceuticals increase further due to world population growth and demographic aging combined with the spread of COVID-19. Dramatic advances in life sciences and digital technology are providing more opportunities for innovation to solve issues in healthcare, but governments are implementing more and more stringent policies to curb medical expenditures, including drug costs, as healthcare finances come under pressure. Given the limited resources available, we expect the medical community to converge even faster on value-based healthcare (VBHC), where only those solutions that deliver true value are adopted.

### Top Innovator in the Healthcare Industry

To create shared value under these circumstances, we have defined the steps we need to take to become a top innovator in the healthcare industry and realize our Envisioned Future for 2030 (see the diagram below). Chugai is a company that generates expectations from patients all over the world, attracts healthcare-related talent and players, and is a global role model that resolves social issues. Through our collaboration with Roche, we will continue to place "innovative new drugs" at the core of our business, while aiming to become a leading innovator in the global healthcare field, where a diverse range of players, not limited to pharmaceutical companies, are taking on the challenge of innovation.

The key to the value created by Chugai is its focus on innovation. We look to create new drugs to address the increasing number of unmet medical needs by searching for new therapeutic targets and further creating innovative drug discovery technologies. We cannot survive in the future business environment without constant innovation. Powered by its unique strengths in science and technology, Chugai will focus all its business resources on innovation through the utilization of digital technologies and the active promotion of external collaborations.

### **Business Model for Value Creation Based on Material Issues**

We believe that this value creation is achievable, as Chugai has a unique business model being a member of the Roche Group while also maintaining autonomy and management independence. Based on this business model, Chugai has established two revenue bases—products from Chugai research and products in-licensed from Roche. The model creates a sustainable cycle in which stable revenue from products in-licensed from Roche enables Chugai to make a concentrated investment in innovation, leading to the continuous creation of innovative products. The subsequent out-licensing of these products to Roche provides Roche with the resources to further invest in the development of innovative products.

In addition, we have established 25 Material Issues in eight categories to be given priority in our efforts to create shared value. We are constantly reviewing the Material Issues alongside changes in the business environment but have made no changes to them in the new growth strategy for 2030.

### Realizing the Vision of Chugai as a Top Innovator in 2030

### Expectation from patients all over the world



With world-class drug discovery capabilities, patients around the world expect that "Chugai will surely create new treatments."

### Attracting talent and players from around the world



Attract passionate talent from all over the world and inspire players globally to think they can create something new by partnering with Chugai.

### Role model for the world



Recognized for its ESG initiatives through its business activities, Chugai will become a global role model as a leader in resolving social issues.

### **Outlook for Chugai's Business Environment in 2030**



### Change in the Market

- Acceleration of controls on drug costs, and continued shift to value-based healthcare (VBHC)
- United States is a market driver, with China becoming increasingly important



- Need to discover innovative new drugs with real value, and find ways to demonstrate value
- Challenge lies in capturing opportunities in growth markets



### Change in Science & Technology

- New modalities will not compete against pharmaceuticals but play a complementary role
- Digital technologies will become a key requirement for business model evolution and competitive advantage



- Pharmaceuticals will continue to be Chugai's core business
- Obtain competitive modalities and accelerate the evolution of various functions through digital transformation (DX)



### Change in Customers

- Increased influence of informed patients and payers
- Evolution of DX at customers
- · Difficulties in transforming healthcare into an information-based industry



- Need to build a value story for each patient
- · Challenge lies in developing a customer engagement model using digital technologies

### Severity of drug pricing policies and shift to VBHC are accelerating; opportunities arise from changes in science, technology, and customers

Above, we summarize the changes anticipated in the market, science, technology, and customers through 2030 and the implications of these changes on our business based on the medium-to-long term scenario analyses of various surveys.

In developed countries as well as in the rest of the world, measures to contain drug costs will surely accelerate due to fiscal pressures, including the impact of population growth, aging, and COVID-19. We are entering an era when only products or solutions that offer true value will succeed. The value of innovative pharmaceuticals to society is expected to grow. Informed patients and payers will have an increasingly important presence, as we are starting to see already through payers moving to merge and expand business scope. More than ever, we must demonstrate value to patients in

terms of QoL and lifetime value. Cell therapies, nucleic acid drugs, and other new modalities need to be developed alongside existing pharmaceuticals in a mutually complementary fashion, and we need to embrace DX to evolve each value chain, including drug discovery, and restructure customer engagement models.

In light of this outlook for the business environment, we conclude that innovative drug discovery will remain as our core business and that Chugai needs to continue providing value across society and to earn the expectations of patients and other stakeholders through innovation that create new treatments and the continued evolution of technologies and platforms. The results from this analysis are the background for materializing the vision of Chugai as a Top Innovator in 2030.

### **Executive Insights**

### No Changes in Our Mission Statement or Material Issues

The year 2030 is not far away for pharmaceutical companies, where the pipeline at hand determines the next 10 years. Chugai's ongoing research of technology trends and business environment forecasts has led to a clearer understanding of the relationship between new modalities and IT platforms than we had when IBI 21 was formulated in 2019. Previously, the prevailing view was that the emergence of new modalities and IT platforms could pose a threat, but subsequent research and analysis has led us to conclude they will complement and evolve with each other through collaboration rather than conflict. It was reaffirmed that our business operations in drug discovery, manufacturing, and supply contribute significantly to social structures and economies, and are essential infrastructure for industry and society in the future.

Our Mission Statement and Material Issues remain unchanged, and we will continue to develop our core competencies in the modalities of antibodies and small molecule drugs; tackle the new challenge of mid-size molecules; and make every effort to discover innovative drugs. By strengthening our technologies and platforms, we can collaborate on new modalities and digital technologies. Currently, new drug discovery projects and development themes are emerging one after another, and we anticipate a very interesting decade ahead. My role is to take these initial ideas and turn them into corporate value and value for society. To do that, we are constantly evolving our business model and management based on careful investigation and analysis of the business environment.

### Tetsuya Yamaguchi

Executive Vice President
Supervisory responsibility for Project &
Lifecycle Management Unit (Marketing),
Corporate Planning, and Quality and
Regulatory Compliance



### Value Shared by a Top Innovator

Stakeholders	Shared Value	Value Indicators (Internal)	Value Indicators (External)
Patients Families of patients	Better drug efficacy and safety Better QoL Treatment choices that fit each patient Burden reduction	Number of new products launched and additional indications Indications Indications Indications	Treatment outcomes in each disease area Treatment adherence rate Medication and post-treatment care costs 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	Number of liaison activities	Treatment adherence rate Drug costs in hospital marke
Countries, payers, and regulatory authorities	Growth of the healthcare industry     Appropriate spending levels     Sustainable healthcare financing	Revenues     Number of new products launched and additional indications	Growth rate of healthcare industry     Taxable capacity of the industry     Health insurance costs
Universities, research institutions, suppliers, and other collaborating organizations and companies	Cocreation of innovation     Elucidation of disease mechanisms     Collaborative solutions	Number of joint research projects     Number of research agreements/alliances     Number of risk evaluations	Number of clinical studies     Growth rate of healthcare industry
Employees	Job satisfaction and sense of fulfillment     Enhanced abilities	Employee awareness survey     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

### Going beyond improvements in drug efficacy and safety to also change the lives of patients

Collaboration with our stakeholders is essential if we are to achieve advanced and sustainable patient-centric healthcare. As such, Chugai has examined the value shared with stakeholders and key value indicators (see the table above).

As we work to become a top innovator by 2030, we do not anticipate any change in the value shared with stakeholders or the key value indicators, but we recognize the need to contribute to patients at a higher level if we are to become a company with global first-class drug discovery capabilities and earn the expectations of patients.

Drug treatment is not the end goal for each patient. Patients value their lifestyle during treatment and convalescence. They want to have a good prognosis, be free from regular hospital

visits, and live without feeling the burden of disease. In other words, our goal should be to provide innovative new drugs that can cure or completely control their disease. If we are to support patients in this way, we must also measure a patient's QoL and level of satisfaction. Rather than only using conventional measures of drug efficacy, we need to establish True Endpoints that can measure the true value to the patient. Our goal is to research various parameters and clarify what the True Endpoints are.

If patients can be treated appropriately through this value-based healthcare (VBHC) approach, we expect to generate even more value shared with healthcare professionals, partners, and all other stakeholders.





### **Key Drivers to Becoming a Top Innovator**

Global First-Class Drug Discovery

**Futuristic Business Model** 

Drug Discovery / Development / Pharmaceutical Technology / Value Delivery / Foundation for Growth



Streamline entire value chain and strengthen digital infrastructure with the goal of creating innovative new drugs using digital technology.



### **RED Shift**

Further increase in funding for Research & Early Development (RED) and focused investment of business resources in our people.



### Open Innovation

Accelerate collaborations with leading external organizations and companies, including joint research with academia, on new technologies, new modalities, and digital applications.

### Key drivers are RED Shift, DX, and Open Innovation

To become a top innovator in 2030, we need to make significant advancements in our drug discovery capabilities over the next decade to achieve global first-class drug discovery and build a futuristic business model that can continuously create solutions to the world's unmet medical needs. Our growth strategy to achieve this is named TOP I 2030, and the key drivers behind this strategy are RED Shift, digital transformation (DX), and Open Innovation. (see page 58 for more details on the new growth strategy TOP I 2030.)

In order to develop our drug discovery capabilities further, we have defined RED functions (which correspond to the research, translational research, and the early development

stages of the pharmaceutical technology functions) as our value creation engine. We will make even bolder investments in both human and financial resources in these areas. We must make greater use of digital technologies to implement this RED Shift. We have defined CHUGAI DIGITAL VISION 2030 and will implement the three basic strategies of creating innovative new drugs using digital technology, optimizing all value chains, and strengthening our digital infrastructure. At the same time, we will accelerate collaborations with external organizations and companies to allow us to respond in an agile manner to developments in life sciences and digital technology.

### **Executive Insights**

### Accelerating DX with a Focus on ROI

Chugai has made great strides in DX under CHUGAI DIGITAL VISION 2030 announced in March 2020.

This vision reflects the management team's determination to focus on innovative drug discovery as a top innovator and foreshadows the approach described in TOP I 2030. Each department is visualizing and integrating their digital programs, which has allowed the drafting of resource allocation plans that reflect the business strategy and enabled agile progress with various initiatives. We have also worked to change employee awareness of DX through the appointment of Digital Leaders in each division, and I feel that one of our biggest successes has been the establishment of organizational structures across all divisions that support a proactive approach to DX initiatives.

As a result of these initiatives, Chugai is recognized by external parties for its outstanding DX, including selection as a DX Stock 2020. As we move forward to achieve TOP I 2030, we need to place an even greater emphasis on cost benefits and timelines. Our goal is to set precise ROI and KPI targets for each initiative and establish appropriate PDCA cycles.

The pharmaceutical industry has huge potential to evolve through DX, particularly with regard to managing the enormous amounts of sensitive data that pharmaceutical companies handle. Progress in DX is also becoming a key element when assessing corporate value, just like ESG. Chugai plans to contribute to DX across the industry as a whole while also accelerating innovation driven by Chugai Digital in order to improve corporate value.

### Satoko Shisai

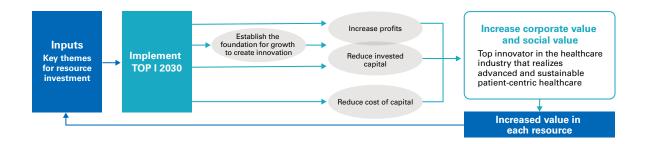
Vice President Head of Digital & IT Supervisory Division



## Capital Investment with a Focus on 2030

Chugai needs a wide range of resources (capital) in order to become a top innovator in the healthcare industry and decisions on how to invest these resources require inputs corresponding to the key themes for resource investment, as shown in the table below. Through this process of capital investment, we aim to establish the foundation for growth to create innovation, increase profits, reduce invested capital, and reduce cost of capital, with the goal of increasing corporate value and creating value for patients and society. These initiatives will lead to an increase in the value of our resources, which will enable further value creation.

Resources	Key themes for resource investment (Inputs)	Scenarios for contributing to inc corporate value and value creati	reased on
		Establish the foundation for growth to create innovation	Increase profits
Human resources (Human capital)	Manage human resources, assigning the right people to the right positions     Acquire, develop, and fulfill highly competent specialists     Develop understanding and support for Mission Statement and TOP I 2030     Continuously pursue diversity and inclusion (D&I)	Develop a culture that encourages bold challenges     Foster active and strategically consistent participation by human resources, ensure appropriate compensation	Create innovation in each function in the value chain
Technology and IP (Intellectual capital)	Enhance drug discovery and pharmaceutical technology platforms for antibodies and small molecules, and build similar platforms for mid-size molecules     Create new modalities     Deepen our understanding of biology research     Expand portfolio of patents for highly competitive technology platforms	Progress multi-modality approach     Strengthen and expand drug discovery platforms using digital technologies	Create innovative new drugs that break through limitations of existing modalities Use digital technologies to accelerate opportunities for innovation Progress to secure rights for products
Collaborations with Roche and external partners (Social capital)	Develop products from Chugai research globally via the Roche Group and other networks     Utilize the Roche Group's information and research infrastructure     Collaborate with cutting-edge companies and academia on DX and state-of-the-art technologies and science     Engage in dialogue with various stakeholders	Create new value through collaborations with the Roche Group and realization of open innovation and digital technologies	Grow innovative products developed in-house on global markets     Secure revenue bases by in-licensing promising Roche products
Pharmaceutical technology and facilities (Manufacturing capital)	Build research facilities and production systems suited to continuously evolving modalities and technologies Achieve digital plants through the use of digital applications and robotics Develop systems for flexible and rapid development and next-generation production Ensure stable supply and rigorous quality assurance	Build research infrastructure that can accelerate innovation     Build development and production infrastructure that can handle drugs of high difficulty	Shorten development timeframes and reduce manufacturing costs     Flexibly respond to changing demand in product supply and sale
Environment and energy (Natural capital)	Invest in new technologies and new facilities to switch energy sources and reduce greenhouse gas (GHG) emissions     Reduce resource use, including energy and water     Recycle resources consistent with a circular economy	Design and plan facilities and equipment for reduced environmental burden, lower costs, and greater productivity	Build foundations for sustainable growth
Financial related (Financial capital)	Increase cash flows to ensure a growth trajectory     Continuously evolve revenue structures     Increase cash to enable strategic investments	Raise funds for innovation Actively invest in digital technologies Investment in RED	_



### Increased value in each resource

### Reduce invested capital Reduce cost of capital · Secure and develop diverse, · Maintain a culture that high-caliber talent prioritizes compliance • Use digital technologies to · Reduce the risk of make business processes high-caliber talent leaving more efficient the Company • Create technology and • Respond to the emergence of research outcomes that new modalities and solutions attract external parties • Reduce IP risk • Use digital technologies to build a futuristic business model Improve resource efficiency • Reduce supply risk and through global development supply chain risk • Use digital technologies • Improve external evaluation of environmental, social, and to build a futuristic governance (ESG) business model • Use digital technologies to · Reduce quality and improve the efficiency of reliability risk business processes Reduce supply risk • Reduce risks from climate • Reduce costs in the future change, water, etc. • Reduce risk from waste • Improve capital efficiency Continuously build up through cash management reputation on capital markets • Reduce credit risk

### Human resources

- Increase employees' job satisfaction, improve sense of fulfillment
- Improve employees' capabilities and skills

### Technology and IP

- Solve unmet medical needs
- Advance global drug discovery technologies
- Increase the level of science in the healthcare industry

## Collaborations with Roche and external partners

- Pursue cocreation of innovation
- Create added value in all functions

## Pharmaceutical technology and facilities

 Develop more advanced, next-generation facilities and equipment

### **Environment and energy**

- Reduce environmental burden
- Promote circular economies

#### Financial related

Increase cash flows

### Collaboration with Roche

#### Win-Win Relationship with Roche

Chugai's unique business model, in which Chugai is a member of the Roche Group while maintaining autonomy and management independence, allows it to concentrate on innovation through an emphasis on originality and diversity. This contributes to the enhancement of Chugai's corporate value as well as the growth of the Roche Group in a business model unlike any other worldwide.

Based on this unique 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 the 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. This 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, both of these revenue bases must grow. Since forming this alliance with Roche, Chugai has launched many products in Japan that were developed and marketed globally by Roche. However, looking at the breakdown of total domestic and overseas sales since 2010, the share from products in-licensed from Roche, on a rising trend in the early part of the decade, started to decline in 2016 due to the rapid growth of Chugai products in the global market. Analysis of global sales of Chugai products supplied through Roche's network shows that this growth has been driven by overseas approvals for Actemra in 2009, Alecensa in 2015, and Hemlibra in 2017, with the Hemlibra approval in particular driving an acceleration in sales growth. Moreover, with the addition of the approval of Enspryng in 2020, we expect further growth driven by these global products.

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.

#### Key Features of the Collaboration 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)

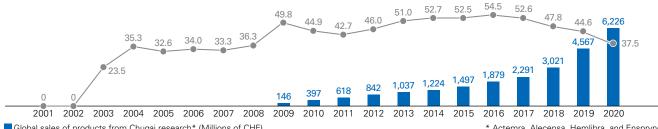
Advantages for Roche

- 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
  - Chugai offers all development projects to Roche at the early proof of concept (PoC) stage Worldwide except in Chuqai's territory
  - · Co-promotion rights in the United Kingdom, Germany, France, etc. (Discussions about China on a drug-by-drug basis)

### Global Sales of Products from Chugai Research, and Sales Share for Products In-Licensed from Roche



Global sales of products from Chugai research\* (Millions of CHF)

Share of total domestic sales from products in-licensed from Roche (%)

\* Actemra, Alecensa, Hemlibra, and Enspryng

### **Business Model Evolution**

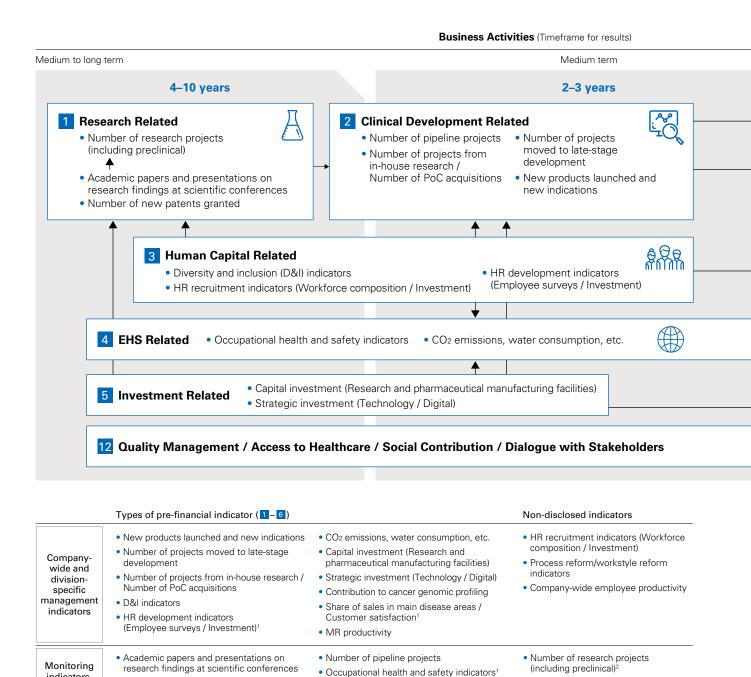
Our business model has continued to evolve since Chugai entered into the strategic alliance with Roche in 2002. For nearly 20 years, we have collaborated with Roche in a wide range of fields, from business management to research, clinical development, pharmaceutical technology, marketing, medical affairs, and drug safety, generating excellent outcomes as a result. In clinical development for example, since 2014, Chugai has been able to offer development projects for licensing to Roche at the early PoC stage, which

is the optimal timing for collaboration. This has allowed licensing agreements with Roche to be signed earlier and global development to continue with a sense of speed and unity without having to pause at the clinical development stage. From the perspective of supply chain management and environment, health, and safety (EHS) as well, we have been able to enhance our operations by drawing on Roche's initiatives and expertise at the cutting edge of global markets. We aim to evolve our collaboration further in order to deliver advanced and sustainable patient-centric healthcare.

### **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     Ensuring the interests of minority shareholders     Management with a broad, long-term view	<ul> <li>Basic agreement emphasizes Chugai's management independence and maintenance of stock listing.</li> <li>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.</li> <li>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.</li> </ul>
Research	Concentration on innovation through independent decision-making Efficient research activities Acceleration of efforts driven by a sense of competition within the Roche Group	<ul> <li>Activities are based on Chugai's independent decision-making, including selection of research projects and investment of resources.</li> <li>Chugai can use Roche's research infrastructure, including its large, high-quality compound library.</li> <li>In the Roche Group, a culture of friendly competition between the research divisions of each company provides mutual motivation.</li> </ul>
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	<ul> <li>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.</li> <li>Out-licensing of products from Chugai research is immediately offered to Roche upon achievement of early PoC. This has enabled faster development by reducing "white space" in the development process.</li> <li>Participation in global studies conducted by Roche for in-licensed and out-licensed products that extend worldwide (Chugai manages clinical trials in Japan).</li> <li>Chugai is establishing its own independent global development system in order to quickly achieve early PoC.</li> </ul>
Pharmaceutical Technology	Optimization of global production system     Conformance with the world's most advanced management standards     Information-sharing in the areas of supply chain management and EHS	<ul> <li>In principle, products from Chugai research are manufactured by Chugai and exported to Roche, but for Actemra, technology has also been transferred to Roche Group production bases.</li> <li>Roche, which manufactures and markets products worldwide, shares its knowledge on the latest good practice guidelines and regulations (GxP) compliance.</li> <li>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.</li> </ul>
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	<ul> <li>Chugai provides solutions in each territory with a focus on local healthcare systems and regional characteristics.</li> <li>However, when necessary Chugai and Roche share information and cooperate across regions in marketing strategy, generation of evidence, and other matters for each product.</li> <li>Safety information on each product is collected and analyzed in real time in cooperation with Roche.</li> </ul>

### Relationships of Indicators



1. Partly non-disclosed 2. Disclosure only of number of research projects applying antibody engineering technology

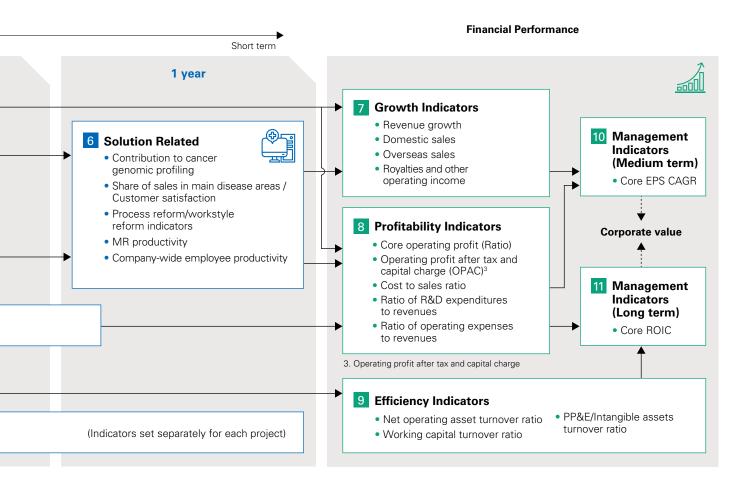
The above diagram sets out Chugai's view of the relationship between financial results that lead to an increase in corporate value and key indicators of the business activities that impact on these financial results, taking into account the timeframes for achievement of results in each case. These indicators are divided into management indicators based on set target values and supported by PDCA cycle activities, and monitoring indicators for monitoring progress based on established plans and qualitative targets.

• Number of new patents granted

### 1 Research Related 2 Clinical Development Related

The time taken for research projects to yield results in business performance is normally a medium- to long-term timeframe of 4-10 years, while for technological infrastructure and pathological research, the management timeframe is still longer. These research results are reflected in the development pipeline, which is decisive in generating revenue, profit, and corporate value. Accordingly, indicators focus on the number and quality of projects and the state of progress.

indicators



#### 3 Human Capital Related

At Chugai, it is human resources who generate innovation, and we therefore recognize them as our most important asset and believe strongly that corporate results are influenced by factors such as HR recruitment, allocation and development, and the organizational culture. We therefore set detailed targets for items such as employee awareness surveys and HR management indicators.

#### 4 EHS Related 5 Investment Related

Environment, health, and safety (EHS), which is the foundation of business activities, is also associated with high levels of risk, and must be managed from a medium- to long-term perspective. Also essential for generating results is investment in research platforms for innovative drug discovery as well as in pharmaceutical technology functions, new technology, and digital applications.

#### 6 Solution Related

We use these indicators to monitor the successful execution of our strategies from a short-term (1 year) perspective. We see indicators relating to sales share in main disease areas and productivity as being among the most important indicators that affect financial results.

# 7 Growth Indicators 8 Profitability Indicators 9 Efficiency Indicators

Growth indicators measure the value provided by products and services. A particularly important aspect is the global contribution to patient wellbeing as reflected in overseas revenues. As profitability indicators, we give the greatest weight to operating profit and the ratio of Core operating profit to revenue, and also see indicators relating to cost structure as important. As efficiency indicators, the turnover ratios of working capital and intangible assets are the key focus.

### 10 Management Indicators (Medium term)

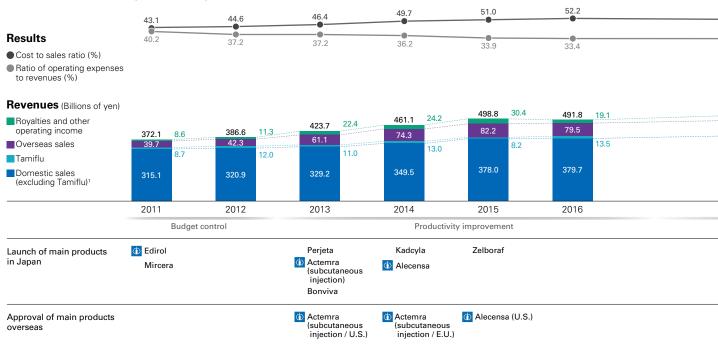
#### 11 Management Indicators (Long term)

For an increase in corporate value, the most important indicators are growth in the profit margin of our core business and in the absolute profit figure. We therefore set Core EPS CAGR as a medium-term KPI for internal management. Additionally, for the pharmaceutical business, where business projects are rolled out with a perspective of 10 years or longer, we believe that measurement of investment efficiency over the long term is essential and focus on Core return on invested capital (ROIC) accordingly.

# Financial and Pre-Financial Highlights (IFRS)

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

### **Financial Indicators (Core Basis)**



(h) 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 2020 due to the overseas market penetration of Hemlibra. Other operating income, which consists of non-recurring income, is dependent on development milestones and other events, and is therefore subject to a relatively high degree of fluctuation.

#### Core Operating Profit / Ratio of Core **Operating Profit to Revenues**

(Billions of yen / %)

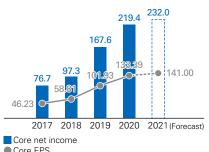


Ratio of Core operating profit to revenues

We have one of the highest levels of performance in the industry for the ratio of Core operating profit to revenues. This is due to the low ratio of operating expenses to revenues and the trend of recent years to increasing ROOI<sup>2</sup> and declining cost to sales ratio. In 2021, we expect our fifth consecutive year of record Core operating profit due to factors including increases in exports to Roche and royalty income from Roche relating to Chugai product Hemlibra.

#### Core Net Income / Core EPS<sup>3</sup>

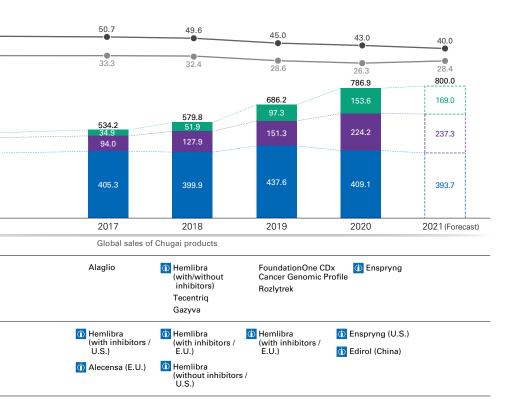
(Billions of yen / Yen)



Core EPS

The mid-term business plan IBI 21, which we completed one year ahead of schedule, set a target for Core EPS CAGR over three years of approximately 30 percent4 (assuming no stock split). With the growth of Chugai products in Japan and overseas making a major contribution to business performance, we were able to post a strong average annual growth rate of 49.5 percent, considerably exceeding the initial target within the two years to 2020.

- 2. Royalties and other operating income
- 3. Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. Calculated based on the assumption that the stock split was implemented at the beginning of 2017
- 4. Three years, based on constant exchange rate
- 5. Return on invested capital: Indicates how efficiently a company uses capital invested for business activities (invested capital) to generate profit.



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. Despite a reduction in domestic sales due to the impact of the National Health Insurance (NHI) drug price revision and market penetration by generics, sales revenues reached a record level for the fourth consecutive year due to increases in items including exports to Roche of Chugai products Actemra and Hemlibra, royalties from Hemlibra, and profit-sharing income. In 2021, we expect further increase in revenues and profits on growth in Hemlibra exports to Roche and in royalty income and profit-sharing, which is projected to outweigh the year-on-year decrease in domestic sales arising from the impact of market penetration by generics and the NHI drug price revision.

#### Core Operating Profit after Taxes / Net Operating Assets (NOA) / Core Return on Invested Capital (Core ROIC)



Net operating assets (NOA)

Core return on invested capital (Core ROIC)

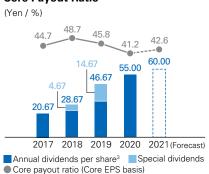
Chugai has been using Core ROIC⁵ as a financial KPI since 2019 to give greater consideration to long-term investment efficiency. NOA (2) increased significantly due to aggressive strategic investments such as Chugai Life Science Park Yokohama, while growth in Core operating profit after taxes (1) resulted in an increase in Core ROIC (1÷2) to 37.3 percent in 2020.

#### Overseas Revenues / **Overseas Revenues Ratio**



Overseas revenues increased steadily with the growth in global sales of Chugai products. In 2020, the COVID-19 pandemic resulted in a major increase in Actemra exports. Hemlibra, meanwhile, continued to penetrate the market, with global sales passing the CHF 2.0 billion mark. With these and other developments, we expect the ratio of overseas revenues to increase further in 2021

#### Dividends per Share / **Core Payout Ratio**



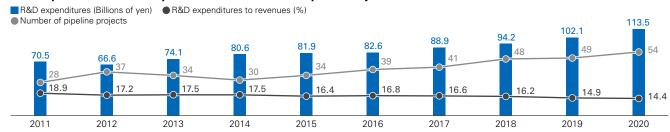
In light of the rapid evolution of life sciences and digital technology, we adjusted our shareholder returns target to take into account future investment opportunities and funding plans. We, therefore, changed the target for Core payout ratio from the previous 50 percent on average to 45 percent on average based on Core EPS from 2020 to maintain our policy of stable return of profit.

#### **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.

### Research, Clinical Development, Pharmaceutical Technology, and Production

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



Development of proprietary antibody engineering technologies

CPR establishment and business expansion, and development of next-generation antibody engineering technologies

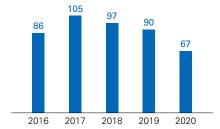
Investment in facilities to handle multiple development projects simultaneously

Comprehensive collaboration in immunology research activities with IFReC

With growing sales revenues, Chugai has increased R&D investment, generating research findings that have created innovative drugs and contributed to the development of healthcare and the pharmaceutical industry worldwide. Moreover, we have been promoting efficient development of new drugs with high success rates under our strategic alliance with Roche, which enables us, for instance, to consider and decide on in-licensing Roche products on the basis of early-stage clinical trial results. In recent years, we have maintained a robust

pipeline in terms of both quantity and quality, with progression to the clinical phase of a number of Chuqai in-house projects based on the application of innovative antibody engineering technology. Going forward, in addition to concentrating Company-wide management resources in Research & Early Development (RED) as a source of value creation, we will also seek to rapidly expand our drug discovery output by applying Al-based drug discovery and other digital technologies and actively driving open innovation.

#### **Publications in Academic Papers and Presentations at Scientific Conferences** regarding Chugai Research Findings<sup>1</sup>



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 developing production technology for mid-size molecules and other drug types where there are strong challenges to overcome. We will continue to successively generate research findings that may contribute to the overall advancement of healthcare, presenting those findings at scientific conferences and publishing them in academic papers.

1. Total of drug discovery and pharmaceutical technology

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



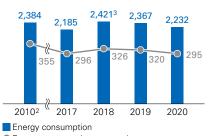
- Number of new products launched and new indications
- Percentage of product sales qualifying for premium pricing

In 2020, the number of new products launched and new indications remained at a high level, with the launch of Chugai product Enspryng, additional indications for mainstay products Tecentriq and Kadcyla, and the expanded use of F1CDx as a companion diagnostic. On the other hand, there was a large decrease in the sales share of products qualifying for premium pricing as Avastin lost this status.

Note: Products subject to special market-expansion repricing (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 per employee

Total and per-employee energy consumption in 2020 decreased by 6 percent and 17 percent, respectively, compared with the base year of 2010. The goal of a 20 percent reduction in per-employee energy consumption was not met, but we plan to use renewable energy certificates to reach a 20 percent reduction in non-renewable energy consumption.

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

#### **HR Management**

#### **Employees / Ratio of Female Employees**



Creation and implementation of managerial talent development program

Introduction of talent management system

Promotion of measures to reduce excessive working hours

Promotion of work-life synergy

Promotion of workstyle reform

Promotion of gender diversity

Diversity Office established

The basic philosophy of Chugai's HR strategies is that people are an invaluable asset that drives the 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 (D&I) as one of our HR strategies because we

recognize that innovation arises from diverse values and expertise. In January 2021, we introduced the Telework System to realize more flexible workstyles through "smart working," which we envisage will increase productivity and promote balanced work-life synergy. 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<sup>4</sup> (Non-consolidated employee basis) (%)

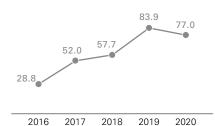


2016 2017 2018 2019 2020

To promote the success of women in the workplace, we set a target ratio of female managers of 17 percent by the end of 2023 (non-consolidated employee basis4). 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.

4. Number of female managers as a percentage of the total number of managers. Calculated based on Chugai (non-consolidated) employees

# Percentage of Male Employees Taking Childcare Leave<sup>5</sup> (Non-consolidated)

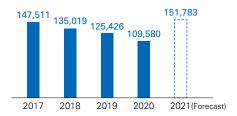


Chugai is working to improve work-life synergy. Although the adoption of more flexible work styles, such as work-from-home (WFH) and a paid leave system in units of hours, led to a slight fall in 2020 in the percentage of eligible male employees taking childcare leave, the trend of recent years is upward. We are promoting the use of the childcare leave system through awareness-raising activities for male employees with newborn children and their supervisors to improve their understanding of the system. We also provide supervisors with a handbook containing guidance on key management points.

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

#### **Education and Training Expenditures** per Employee<sup>6</sup> (Non-consolidated employee basis)

(Yen)



To realize advanced and sustainable healthcare from a patient-centric approach, we aim to cultivate innovation-oriented human resources that can deliver new value to patients by creating innovative drugs and proposing other creative solutions. Our education and training system is structured into Company-wide education and training<sup>7</sup> and specialized education and training provided on a departmental basis.8 In addition to cultivating the right mindset for the required roles and strengthening business skills, the system also supports career development and other objectives. By also focusing on the acquisition of advanced specialist knowledge and skills relevant to the specific department, we encourage the development of self-motivated human resources dedicated to the pursuit of innovation.

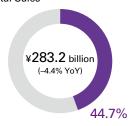
- 6. Calculated based on Chugai (non-consolidated) employees (As of Jan. 1 of each year).
- 7. Grade-specific training, career independence training, Leadership Competency Program, English-language training, next-generation managerial HR training, self-directed learning support, etc.
- 8. Department-specific specialist knowledge and skill improvement training, specialized English-language training, etc.

# Review by Disease Area

#### Opportunities and Risks

# Oncology

Sales and Percentage of **Total Sales** 



#### Opportunities

- Cancer is the largest area of unmet medical needs<sup>1</sup> (the leading cause of death in Japan).
- Personalized healthcare (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, which will promote 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
- Entry of large pharmaceutical companies into biosimilar<sup>2</sup> markets

# Review of 2020 Performance

Sales in Japan decreased 4.6 percent year on year to ¥229.5 billion. The decrease occurred despite steady market penetration by new product Tecentriq and mainstay products Alecensa and Perjeta and was caused by decreased sales of Avastin, Herceptin, and other products under the impact of the National Health Insurance (NHI) drug price revision and competition from generics Overall sales, including overseas sales, decreased 4.4 percent year on year to ¥283.2 billion. Although exports to Roche of Chugai in-house product Alecensa decreased 3.6 percent year on year to ¥43.0 billion due to the impact of a lower unit price for exports, its penetration of first-line markets progressed, primarily in the United States, Europe, and China.

#### Bone and Joint Diseases / Autoimmune Diseases

Sales and Percentage of Total Sale<sup>3</sup>



#### 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
- Emergence of generics in competition with the osteoporosis drug Edirol

Sales in Japan decreased 14.8 percent year on year to ¥92.4 billion. The main factors in the decrease were the impact of the NHI drug price revision, which reduced sales of Actemra, a Chugai in-house product indicated for RA and related conditions, and the impact of generics on Edirol, another Chugai in-house product, which experienced a large reduction in sales from the previous year. Overall sales, including overseas sales, increased 15.3 percent year on year to ¥226.8 billion. Exports of Actemra, which is approved in more than 110 countries and distributed through Roche experienced significant growth due notably to increased demand from clinical studies for COVID-19-associated pneumonia, and increased 52.6 percent year on year to ¥132.0 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 (MHLW), 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 a competing biosame and other generics

Sales in Japan decreased 17.3 percent year on year to ¥28.6 billion. Sales of Oxarol, an agent for secondary hyperparathyroidism, and Mircera, a long-acting erythropoiesis stimulating agent, decreased in part because of the NHI drug price revision and the impact of generics.

### Neurology / Other Diseases

Sales and Percentage of



#### 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 needs, 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

 Possibility of few target patients despite high unmet medical needs in the neurology area

In Japan, sales of Hemlibra, a Chugai product for treating hemophilia A, increased 35.3 percent to ¥34.1 billion despite the delay in market penetration due to the COVID-19 pandemic. Ordinary sales of anti-influenza agent Tamiflu decreased 89.2 percent year on year to ¥0.8 billion, and sales for government stockpiles increased 15.6 percent to ¥3.7 billion. Exports to Roche of Hemlibra, which switched to the regular shipment price in 2019, increased 645.5 percent to ¥24.6 billion, and overall sales, including overseas sales, grew 54.1 percent to ¥94.8 billion.

Medical needs that are not adequately met due to a lack of effective treatments

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.

#### **Development Pipeline** (Including additional Sales Sales of Major Products indications) (Billions of yen) **Domestic market** RG7446 share in oncology: No. 14 RG3502 **©** ERY974 Avastin 81.5 (-14.7%) RG435 RG7421 **37.5** (+82.0%) Tecentriq (Billions of yen) RG7596 RG7802 296.2 Perjeta 33.5 (+9.1%) 283.2 266.7 RG7440 RG7828 Alecensa (Domestic) **26.0** (+13.0%) 240.5 229.5 225.7 RG6264 RG6026 Herceptin 15.9 (-40.4%) AF802 **M** AMY109 Kadcyla 10.2 (+13.3%) RG6058 Rituxan 7.2 (-39.5%) RG6171 SPYK04 Gazyva 4.6 (+27.8%) OBP-301 RG6194 Xeloda 3.6 (-55.0%) Foundation Medicine 2.8 (+600.0%) 2018 2019 2020 Alecensa (Overseas) 44.3 (-2.2%) Domestic Domestic and overseas total Meutrogin (Overseas) 9.0 (-9.1%) **Domestic market** (Billions of yen) share in osteoporosis: No. 1<sup>4</sup> Actemra (Domestic) 39.3 (-6.0%) **®** NRD101 RG7880 **27.8** (-24.3%) Domestic market share in RA: Bonviva 8.9 (-8.2%) No. 2⁴ Actemra (Overseas) 134.4 (+52.2%) (Billions of yen) 226.8 196.7 181.0 108.4 100.5 92.4 2018 2019 2020 Domestic Domestic and overseas total Note: Graph shows sales for bone and joint diseases only (Billions of yen) **Domestic market** share in renal diseases: No. 24 Mircera 17.5 (-21.2%) 6.4 (-7.2%) Oxarol (Billions of yen) 36.3 36.3 34.6 34.6 28.6 28.6 2018 2019 2020 Domestic Domestic and overseas total **Neurology / Other Diseases** (Billions of yen) MRA RG7916 RG7716 Hemlibra (Domestic) 34.1(+35.3%) RG1450 (Billions of yen) 94.8 CellCept 9.1(-2.2%) RG6042 SKY59 Enspryng (Domestic) 1.3(-) RG7906 **1** NXT007 61.5 58.7 54.1 Hemlibra (Overseas) **26.1**(+625.0%) 37.5 43.8 RG7935 **D** PCO371 Enspryng (Overseas) 5.6(-) **M** AMY109 RG6100 2018 2019 2020 Domestic Domestic and overseas total

n Products from Chugai research

<sup>3.</sup> Bone and joint diseases only
4. Copyright © 2021 IQVIA. Source: JPM 2020 (calendar year). Reprinted with permission. The scope of the market is defined by Chugai. The analysis is conducted by Chugai.

# Development Pipeline (As of February 4, 2021)

<u>`</u>	Origin (Collaborator)					Approved
ncology						
RG7446*	Roche	Hepatocellular carcinoma				<del>-</del>
		Non-small cell lung cancer (NSCLC) (adjuvant)				
		NSCLC (neoadjuvant)				
		NSCLC (Stage III / combination with RG6058)			<del></del>	
		Urothelial carcinoma				
		Renal cell carcinoma (adjuvant)				
	Roche (Takeda Pharmaceutical)	Renal cell carcinoma [2nd line] (combination with cabozantinib)			<del></del>	
	Roche	Early breast cancer				
		Ovarian cancer				
		Hepatocellular carcinoma (adjuvant)				
		Head and neck carcinoma (adjuvant)				
		Esophageal cancer (combination with RG6058)			<del>-</del>	
		Pancreatic adenocarcinoma (combination with RG1569 or RG6058)	<u> </u>	l		
RG3502*	Roche	Breast cancer (adjuvant)				<del></del>
RG435*	Roche	Hepatocellular carcinoma (combination with RG7446)				
110400		Hepatocellular carcinoma (adjuvant / combination with RG7446)				
		Small cell lung cancer (combination with RG7446)				
DOZEGO.	D					_
RG7596	Roche	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)				 
		DLBCL				
RG7440	Roche / Array BioPharma	Breast cancer				
		Prostate cancer				
RG6264	Roche	Breast cancer (fixed-dose combination, subcutaneous injection)				
AF802 / RG7853*	In-house (Roche)	NSCLC (adjuvant)				
RG6058	Roche	Small cell lung cancer (combination with RG7446)			<del></del>	
		NSCLC (combination with RG7446)			<del></del>	
		NSCLC (Stage III / combination with RG7446)			<del></del>	
		Esophageal cancer (combination with RG7446)			<del>-</del>	
RG6171	Roche	Breast cancer				
OBP-301	Oncolys BioPharma	Esophageal cancer				
05. 00.		Hepatocellular carcinoma (combination with RG7446 and RG435)	$\overline{}$			
CC33	In-house	Hepatocellular carcinoma				
GC33						
ERY974	In-house	Solid tumors				
RG7421	Roche / Exelixis	Solid tumors		<u> </u>		
RG7802	Roche	Solid tumors		l		
RG7828	Roche	Hematologic tumors		ı		
RG6026	Roche	Hematologic tumors	<del>-</del>	ı		
AMY109	In-house	Solid tumors	-	ı		
STA551	In-house	Solid tumors	<u> </u>	1		
SPYK04	In-house	Solid tumors	-			
RG6194	Roche	Solid tumors				
one and Joint Dis	seases					
ED-71	In-house	Osteoporosis				
NRD101	In-house	knee osteoarthritis / shoulder periarthritis				
TATIO TO T						
utoimmune Dise	ases					
RG7880	Roche	Inflammatory bowel disease				
enal Diseases						
EOS789	In-house	Hyperphosphatemia				
200700		Турогриоориасына				
eurology						
SA237 / RG6168	In-house (Roche)	Neuromyelitis optica spectrum disorder (NMOSD)				 
3A237 / 11G0100	III-libuse (Nocile)	Neuroniyenus optica spectrum disorder (NiviO3D)				
D.07040	B 1 (BTOT)	0.1.1				
RG7916	Roche / PTC Therapeutics	Spinal muscular atrophy (SMA)				
RG1450	Roche / MorphoSys	Alzheimer's disease				
RG6042	Roche / Ionis Pharmaceuticals	Huntington's disease				
RG7906	Roche	Schizophrenia		<del>_</del>	·	
RG7935	Roche / Prothena	Parkinson's disease		ı		
GYM329 / RG6237	In-house (Roche)	Neuromuscular disease		1		
RG6100	Roche / AC Immune	Alzheimer's disease				
ther Diseases						
MRA/RG1569*	In-house	COVID-19 pneumonia			<del></del>	
RG7716	Roche	Diabetic macular edema				
		Neovascular age-related macular degeneration (nAMD)				
ACE010 / DC0010	In house					
ACE910 / RG6013	In-house	Acquired hemophilia A				
SKY59 / RG6107	In-house (Roche)	Paroxysmal nocturnal hemoglobinuria (PNH)				
NXT007	In-house	Hemophilia A			(1/11)	
	La la accesa	Hypoparathyroidism				
PCO371	In-house	Турорагалутогаютт				

Approved / Filing Date [Planned Year of Filing]	Generic Name / Planned Product Name	Mode of Action
2020/0	atazalizumah /Tacantria	Engineered anti DD L1 managland antihadu (laigatian)
2020/9 [2022]	atezolizumab / Tecentriq	Engineered anti-PD-L1 monoclonal antibody (Injection)
[2023] [2023 or later]		
[2023 or later]		
[2022]		
[2022]		
[2023 or later]		
[2021]		
[2022]		
[2022]		
[2022]		
[2023 or later]		
2020/8	trastuzumab emtansine / Kadcyla	Anti-HER2 antibody-tubulin polymerization inhibitor conjugate (Injection)
_		Anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody (Injection)
2020/9	bevacizumab / Avastin	Anti-vascular endotriellar growth factor (VEGF) numanized monocional antibody (injection)
[2022]		
[2023 or later]	a late and a late of Day do not a source of a factor of	And ODTOL and had a service to the service to
2020/6	polatuzumab vedotin / Product name undetermined	Anti-CD79b antibody-drug conjugate (Injection)
[2021]	in standard / Denduce	AVT in Link in a (One)
[2023 or later]	ipatasertib / Product name undetermined	AKT inhibitor (Oral)
[2022]		A CHEROL COLOR OF THE COLOR OF
[2021]	trastuzumab, pertuzumab / Product name undetermined	Anti-HER2 humanized monoclonal antibody / HER2 dimerization inhibitory humanized monoclonal antibody (Injection)
[2023 or later]	alectinib / Alecensa	ALK inhibitor (Oral)
[2022]	tiragolumab / Product name undetermined	Anti-TIGIT human monoclonal antibody (Injection)
[2023 or later]		
[2023 or later]		
[2023 or later]		
[2023 or later]	Generic and product names undetermined	Selective estrogen receptor degrader (SERD) (Oral)
[2023 or later]	Generic and product names undetermined	Oncolytic type 5 adenovirus (Injection)
	codrituzumab / Product name undetermined	Anti-Glypican-3 humanized monoclonal antibody (Injection)
	Generic and product names undetermined	Anti-Glypican-3 / CD3 bispecific antibody (Injection)
	cobimetinib / Product name undetermined	MEK inhibitor (Oral)
	cibisatamab / Product name undetermined	Anti-CEA / CD3 bispecific antibody (Injection)
	mosunetuzumab / Product name undetermined	Anti-CD20 / CD3 bispecific antibody (Injection)
	glofitamab / Product name undetermined	Anti-CD20 / CD3 bispecific antibody (Injection)
	Generic and product names undetermined	— (Injection)
	Generic and product names undetermined	Anti-CD137 agonistic switch antibody (Injection)
	Generic and product names undetermined	— (Oral)
	Generic and product names undetermined	Anti-HER2 / CD3 bispecific antibody (Injection)
	deficit and product flames undetermined	Anti-Heriz / CD3 dispectific antibody (injection)
(China) Dec. 2020	eldecalcitol / Edirol	
(China) 2021	purified sodium hyaluronate / Suvenyl	Sodium hyaluronate (Injection)
(Offinal 2021	parmed dedican riyalarenate / earenyi	- Journal Mydiatoriate (Injection)
	Generic and product names undetermined	Human IL-22 fusion protein (Injection)
	25 and product ramos undetermined	
_	Generic and product names undetermined	— (Oral)
_	Genone and product names undetermined	(Oral)
(lanan / II C ) A 2000	satralizumab / Enspryng	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody (Injection)
(Japan / U.S.) Aug. 2020	Sauanzullau / Elispiyilg	pre-dependent winding numanized anti-it-o receptor monocional antibody (injection)
(E.U.) Aug. 2019	rindinlam / Product name undetermined	CMM2 adjains modifier (Oral)
2020/10	risdiplam / Product name undetermined	SMN2 splicing modifier (Oral)
[2023 or later]	gantenerumab / Product name undetermined	Anti-amyloid-beta human monoclonal antibody (Injection)
[2023 or later]	tominersen / Product name undetermined	Antisense oligonucleotide targeting HTT mRNA (Injection)
	ralmitaront / Product name undetermined	Partial TAAR1 agonist (Oral)
	prasinezumab / Product name undetermined	Anti-a-synuclein monoclonal antibody (Injection)
	Generic and product names undetermined	Anti-latent myostatin sweeping antibody (Injection)
	semorinemab / Product name undetermined	Anti-tau humanized monoclonal antibody (Injection)
[2021] (Japan)*	tocilizumab / Actemra	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
[2021]	faricimab / Product name undetermined	Anti-VEGF / Ang2 bispecific antibody (Injection)
[2021]		
[2022] (Japan)	emicizumab / Hemlibra	Anti-coagulation factor IXa / X bispecific antibody (Injection)
(====) (==p===)		
[2022]	crovalimab / Product name undetermined	Anti-C5 recycling antibody (Injection)
	crovalimab / Product name undetermined Generic and product names undetermined	Anti-C5 recycling antibody (Injection)  Anti-coagulation factor IXa / X humanized bispecific monoclonal antibody (Injection)
	Generic and product names undetermined	Anti-coagulation factor IXa / X humanized bispecific monoclonal antibody (Injection)

<sup>\*</sup> Roche is conducting multiple global phase III studies of Actemra against COVID-19 pneumonia separately.

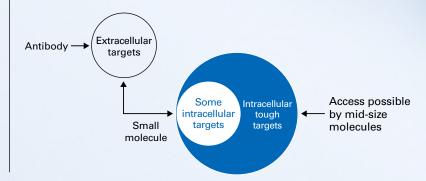
# **Sustainability and Growth Strategies**

In 2021, Chugai embarked on the new growth strategy, TOP I 2030 as part of its goal to become a top innovator in the healthcare industry in 2030. The Company will implement reforms in (1) Drug Discovery, (2) Development, (3) Pharmaceutical Technology, (4) Value Delivery, and (5) Foundation for Growth. By broadening the potential scope for value creation, Chugai aims to achieve global first-class drug discovery and a futuristic business model.

#### Case Study

# Potential of Mid-Size Molecule Drugs

In addition to the Company's portfolio of therapeutic antibodies and small molecule drugs, Chugai is also working to establish new technologies for drug discovery in the modality (therapeutic approach) of mid-size molecule drugs. Our objective is to develop drugs that can be given orally and treat targets that have been difficult to reach with conventional technologies like small molecule drugs. Multiple technological issues have made it difficult to create metabolically stable mid-size molecule drugs that can penetrate within the cells. After focusing business resources in this field for over 10 years, we have now established unique mid-size molecule technologies that provide the Company with a competitive advantage, including the creation of a huge and diverse library of mid-size molecule compounds with structures that are relatively easy to formulate as drugs. We expect our first mid-size molecule drug project to move into clinical studies soon and are working to progress clinical development and pharmaceutical technology aspects as well. We believe mid-size molecule drugs have enormous potential as a solution to medical needs that cannot be solved with conventional modalities and hope to make this new approach available to patients as soon as possible.







We are evolving our efforts to create shared value by stepping up dialogue with stakeholders and factoring their hopes, expectations, and suggestions into the management of our business.

#### **Progress toward Creating Shared Value**

Chugai's goal is to achieve advanced and sustainable patient-centric healthcare based on the creation of shared value with stakeholders. This is precisely the philosophy of the Sustainable Development Goals (SDGs), which Chugai has committed to supporting. Focusing on patient-centric value, namely outcomes, will enable Chugai to further promote collaboration with stakeholders who share our goals.

Under this policy, our mid-term business plan IBI 21 considered sustainability and growth strategies from the same perspective, and sustainability initiatives previously implemented by each department were incorporated into the management strategy. We also set targets for every Material Issue and implemented initiatives while clarifying our priorities.

As a result, we were able to exceed both the quantitative and qualitative targets in IBI 21 and made steady progress in Strategy 5, "Strengthen Sustainable Platforms." In quality management, for example, we established quality requirements for cross-divisional management of good practice guidelines and regulations (GxP) for pharmaceuticals, while for supply chain management, we are applying our evaluation system for comprehensive due diligence including environmental and human rights issues. In the area of environment, we conducted scenario analysis based on the

recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) and published the results. I believe that Chugai's sustainability initiatives have evolved further thanks to the plan-do-check-act (PDCA) cycle, in which Chugai actively engages in dialogue both inside and outside the Company and uses the feedback to improve our activities. We have been recognized as a highly sustainable business by external audiences and selected for the first time as a constituent of DJSI World, an index of top global companies for environmental, social, and governance (ESG) investment.

#### Formulating Sustainability and Growth Strategies through to 2030

In the new growth strategy TOP I 2030, we have placed an even greater emphasis on shared value with stakeholders as part of our goal of becoming a top innovator in 2030. With the time span now set at 10 years, the growth strategy represents an evolution of our business strategy, moving away from thinking about sustainability and growth from the same perspective to developing an integrated approach.

Of particular note, in my view, is the fact that this strategy incorporates what we have learned from our experience in dealing with the unprecedented COVID-19 pandemic. In terms of the healthcare market and customers, the convergence on value-based healthcare (VBHC), which we have assumed

would occur over the medium to long term, has accelerated rapidly. Looking at the economy as a whole, this type of discontinuous change has reminded us of the importance of adapting flexibly to change as we move toward our Envisioned Future. We are rethinking all of our business activities and ways of working in this "new normal." Sustainability initiatives will become even more important from the perspective of risk management and from a broader, long-term perspective. We are determined not to slow down the progress with ESG.

Based on this thinking, we reexamined our Material Issues again at the time of formulating the growth strategy. This process confirmed that there was no need to change our management policy of creating shared value, and that there would be no changes in our Material Issues, even in the face of the social transformation caused by the pandemic. The careful scrutiny of risk factors has also been prioritized. To manage strategic and operational risks in an integrated manner, we have formulated a Risk Appetite Statement and restructured our enterprise risk management (ERM) system to enhance management and operations.

#### **Future Sustainability Initiatives**

To develop the ESG aspects of TOP I 2030, we consider it particularly important not only to design and promote priority initiatives in each Material Issue, but also to innovate in the environmental area, which is taken up as a reform in "Foundation for Growth."

Engaging more proactively with global issues will be key for Chugai, starting with measures to combat climate change, which is increasingly important, as well as progress in protecting biodiversity and promoting the use of renewable and recyclable resources. These are precisely our Material Issues. In our mid-term environmental goals for 2030 (2021–2030), we have increased the number of target items from four under the previous plan to 10 in order to meet the expectations and demands of society. To reduce CO2 emissions, which requires long-term and large-scale

measures to decarbonize society, we have set a goal of zero emissions by 2050. This will not be easy to achieve, but goals that are simply an extension of the past will not lead to innovation. Particularly in the area of climate change, we will incorporate the evolution of technology, design strategies in conjunction with our sites and facility plans, and promote the investment of resources with a sense of urgency.

#### **Collaboration and Dialogue with Stakeholders**

In TOP I 2030, Open Innovation, meaning collaboration with stakeholders, is essential for the promotion of the Research & Early Development (RED) Shift and digital transformation (DX). But above all, we need to have a sense of shared values and ideas with our collaborators. The reality of these companies and organizations will be reflected in their sustainability initiatives. At Chugai, we will actively communicate our own ESG activities and work to promote understanding, and we will also emphasize sustainability when choosing partners. For the SDGs as well, we have identified 11 development goals where we are focusing our efforts, and we will share this policy with our partners.

Engagement with employees and dialogue with stakeholders will be even more important in the rapidly changing business environment. We aim to remain alert to changes in society, enhance information disclosure, and reflect the hopes, expectations, and suggestions of stakeholders into the management of the Company. To give one example of this, at an ESG briefing in 2020, we were able to understand the information needs of investors through interviews and questionnaires prior to the actual event. This provided a wide range of suggestions that led us to discuss our governance system for sustainability and our management methods for non-financial targets, which we had not previously disclosed.

As part of our vision of becoming a top innovator by 2030, we aim to be a global role model through our ESG activities, and we plan to step up our communication and dialogue on these issues even further. Thank you for your ongoing support.

#### Chugai Contributions to 11 SDGs



The top priority goal directly linked to our Mission (3)









Four goals required to achieve the top priority goal (8, 9, 12, and 17)













Six goals that form the basis of our business activities (5, 6, 10, 13, 15, and 16)

# Executive Officers (As of April 1, 2021)

# Top Executives and Executive Officers in Their Area of Responsibility



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



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



Dr. Osamu Okuda Representative Director, President & CEO



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



Dr. Hisafumi Okabe Executive Vice President Supervisory responsibility for Project & Lifecycle Management (R&D), Research and Translational Research



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



Tetsuya Yamaguchi Executive Vice President Supervisory responsibility for Project & Lifecycle Management Unit (Marketing), Corporate Planning, and Quality and Regulatory Compliance



Junichi Ebihara Executive Vice President In charge of Intellectual Property Dept.



Mark Noguchi Executive Vice President General Manager of Business Development Dept.

#### **Membership of Committees**

			С	ommittees ( 🌘	Chair Partic	ipating membe	r)		
Name		Enlarged	(	Corporate Manage	ement Committee	es	F	RDPM Committee	s
Ivaine	Executive Committee	Executive Committee	Corporate Communications Committee <sup>1</sup>	Risk Management Committee <sup>2</sup>	Compliance Committee <sup>3</sup>	EHS Committee <sup>4</sup>	Portfolio Management Committee <sup>5</sup>	Strategic Marketing Committee <sup>6</sup>	Digital Strategy Committee <sup>7</sup>
Tatsuro Kosaka									
Motoo Ueno				•	•	•			
Dr. Osamu Okuda	•	•						•	
Shinya Unno									
Dr. Hisafumi Okabe							•		
Toshiaki Itagaki			•						•
Tetsuya Yamaguchi									
Junichi Ebihara									
Mark Noguchi									
Dr. Minoru Watanabe									
Shinji Hidaka									
Yoshiyuki Yano									
Satoko Shisai									
Tsukasa Kusano									
Dr. Kaori Ouchi									
Shinya Takuma				<u> </u>					
Dr. Hitoshi likura									
Dr. Tomoyuki Igawa									
Masayoshi Higuchi									

<sup>1.</sup> Committee members also include the general managers of the following departments: Corporate Communications, Corporate Planning, Finance & Accounting, Sustainability, and General Affairs. 2. Committee members also include the general managers of the following departments: Corporate Planning, Corporate Communications, General Affairs, Legal, and Sustainability. 3. Committee members also include the general managers of the following departments: Corporate Planning, Legal, General Affairs, Finance & Accounting, Corporate Communications, IT Solution, Sustainability, and the heads of other relevant department managers. 4. Committee members also include the general managers of the following departments: Corporate Planning, General Affairs, Finance & Accounting, Corporate Communications, and Sustainability. 5. Committee members also include the general managers of the following departments: R&D Portfolio Management, Business Development, Regulatory Affairs, Corporate Planning, and External Affairs.



Dr. Minoru Watanabe Head of Drug Safety Div. and Head of Foundation Medicine Unit



Shinji Hidaka Head of Marketing & Sales Div.



Yoshiyuki Yano Vice President Head of Human Resources Management Dept.



Satoko Shisai Head of Digital & IT Supervisory Div. Head of Clinical Development Div.



Tsukasa Kusano



Dr. Kaori Ouchi Vice President Head of Medical Affairs Div.



Shinya Takuma Vice President Head of Pharmaceutical Technology Div. Chugai Pharma Manufacturing Co., Ltd. Representative Director, President



Dr. Hitoshi likura Head of Research Div.



Dr. Tomoyuki Igawa Head of Translational Research Div.



Masayoshi Higuchi Head of Quality & Regulatory Compliance Unit

#### Areas of Supervisory Responsibility and Areas in Charge of

				А	reas of super	visory respo	nsibility (🔳)	and areas i	n charge of (	)		
	Name			Pharma- Ma	Marketing &	Cross-divisional functions						
	Ivalile	Research	Develop- ment / TR	ceutical Technology	Sales / MA / Safety	Human Resources	Digital / IT	EHS	Quality & Regulatory Compliance	PLCM <sup>8</sup>	Business Development	Other Corporate Functions <sup>9</sup>
	Tatsuro Kosaka										•	•
	Motoo Ueno							● 15				•
	Dr. Osamu Okuda		●10	•	12,13,14							•
	Shinya Unno					•						•
	Dr. Hisafumi Okabe	•	●11							•		
	Toshiaki Itagaki						•					•
	Tetsuya Yamaguchi								•	•		•
	Junichi Ebihara											
	Mark Noguchi											
	Dr. Minoru Watanabe				14							
	Shinji Hidaka				12							
	Yoshiyuki Yano											
	Satoko Shisai											
	Tsukasa Kusano		10									
	Dr. Kaori Ouchi				13							
<u> </u>	Shinya Takuma								·		·	
	Dr. Hitoshi likura											
	Dr. Tomoyuki Igawa		11									
	Masayoshi Higuchi											

<sup>6.</sup> Committee members also include the general managers of the following departments: Business Development, Regulatory Affairs, Corporate Planning, External Affairs, and Marketing & Sales Planning. T. Committee members also include the general managers of the following departments: Corporate Planning, External Affairs, and Marketing & Sales Planning. T. Committee members also include the general managers of the following departments: Corporate Planning, Digital Strategy, Science & Technology Intelligence, and IT Solution. 8. PLCM: Project & Lifecycle Management 9. Corporate Planning, General Affairs, Risk Management, Compliance, Audit, Intellectual Property, External Affairs, Finance & Accounting, Corporate Communications, Purchasing, Foundation Medicine 10. Development 11. Translational Research 12. Marketing & Sales 13. MA (Medical Affairs) 14. Safety 15. Also in charge of Sustainability Dept., which is responsible for EHS

# Targets and Progress in Material Issues

# Specification of Material Issues

#### Sustainable Healthcare

- Creation of innovative drugs and services
- Provision of solutions for patients
- Fair marketing
- · Fair pricing
- Adverse event management
- · Quality assurance and stable supply of products

#### **Corporate Governance**

- Corporate governance
- Risk management • Disclosure and engagement

#### **Ethics and Compliance**

- Compliance
- Code of conduct
- · Fair transactions

#### **Supply Chain** Management

• Supply chain management

#### **Global Environment**

- · Climate change countermeasures (energy, etc.)
- Use of renewable/recycled resources (water, waste, etc.)
- Biodiversity protection (environmental burden mitigation)
- Environmental management system

#### **Human Resources**

- Employee job satisfaction
- Development of employee potential
- Diversity and inclusion (D&I)
- Improvement of occupational health and safety

### **Human Rights**

- Human rights
- · Safety of clinical trial subjects

## **Social Contribution**

- Social contribution activities
- Improvement of access to healthcare

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

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.

For each of the Material Issues, we have set a target to attain in the medium to long term and indicators to measure progress and the degree of achievement. The aim is to communicate to society Chugai's areas of focus as a starting point for dialogue going forward.

We will review the selected Material Issues regularly and adjust them in response to changing business environments and the evolution of Chugai's business activities. In 2020, we reexamined the Material Issues in light of the impact of the COVID-19 pandemic and the upcoming formulation of a new growth strategy, and confirmed that no changes were required.

# **Process for Establishing Material Issues**

#### STEP 1

Analysis of medium- to long-term conditions and identification of risks and opportunities

#### STEP 2

Discussion of management policies (Executive Committee)

### STEP 3

Interviews of outside experts

#### STEP 4

Gap analysis (Requests from outside stakeholders, comparison with other companies)

#### STEP 5

Analysis of social issues we want to resolve (value) and Material Issues

#### STEP 6

Consultation with internal divisions

## STEP 7

Specification of Material Issues (Outside directors, Executive Committee, Board of Directors)

# Targets and Progress up to 2020

Material Issue	Target	5 strategies	Indicators (2020 results)	Results during the period of IBI 21 (2019–20 performance
Sustainable Heal	thcare			
Creation of innovative drugs and services	Creation of innovative drugs	1 3	Number of new products launched and additional indications (9)  Number of projects and products based on PHC  Number of projects added to portfolio  Number of in-house projects achieving PoC  Number of in-licensed projects progressing to LCM stage	Mid-size molecule project: Progressed as planned toward phase I launch in 2021     Antibody project: Phase I started for next-generation switch antibody STA551     Launch of global phase III for crovalimab/SKY59     Approval of Enspryng and start of sales     Total 5 progressing to pre-clinical stage     Nemolizumab: Filing in Japan for approval for atopic dermatitis (Maruho Co., Ltd.), acquisition of breakthrough therapy designation for prurigo nodularis (Galderma S.A.)
Provision of solutions for patients	Realize patient-centric healthcare	2	Market share in therapeutic area (Oncology No. 1 <sup>1</sup> , hemophilia No. 1 <sup>1</sup> )  Customer satisfaction (Oncology No. 1 <sup>2</sup> , hemophilia No. 1 <sup>3</sup> )  Domestic sales per MR (No. 1 <sup>4</sup> )  Contribution to cancer genomic profiling (No. 1 <sup>5</sup> )	Hemlibra: Market penetration in Japan and overseas, expansion of number of overseas approvals     Tecentriq: Additional indications including three first-in-class designations     Formulation of CHUGAI DIGITAL VISION 2030     Progress of company-wide digital strategy and acceleration of AI drug discovery, etc.     Steady market introduction of F1CDx, additional indications Filing for approval of F1L     Filing for ROS1 indication of Rozlytrek using real-world data (RWD) as reference data     Joint development of digital solution for objective evaluation of pain in endometriosis
Fair marketing	Marketing in compliance with national guidelines	2	No infringements of promotional code of conduct in overseas sales-related information provision activity (achieved)     Formulation of information provision guidelines for prescription pharmaceuticals, etc., and conduct of employee education (achieved)	Enhancement of governance of overseas subsidiaries:     Dissemination of understanding of Chugai Group management guidelines, enhancement of independent compliance system     Establishment and strengthening of Chinese business structure: Strengthening of cooperation between affiliates, enhancement of Head Office support system     Adaptation to change in Chinese Drug Administration Law     Formulation of guidelines on sales-related information provision activity and upgrading of internal monitoring system     Formulation of guidelines on information provision in response to requests from patients and their families, etc.
Fair pricing	Pricing that reflects drug and service value	2	_	Establishment of drug price reflecting value of new drugs (Rozlytrek, Enspryng, etc.)
Adverse event management	Perform appropriate pharmacovigilance activities and promote proper drug use	2	Customer satisfaction (Oncology No. 1², hemophilia No. 1³)	Progress with digitalization of customer interface coordinated between three divisions     Launch of adverse event database tool for healthcare professionals
Quality assurance and stable supply of products	Ensure quality and stable supply of products and services	5	_	Maintenance of stable supply system for products including Actemra during the COVID-19 pandemic     Maintenance and enhancement of world-class quality including in handling of FMI and other new businesses
Corporate Gover	nance			
Corporate governance	Realize sustained growth and corporate value	5	Review of Board of Directors effectiveness	Conduct of analysis and evaluation of effectiveness of Board of Directors by external third-party (law firm)
Risk management	Perform risk assessment and evaluate responses	5	_	Introduction of enterprise risk management (ERM) framework including strategic risk management     Centralized company-wide management of risk information relating to IT systems     Formulation of business continuity management (BCM) guidelines

- 1. Copyright@ 2021 IQVIA. Source: JPM 2020 (calendar year). Reprinted with permission. The scope of the market is defined by Chugai.

- Source: INTAGE Healthcare Inc., CS Survey of Oncology, 2020. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
   Source: INTAGE Healthcare Inc., CS Survey of Hemophilia 2020. Based on a survey of overall assessments of companies by physicians, as defined by Chugai.
   Calculated by Chugai based on 2020 Pharmaceutical Marketing Strategy by Fuji Keizai Management Co., Ltd.
   Copyright© 2021 IQVIA. Source: Survey of Degree of Customer Satisfaction with Cancer Genome Therapy. Overall Assessments of Companies by Physicians. Based on a survey of overall assessments of companies by physicians, as defined by Chugai. Survey target: "Internet survey of members of m3.com, a website specializing in medical information"

Material Issue	Target	5 strategies	Indicators (2020 results)	Results during the period of IBI 21 (2019–20 performance)
Corporate Gove	rnance			
Disclosure and engagement	Earn market trust through appropriate information disclosure	5	Selection as component of DJSI World (achieved)	Promotion of dialogue with stakeholders by holding annual ESG meeting Improvement of external evaluation of investor relations (IR)
Ethics and Comp	oliance			
Compliance	Appropriately manage compliance risks	5	Compliance monitoring	Confirmation of state of progress of compliance action plans of organizations in Japan and overseas Conduct of monitoring survey to identify compliance status Company-wide including at affiliates in Japan and overseas Conduct of compliance awareness survey of all Group employees in Japan and overseas
Code of conduct	Promote understanding and awareness of the Chugai Group Code of Conduct (CCC)	5	CCC and human rights training in Japan: twice a year 2019 participation rate: 100%¹ 2020 participation rate: 100%¹	Revision of the Code of Conduct in line with the formulation of new management policies (Revisions to CCC)     Provision of training to all Chugai Group employees
Fair transactions	Ensure compliance with trading laws and regulations and build fair and transparent business relationships	5	Formulation of related policies and regulations and conduct of employee education (achieved)	Formulation of purchasing policy and purchasing-related regulations and rollout to subsidiaries     Completion of incorporation in purchasing policy and purchasing-related systems and conduct of employee education     Formulation of regulations relating to fair competition policy and conduct of employee education
Supply Chain M	anagement			
Supply chain management	Perform comprehensive supplier evaluations	5	Risk assessment of major contract manufacturing organizations (CMOs)	Participation in Pharmaceutical Supply Chain Initiatives (PSCI) Formulation of supplier code of conduct, start of confirmation of consent from suppliers (31 confirmed in 2020) Formulation of supplier EHS compliance risk assessment guidelines, start of supplier risk assessment (86 assessed in 2020) Conduct of employee education on supplier EHS compliance risk assessment guidelines Holding of information exchange meetings with CMOs
Global Environn	nent			
Climate change countermeasures <sup>2</sup> (energy, etc.)		5	Reduce energy consumption per employee by 20% vs 2010 (17% reduction³)     Eliminate use of specific fluorocarbons (achieved)     Fuel economy of sales vehicles: ≥16 km/L (27 km/L)	Introduction of highly energy-efficient facilities and promotion of energy-saving measures through energy visualization system     Ending of use by 2020 of all 4 tons of specific fluorocarbons held as of 2018     Progress with introduction into sales fleet of hybrid vehicles and highly fuel-efficient vehicles
Use of renewable/ recycled resources <sup>2</sup> (water, waste, etc.)	Minimize impact on global environment	5	Zero waste emissions (≥99% recycling of waste): 3 sites (achieved at 2 sites)	Preferential selection of waste treatment operators for recyclable industrial waste and improvement of recycling rate
Biodiversity protection (environmental burden mitigation)		5	Wastewater measurement using whole effluent toxicity (WET) testing: 5 sites (implemented at 5 sites)	WET test conducted annually at all plants and research laboratories since 2013, with no issues identified
Environmental management system	Third-party assurance of performance data	5	Expand verification items and scope	Environmental performance data (emissions of atmospheric pollutants, Scope 3 all categories, Scope 1) and inclusion of overseas plants in collection of statistics     Social performance data (incidence and severity of occupational accidents) and inclusion of contractor employees in collection of statistics

Material Issue	Target	5 strategies	Indicators (2020 results)	Results during the period of IBI 21 (2019–20 performance)
Human Resource	es			
Employee job satisfaction <sup>4</sup>	Develop work environment where employees can continue their careers	4	Rate of paid leave taken ≥ 80% (65.6%) <sup>5</sup> Work-from-home (WFH) participation rate: 35% <sup>6</sup> Employee awareness survey (Improvement in positive response rate in Employee Engagement and Environment for Utilizing Employees surveys)	Employee awareness survey—Improvement on 2018 results     Design of new workstyles (smart working) to realize productivity improvement and work-life synergy (introduction in 2021)
Development of employee potential	HR recruitment and training to realize strategic targets and accelerate innovation	4	Increase in next-generation leader candidates, implementation of development programs	Selection and development of candidates for key positions (department manager level)     Appointment of highly competent talent     Review of plans for individual development of next-generation leader candidates and implementation of strategic allocation
Diversity and inclusion (D&I) <sup>4</sup>	Create new value through diverse talents	4	<ul> <li>Ratio of female managers: 16% (14.6%)<sup>7</sup></li> <li>Ratio of female managers (With subordinates): 15% (13.0%)<sup>8</sup></li> </ul>	Appointment of female executive officers     Establishment of female manager (with subordinates) appointment promotion committee consisting of department managers including executive management     Conduct of e-learning program on unconscious bias for managers (approx. 800 participants), who are key players in promoting D&I
Human Rights				
Human rights	Respect human rights of all persons involved in business	5	Human rights due diligence on contractors	Formulation of policy on respect for human rights     Conduct of employee education on policy relating to business and human rights and respect for human rights     Identification of human rights issues     Formulation of guidelines for evaluation of supplier human rights, start of supplier risk assessment (86 assessments in 2020)     Holding of individual dialogue with overseas experts on human rights initiatives
Safety of clinical trial subjects	Conduct clinical trials under high ethical and scientific standards with safety	5	Introduction of adverse event evaluation tool for direct use by patients     Securing of safety of trial subjects using home-based devices	Completion of preparations for three phase I pilot studies in solid tumors and start of one study     Measurement of safety indicators using home-based devices implemented in one study, issues identified, and other data collected
Social Contributi	on			
Social contribution activities	Develop networks in key areas	5	Cumulative number of para-transit vehicles donated to welfare services (263)	Support to healthcare professionals in Japan during the COVID-19 pandemic: Donation of total of ¥55 million to Japanese foundations, the Tokyo metropolitan government, and Kanagawa Prefecture     Support for recovery: Donation of ¥10 million to areas affected by typhoon damage in 2019, and ¥10 million to areas affected by torrential rainfall in July 2020
Improvement of access to healthcare	Improve access to healthcare including drug development	5	Number of participants in team care workshop for health professionals at Children's Medical Center of Cambodia-based NPO Japan Heart (21)  Number of locations and number of patients examined in treatment and support program for non-communicable diseases (NCDs) in rural areas of Myanmar (28 locations, approx. 2,500 patients)	Promotion of early treatment and follow-up of NCDs in Myanmar  Establishment of medical transport fund and provision of ultrasound diagnostic equipment for nursing and expectant mothers in Myanmar  Provision of Hemlibra to developing countries through World Federation of Hemophilia (WFH)  Start of partnership with City Cancer Challenge Foundation

Excluding employees on secondment or leave
 Target for December 31, 2020
 We aim to reach a 20 percent reduction in non-renewable energy consumption by using renewable energy certificates.
 April 2019–March 2020 results
 WFH adopted as norm during state of emergency
 Calculated based on Chugai (non-consolidated) employees.
 Calculated based on Chugai (non-consolidated) employees and its affiliates in Japan.

# Main Risks and Countermeasures (Strategic Risk and Operational Risk)

Main risks <sup>1</sup>		Specific risk scenarios	Impact on corporate value
	Technology and Innovation	Delay or failure in in-house drug discovery or technology development  Underperformance in development of mid-size molecule drugs  Development of innovative products and solutions by competition  Emergence of disruptive new technologies and solutions  Infringement of IP rights (by Chugai or competitor)	<ul> <li>Delays in creating in-house products, rise in R&amp;D expenditures</li> <li>Revision of development and investment plans</li> <li>Decline in value of in-house technologies and projects</li> <li>Weakening of in-house technology and product value, decrease in revenues, lawsuits by other parties, suspension of manufacturing and sales or of technology utilization, incurring of utilization fees</li> </ul>
Strategic	Healthcare System / Pharmaceutical Laws and Regulations	Further strengthening of policy of National Health Insurance (NHI) drug price reduction     Expansion of policy of promoting generics     Sudden regulatory change or delay in awareness thereof (especially overseas)	Decrease in revenues Decline in product volume or worsening of cost to sales ratio Amendment or delay of development or regulatory plans
Risk	Markets and Customers	Accelerated emergence of innovative products from competitors and generics     Sudden change in customer contact points     Relative decline in value of medical treatments	<ul> <li>Decline in market position or product competitiveness, decrease in revenues</li> <li>Underperformance in information provision activities, excessive number of staff</li> <li>Decline in number of target patients</li> </ul>
	Business Platforms	Change in content of alliance with Roche Underperformance of Roche's drug discovery and global networks Underperformance in HR development or securing of strategic human resources Stagnation of organizational culture Delay or underperformance in implementation of digital transformation (DX) Impact on earnings structure of surging R&D expenditures and other cost increases	Revision of management strategy or business model Decline in products in-licensed from Roche as a stable revenue source, decrease in value of products out-licensed to Roche Stagnation in innovation Failure to meet strategic goals, revision of business plans Staff mismatch, shortage, or surplus due to change in operations or quality levels required
	Quality and Side Effects (→)	Emergence of product quality issue, emergence of side effects of unexpected seriousness	Decrease in revenues due to product recall, sales suspension, etc., product liability litigation, compensation for damages, loss of public trust
	IT Security and Information Control (メ)	Operational impairment, suspension of external service delivery, interference with the content of information provided, the leakage of trade secrets relating to research and development or other areas, or of personal or other information, as a result of cyberattack or incident in-house or in supply chain	Suspension or delay of business activities, revision of business plans, loss of competitive advantage, loss of public trust, compensation for damages, incurring of expenses for urgent response and related measures
Operational	Large-Scale Disasters (→)	Damage to business site or supplier from earthquake, typhoon, fire, or other large-scale disaster, COVID-19 and other infectious diseases	Suspension of drug supply, incurring of costs for facility repair, etc., restriction of business activities, decrease in revenues
Risk	Human Rights (→)	Delay in taking action on occupational health and safety, or other human rights issues	Deterioration in employee physical or mental health or HR capabilities, loss of public trust due to harassment, or other human rights issues
	Supply Chain	Delay or slowing of delivery from suppliers, environment, health, and safety (EHS)-related risk at suppliers	Decrease in revenues or market share, loss of public trust
	Global Environmental Issues (→)	Delay in technology- and facility-related response to climate change     Unexpected environmental contamination or damage by harmful substances     Insufficient response to social expectations and requirements relating to environmental protection     Further strengthening of environment-related regulations	Revision of capital investment plans, incurring of additional expenses Incurring of expenditures for remedial measures or compensation for damage, loss of public trust Reputational decline among customers and capital markets Increase in expenditures for environmental measures, limitation of business activities

Operational risks are classified into the two following types:
 (戌) Risks whose probability of materializing and degree of impact have increased rapidly (→) Important long-standing risk
 This table presents only the principal risks whose degree of impact on corporate value would be relatively great in the case of the risk materializing. Risks whose degree of impact is extremely great are marked ★★; those whose degree of impact is great are marked ★★.

Degree of impact at time of occurrence <sup>2</sup>	Related material issues <sup>3</sup>	Risk appetite framework	Main countermeasures
***	1, 2, 8, 19, 20	Accept risk and aggressively seek opportunities to generate innovation     Reduce risk that hinders innovation	Seek access to latest science and technologies Diversify by strengthening external collaborations Strengthen alliances for drug discovery, development, and pharmaceutical technology Pursue a multi-modality strategy Further strengthen IP strategy, respond actively to generics with IP measures
***	1, 2, 4, 8, 25	Continuously demonstrate new value by pursuing innovation	Visualize and demonstrate patient value Enhance revenue structure, develop next-generation products, put in place IP measures Strengthen advocacy activities Enhance overseas intelligence functions
***	1, 2, 3, 5, 6, 8, 25	Continuously deliver new value by pursuing innovation	<ul> <li>Strengthen customer engagement</li> <li>Diversify product range</li> <li>Build organizational structure able to respond flexibly to fluctuations in demand</li> <li>Promote advanced development of personalized healthcare (PHC)</li> </ul>
***	1, 2, 7, 8, 18, 19, 20, 21	Accept risk and implement reform for continuous evolution of business model     Reduce all risks that are factors hindering innovation	Ongoing contribution to value creation of the entire Roche Group Clear definition of strategic human resources and plan-based securing and development Increase investment in organization and human resources Build organizational structure and recruitment plans based on careful monitoring of trends in the business environment Strengthen DX strategy and capabilities, deploy external competent human resources Minimize operational costs through business model reform
***	5, 6, 8, 9, 13, 23	Avoid or reduce risk that hinders efficacy, safety, and quality assurance	Strengthen quality assurance activities and ensure comprehensive rollout     Strengthen safety information provision activities to strengthen and ensure comprehensive rollout of pharmacovigilance activities and to promote proper use
***	6, 8, 10	Reduce information security risk by implementing comprehensive countermeasures	Strengthen security management system and system robustness and availability, strengthen functions to detect cyberattacks and viruses and upgrade monitoring systems, strengthen system for responding to information security incidents, enhance employee security training, monitor status of countermeasures
***	6, 8, 13	Reduce risk that hinders stable supply	Maintain operation of business continuity plan (BCP) and earthquake resilience strategy, strengthen safety stock and related systems
**	8, 10, 11, 12, 13, 22, 23	Reduce risk by working to eliminate discrimination in society and human rights infringements	Continue implementation of in-house training, promote health and productivity management, provide internal reporting hotlines, conduct enhanced human rights due diligence on suppliers
**	6, 8, 13, 22	Reduce risk that hinders stable supply	Establish stable drug supply system for whole supply chain, strengthen EHS activities
**	8, 9, 14, 15, 16, 17, 24	Reduce risk by taking positive action on global environmental issues	Planned medium- to long-term environmental investment Strengthen access to latest environmental technology Enhance dialogue with external experts and evaluation organizations Ongoing monitoring and analysis of latest trends

<sup>3.</sup> Chugai's material issues are listed below (see page 50 for details)

<sup>1:</sup> Creation of innovative drugs and services 2: Provision of solutions for patients 3: Fair marketing 4: Fair pricing 5: Adverse event management 6: Quality assurance and stable supply of products 7: Corporate governance 8: Risk management 9: Disclosure and engagement 10: Compliance 11: Code of conduct 12: Fair transactions 13: Supply chain management 14: Climate change countermeasures 15: Use of renewable/recycled resources 16: Protection of biodiversity 17: Environmental management system 18: Employee job satisfaction 19: Development of employee potential 20: Diversity and inclusion 21: Improvement of occupational health and safety 22: Human rights 23: Safety of clinical trial subjects 24: Social contribution activities 25: Improvement of access to healthcare

# **Background to Growth Strategy Development**

#### Previous Mid-Term Business Plans

2008 2009 2010 2011 2012 2013 2016 2019 2020<sup>8</sup> Sunrise 2012 **ACCEL 15 IBI 18 IBI 21** 

Formulation and launch of the "top pharmaceutical company" goal1

#### **Business environment**

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

#### 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 personalized healthcare

#### Quantitative guidance

	Sales (Billions of yen)	profit (Billions of yen)	profit margin (%)
2012 targets	460.0	80.0	17.4
Results	391.2	76.4	19.5

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

#### **Business environment**

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

#### **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
- Strengthened R&D structure with expansion of CPR,2 establishment of TCR Division,3 etc.
- Enhanced functions for providing

#### Quantitative guidance

	COLE EL 2 CAGIT
3-year target (2012–2015)	Mid to high single digit <sup>6</sup>
Results	18.3%

Realization of the "top pharmaceutical company" goal

#### **Business environment**

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

#### **Strategies**

- Acquisition and implementation of competitiveness at a top
- 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 mid-size molecule drug creation technology platform
- Prepared for approval and accelerated growth of Hemlibra and Tecentria
- Created a structure for providing solutions by region

#### Quantitative guidance

	COLE EL 2 CAGIL
3-year target (2015–2018)	Low single digit
Results	17.1% <sup>7</sup>

Creating shared value through innovation

#### **Business environment**

- Increased demands to reduce drug prices
- More competitive environment including generics
- Further advances in life science technologies

#### Strategies

Create global growth drivers and maximize value, and strengthen HR and infrastructure that support Chugai's business through the following five strategies: Value creation, value delivery, promote advances in PHC, strengthen human capital and fundamental structural reform, and strengthen sustainable platforms.

#### Results and issues

- · Achieved record-high results
- Global growth of products from Chugai research, domestic growth of new products
- Steady progress with in-house drug discovery themes, including next-generation antibodies and mid-size molecules
- Progress with in-house drug discovery projects, including launch of Enspryng as a next-generation growth driver
- Enhanced foundation for growth, including introduction of new HR system and development of digital infrastructure

Quantitative guidance				
	Core EPS CAGR			
3-year target (2018–2021)	Around 30% <sup>9</sup>			
Results (2018–2020)	49.5%			

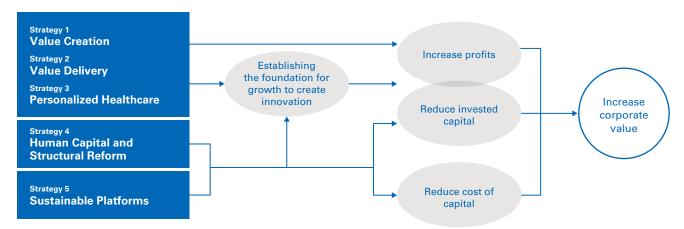
- 1. A vision for Chugai to be realized in the second half of the 2010s. It sets numerical targets including ranking within the top three major Japanese pharmaceutical companies, the No. 1 domestic presence in our strategic disease areas, and expansion of global presence, and qualitative targets including becoming a company that receives the support and trust of all stakeholders and conducts independent activities.
- Chugai Pharmabody Research Pte. Ltd. Established in Singapore in 2012.
   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 2018 8. Completed one year ahead of schedule 9. Based on average exchange rates for 2018. Does not take into account the stock split during the year.

#### EPS / Core EPS<sup>10</sup>



<sup>10.</sup> Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. Calculated based on the assumption that the stock split was implemented at the beginning of 2008

### **IBI 21 Review**



All of Chugai's strategic initiatives feed into increasing corporate value over the medium and long term. The various strategies in IBI 21 were all strategically designed and managed to produce the outcomes listed above, namely establishing the foundation for growth to create innovation,

increasing profits, reducing invested capital, and lowering cost of capital. The chart below provides a review of IBI 21, summarizing each strategy from the perspective of the impact it has on increasing corporate value.

Strategies Summary		Contribution to higher corporate value	
Strategy 1 Value Creation	Steady progress in drug discovery, including progress of in-house projects  • Mid-size molecule project: Progressed as planned toward phase I launch in 2021  • Antibody project: Phase I started for next-generation switch antibody-STA551  • Launch of global phase III for crovalimab/SKY59, approval of Enspryng and start of sales	Innovation that drives future profit growth     Establish a foundation to create innovation in science and technology	
Strategy 2 Value Delivery	Expand market penetration of growth drivers and accelerate value maximization  Hemlibra: Significant increase in overseas revenues and expanded the number of countries with approval  Tecentriq: Progress in expanding indications including first in class (FIC)	Maximize product value to grow medium- and long-term profits	
Strategy 3 Promote Advances in Personalized Healthcare	Formulation of CHUGAI DIGITAL VISION 2030 and promotion of cancer genomic medicine  Digital: Progress of company-wide digital strategy and acceleration of AI drug discovery, etc.  Launch of FoundationOne CDx and approval of additional indications, approval filing for FoundationOne Liquid CDx  Filing for ROS1 indication of Rozlytrek using RWD as reference data	Improve capital efficiency, productivity     Reduce future costs for digital applications and new modalities	
Strategy 4 Strengthen Human Capital and Conduct Fundamental Structural Reform	Progress in transforming systems to support innovation  Started operation of a new HR system  Progress with structural reforms in corporate and prioritized divisions	Build corporate culture that fosters innovation     Recruit and develop diverse, high-caliber talent     Improve productivity	
Strategy 5 Strengthen Sustainable Platforms	Enhancing platforms to support efforts for innovation  • Selected to DJSI World for the first time  • Enhanced stakeholder communication	Reduce EHS and supply chain risk     Reduce quality and reliability risk     Understand society's expectations and requirements	

# New Growth Strategy TOP I 2030



"Double R&D output" "Launch in-house global products every year"

#### Global First-Class Drug Discovery

- Expansion of existing technological bases and building a new technological foundation to materialize unique drug discovery ideas
- Launch in-house global products every year by doubling R&D output
- Acceleration of innovation opportunities by leveraging digital technologies and strengthening collaboration with leading global players

#### **Futuristic Business Model**

- Dramatic improvement in product/patient value by restructuring business model, having digital utilization as a core
- Improve productivity of entire value chain by leveraging digital technologies
- Commercialization of Insight Business with the aim of maximizing the value of pharmaceuticals and having a new business pillar

• RED\* Shift Key Drivers • DX Open Innovation

\* RED: Research & Early Development

#### Overview of TOP I 2030

#### **Summary of Strategy**

The new growth strategy TOP I 2030\* is based on two pillars—global first-class drug discovery and a futuristic business model—and we have defined three key drivers and five reforms to achieve this strategy. Our targets for 2030 are to double R&D output and become a company that can launch innovative in-house global products every year.

\* TOP expresses our aspiration to become "the world's top innovator, not just in Japan." The "I" has two meanings: in addition to "innovator," it also expresses that each and every member of the Chugai Group plays an important role in our efforts to realize TOP I 2030.

#### Two Pillars to the Strategy

To achieve global first-class drug discovery, we will expand our existing technological bases and establish a new technological foundation. At the same time, we will build a futuristic business model that takes into account environmental changes and technological advances. We will fundamentally rebuild our value creation model with the goal of achieving a dramatic increase in productivity across the entire value chain and delivering greater value to patients.

#### **Three Key Drivers**

Under RED Shift, we will focus the investment of business resources in the processes involved from drug discovery through early development in order to create a continuous cycle of innovation in the future. Under digital transformation (DX), we will enhance our digital infrastructure and improve productivity across all value chains, with the goal of utilizing digital applications for innovative new drug discovery. Under open innovation, we will step up collaborations with external partners, focus on the application of external technologies, take a flexible approach to the adoption of new advances in science and technology, and work to create new opportunities for innovation.

#### **Policy on Shareholder Returns**

Our policy on shareholder returns is to aim for a dividend payout ratio of 45 percent on average based on Core EPS to provide stable dividends, taking into account the balance between shareholder returns and the internal reserves necessary for increasing corporate value.

### Five Reforms

#### 1. Drug Discovery

- Expansion of existing technological bases and building a new technological foundation to materialize unique drug discovery ideas
- Acceleration of innovation opportunities by leveraging digital technologies and strengthening collaboration with leading global players

### 2. Development

- Early maximization of product value through advanced human prediction and simultaneous drug development for multiple diseases
- Realization of advanced and efficient clinical development operations using digital technologies

# 3. Pharmaceutical Technology

- Establishment of competitive mid-size molecule production technology
- Establishment of world-class antibody drug manufacturing technology and acceleration of development
- Set up efficient production systems by utilizing digital and external resources

### 4. Value Delivery

- Maximize customer value by innovative digital-based customer engagement model
- Realization of further personalized medical care by the creation of unique evidence

## 5. Foundation for Growth

- Acquisition of the talent and the establishment of an organizational structure / HR system to support creation of innovation
- Realization of CHUGAI DIGITAL VISION 2030
- Conduct global environment measures
- Quality management that achieves both quality and efficiency
- Pursue opportunities of Insight Business

# Basic Principles of Increasing Corporate Value and Shareholder Returns



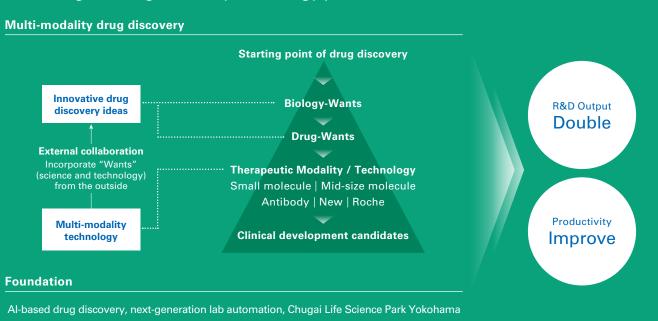
#### Direction in 2021

Maximizing value of growth drivers	<ul> <li>Accelerate market penetration by mainstay products, successful launch of new products</li> <li>Distribution system reform</li> </ul>	
Continuous creation of R&D output	<ul> <li>Steady achievement of plans for submissions and approvals</li> <li>Convert in-house post-proof of concept (PoC) projects into growth drivers, demonstrate value of in-house pre-PoC projects</li> <li>Start phase I clinical trials and expansion of mid-size molecule projects</li> <li>Continuous creation of drug discovery projects</li> </ul>	
Acceleration of DX	Accelerate DX across the entire value chain     (Al drug discovery, clinical predictability, clinical/pharmaceutical operations, customer engagement models, DX infrastructure)	
Strengthen business foundation		

# 1. Drug Discovery



To realize innovative drug discovery ideas, we aim to double output by strengthening digital capabilities, promoting external collaboration, and enhancing our drug discovery technology platforms.



#### **Global First-Class Drug Discovery**

Chugai has created many innovative new drugs thus far by leveraging the Company's unique capabilities in science and technology. In TOP I 2030, we will build on the strengths of our in-house drug discovery capabilities accumulated over the years, while further enhancing our drug discovery technology platforms to realize creative drug ideas.

#### **Multi-Modality Drug Discovery**

Chugai's proprietary small molecule and antibody technologies have successfully expanded our technology base. We continue to accelerate drug discovery using our unique technologies, including switch antibody technology, and are focusing on further technology developments. As for mid-size molecules, our third modality, the first project is scheduled to enter clinical trials during 2021. We expect this modality to become a main pillar of medium- to long-term growth, and will prioritize the allocation of business resources to technology development and clinical projects in this field. Mid-size molecule drugs can reach targets that were previously difficult to access, and have high binding activity, and good oral absorption. We hope this will enable us to solve unmet medical needs that cannot be addressed with conventional modalities.

In addition, we are leveraging our expertise in protein engineering technologies to establish new modalities. We will pursue a multi-modality strategy by flexibly incorporating external science and technology as necessary, identifying "Drug-Wants" (profiles and mechanisms of action wanted in drug discovery) not achievable with conventional technologies, and creating platforms as a means to solve them. In addition to stepping up our collaborations with Roche and the Immunology Frontier Research Center (IFReC) at Osaka University, Chugai will actively collaborate with external parties who have new technologies or knowledge in order to accelerate technology development and explore potential modalities.

#### **Reinforcing Drug Discovery Platforms**

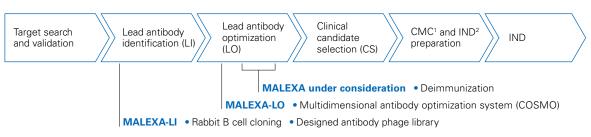
The application of digital technologies, including Al drug discovery, is essential to advance drug discovery technology and transform the drug discovery process. We are already working to utilize AI in our antibody discovery platforms, and to improve the efficiency of our drug discovery process using digital technology. We plan to expand and accelerate these initiatives going forward. Focus will also be placed on a smooth transition to Chugai Life Science Park Yokohama, which is scheduled to officially start operations in 2023, and on next-generation laboratory automation.

#### Case Studies

#### **Innovating Drug Discovery Processes Using Al**

In the field of drug discovery, we are using Al to transform various processes. For example, in the creation of antibody drugs, we are promoting an initiative called Al Machine Learning x Antibody (MALEXA) to select therapeutic antibodies for drug discovery purposes. By learning the patterns of a large number of antibody amino acid sequences during the selection process, we are able to propose candidate sequences in a short timeframe. Antibodies with strong binding activity have already been successfully obtained in a number of projects. For antibody optimization as well, we have confirmed that machine learning can be used for sequence generation and

predictive modeling, which allows us to propose antibody sequence groups based on optimal pharmaceutical characteristics, including binding activity, pH dependency, and physical properties. Currently, we are investigating the application of this technology to reduce immunogenicity, and have started to apply AI technologies in mid-size molecule drug discovery platforms as well. In addition, through a collaboration with FRONTEO, Inc., we are using Al-based text mining technology to vectorize 16 million published papers and build a system that can extract information from multiple sources. The goal is to achieve greater efficiencies in research processes and the prediction of disease-related genes.



1. Chemistry, manufacturing, and control 2. Investigational new drug

### **Evolution of Antibody Engineering Technologies: Progress in Switch Antibodies**

Chugai is continuously developing proprietary antibody engineering technologies, and currently we are working on a number of drug discovery projects using these novel technologies. One major development in 2020 was the entry of STA551, which uses our switch antibody technology (Switch-Ig®), into the pipeline. Conventional antibodies bind to target antigens in normal tissues as well as at sites of disease, resulting in side effects. Our switch antibody technology is expected to solve this issue by increasing the specificity of

antibodies to the sites of disease. STA551, which applies this technology, is designed to only bind to CD137, the target antigen, and activate T cells in the presence of the small molecule adenosine triphosphate (ATP) (switch molecule), whose extracellular concentration increases in cancer tissues. When ATP concentrations are low, STA551 does not bind to the antigen and does not activate T cells. Conventional CD137 antibodies produced liver toxicity and other serious side effects, and it was difficult to target CD137 as the antigen of the therapeutic antibody. The application of the switch antibody technology is expected to resolve these safety issues and produce good efficacy.

	Drug discovery	Preclinical	Clinical	Launched
Recycling antibody®, Sweeping antibody® Others	2	3	• Nemolizumab • Crovalimab • AMY109 • GYM329 / RG6237	• Enspryng
Bispecific antibodies (1st, 2nd, and 3rd generation)	6	2	• ERY974 • NXT007	• Hemlibra
Switch antibody	5		• STA551	
Antibodies applying other new technologies	2			

Note: Numbers indicated at the drug discovery and preclinical stages show the number of projects.

# 2. Development



Leveraging digital technology to realize a world-class clinical development model that can improve success rates and maximize product value

#### Early-stage development

Improvement of success rate

 Improvement of predictability in humans through intricate understanding of biological responses and utilization of innovative technologies such as modeling & simulation (M&S) and human organoid

Maximizing product value

- Early demonstration of QoL/True Endpoint
- Simultaneous development for multiple indications by early identification of candidate diseases

# Clinical trial success rate **Improve Expand** indications Accelerate **Productivity** Double

#### Late-stage development

Transformation of operational model Improve efficiency of monitoring/management tasks by using digital technologies

#### **Early-Stage Clinical Development**

Early-stage clinical development up to proof of concept (PoC)1 is a component of the value creation engine, one of the TOP I 2030 investment priorities as part of the Research and Early Development (RED) function. Here, the key issues are to improve success rates and maximize product value in order to double R&D output. Specifically, from the preclinical stages, we are working to develop an intricate understanding of biological responses utilizing innovative technologies such as M&S<sup>2</sup> and human organoid construction.3 These will be combined with the full use of real-world data (RWD) and a wealth of data on diseases and treatments that we have accumulated to improve the predictability of dosage and administration, efficacy, and safety, and to increase the success rates of clinical trials.

In the past, additional indications were developed in stages, but by using M&S and other scientific evidence, we now aim to identify target diseases at an early point and develop indications for multiple diseases simultaneously. Combining this with an understanding and analysis of biological responses, we will focus on the development of digital biomarkers (dBMs) and digital devices while identifying healthcare issues for each disease and linking the results from this work to appropriate diagnosis and treatment. Furthermore, by combining the data obtained in this way with RWD, we will demonstrate the True Endpoints that can help to improve patient QoL at the early stages, thereby maximizing the value delivered to patients.

- 1. Proof of concept: Confirmation that the therapeutic effect conceived in the research stage is effective in humans
- 2. Technology that integrates computer-based mathematical simulations with biological sciences. Supports key decision-making during pharmaceutical development.
- 3. Tissue structures designed to have similarities to organs in the human body

#### **Late-Stage Clinical Development**

In late-stage development, we are currently conducting over 100 studies primarily in Japan. As R&D output will further increase in the future, improving productivity by changing operational models is an urgent issue. We will actively use digital technologies for monitoring and management tasks, and at the same time, we will promote reductions in the size and duration of studies through the use of RWD. In this way, we aim to deliver products to the market faster and reduce the burden on patients.

Our target for late-stage clinical development is to double productivity by 2030.

#### Case Studies

#### **Development of New dBMs**



Sayumi Higashi Digital Strategy Department

The use of dBMs is significant in that it enables more appropriate diagnosis and treatment by continuously and quantitatively measuring the biological information of patients. dBMs are expected to play an important role in the future of medical care, contributing to more immediate and efficient diagnoses, supporting the accumulation of data for evaluation, and being applied in drug discovery.

For example, from the end of 2018, I have been responsible for developing dBMs for endometriosis. This condition is particularly problematic, as patients find it difficult to accurately communicate their symptoms to doctors during consultations, and it has not been possible to measure frequently enough to detect changes in subjective symptoms such as pain in order to measure outcomes. To address these issues, Chugai is currently working with Biofourmis on the

development of digital solutions that use Al algorithms and biosensors for continuous and objective measurement of pain and reporting to physicians.

We will continue to focus on the development of various dBMs in the future. It is important, however, to carry out a process of in-depth analysis of measurable items and choose the right technologies, because medical challenges and needs differ depending on the disease and product. My goal is to build up a track record in development and create development schemes.

dBMs are an extremely new technology, so the healthcare industry is also only just starting to develop methods and

frameworks for dBM use and data application. Measures to protect personal information and other security issues are essential. To maximize patient and product value, Chugai will support the establishment of new diagnostic and therapeutic frameworks for the industry and take a leading role in the discussion over best practice.



E4 wristband\* Source: Empatica company website

\* Wearable device being tested for the development of the endometriosis dBM

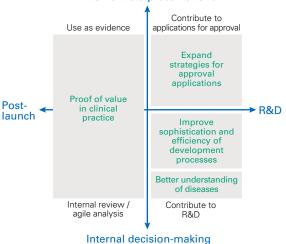
#### **Initiatives for Using RWD**

In the future, the use of RWD, including health insurance claims and electronic patient records, is expected to enhance the efficiency and sophistication of healthcare in various ways, such as improving patient value, selecting better treatment strategies, and understanding the actual medical conditions of patients in real time. However, there are numerous national, regulatory, and healthcare system-related issues that need to be addressed first, including ensuring that the quality and quantity of the data is suitable for use in regulatory submissions, and establishing highly transparent analytical methods and infrastructure. Against this backdrop, Flatiron Health Inc., a Roche Group company, collects and regularly updates the electronic medical record data of 2.2 million cancer patients, and is working with academia, pharmaceutical companies, and the U.S. FDA on initiatives to utilize a wide range of RWD.

Chugai is also working in collaboration with Flatiron Health to build environments where RWD can be used in a timely and appropriate manner. The figure to the right summarizes our initiatives in four different areas. For example, in the section on expanding strategies for

regulatory submissions, we have added RWD as reference data to the application documents for a drug in patients with ROS1-positive lung cancer. At academic conferences, we have also presented on the incidence of infections in patients with lupus nephritis and rheumatoid arthritis, and are working to enhance the sophistication and efficiency of the development process.

#### External data presentations



# 3. Pharmaceutical Technology



Realize pharmaceutical technology functions befitting a top innovator by combining high cost competitiveness with world-class technologies for turning drug discovery ideas into drugs

#### Early-stage development

Pursuit of world-class technologies

- Strengthen collaboration with drug discovery, making full use of state-of-the-art technology to manufacture drugs of high difficulty, such as mid-size molecules and highly active substances
- Evolution of the world's most advanced antibody technology and realization of development speed

#### Late-stage development

Pursuit of cost competitiveness

- Establishment of a manufacturing system that balances the strengthening of manufacturing technology functions and cost efficiency
- Maximization of productivity by promoting a second-site strategy and utilizing digital and robotics technologies



#### **Early-Stage Technology Development**

In the area of early-stage technology development for pharmaceutical technology, which is a component of the Research and Early Development (RED) function, our priority is to pursue world-class pharmaceutical technologies in terms of both technological sophistication and development speed in order to ensure the commercialization of innovative pharmaceuticals while responding to the significant expansion of R&D output. Development programs involving mid-size molecules, highly active substances, and new modalities—all addressed in the TOP I 2030 strategy—are extremely difficult to formulate. This means that establishing pharmaceutical technologies for these types of products would give us a competitive edge. We will further strengthen collaboration between the functions of drug discovery, development, and pharmaceutical technology; establish technologies for the active pharmaceutical ingredients (APIs), formulation, and analytical technologies of new compounds; and also accelerate the establishment of systems linking investigational drug development and early-stage production in preparation for the global competition in drug development.

For therapeutic antibodies, which are also expected to continue evolving, we will work to achieve world-class development speeds by further advancing manufacturing technologies in

response to the advancements in antibody engineering technology. We also plan to actively invest in the human capital, facilities, and technologies needed for these initiatives.

### **Late-Stage Development and Commercial Production**

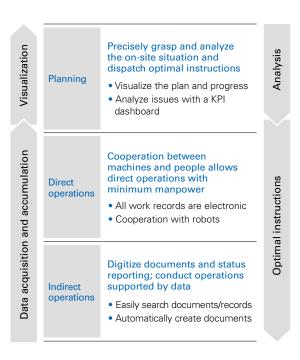
In production functions, we are establishing new systems that balance strengthening production technology functions with low-cost operations to ensure stable supply and improve productivity. We are accelerating efforts to improve production efficiency through the development of IT infrastructure using digital technology, as well as through the realization of digital plants and the application of robotics. As for digital plants, we are currently implementing various measures using the Ukima Plant as a model case, and we have plans to roll out measures to other sites in the future.

To reduce costs, we are developing next-generation biopharmaceutical plants for the production of antibody APIs. Our aim is to achieve significant improvements in productivity by reducing the size of plants and the amount of resources invested. We are currently in the final stages of technology development and plan to introduce pilot facilities in the future. Furthermore, as a second-site strategy, we will consider optimizing commercial production by using contract manufacturing organizations (CMOs) for products that can be outsourced to external partners.

#### Case Studies

#### **Realization of Digital Plants**

Chugai has implemented initiatives to help realize digital plants that can accelerate in-house drug discovery and respond flexibly to changes in the environment. Under the concept of "digitally transforming production operations to increase productivity and add high value to human capital," we are partnering with IBM Japan, Ltd. to link and optimize people and operational data for planning, direct operations, and indirect operations. As a first step, we will establish digital infrastructure to support new operations in the Ukima Plant as our model case by mid-2022 and validate each measure for expansion to other production sites. Conceptualization and requirements definition began in 2020, and implementation of each measure begins from 2021. We will build a digital platform that consolidates various data, including manufacturing, quality, and manpower systems, and utilize it to reform operations for greater efficiency, including planning and progress management, Good Manufacturing Practice (GMP) document retrieval, and remote site support.



# Realizing Next-Generation Plants for Biopharmaceuticals

#### Akihiro Yanagita

API Process Development Department, Pharmaceutical Technology Division (Biotechnology) Professional of Next Generation Manufacturing & Technology for Bio-Product



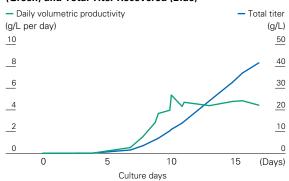
Chugai has started to work on developing next-generation biopharmaceutical plants that incorporate continuous production processes, with the goal of achieving substantial cost reductions in the manufacturing of antibody APIs. In continuous production, the non-stop manufacturing processes allow effective use of time and smaller scale plants. When combined with digital applications and robotics, this approach increases operational efficiency and improves productivity.

In the cell culture method that uses "perfusion culture," antibodies are collected while nutrients are continuously provided to a culture tank in which antibody-producing cells mature at high densities. The challenge is to maintain the cells at high densities while increasing antibody production efficiency. We are making steady progress in the development of this method and have reached world-class production efficiency at a lab scale

of 4–5 g/L per day (see graph below). For purification processes, we are also working with external parties to link multiple steps, such as chromatography and filtration.

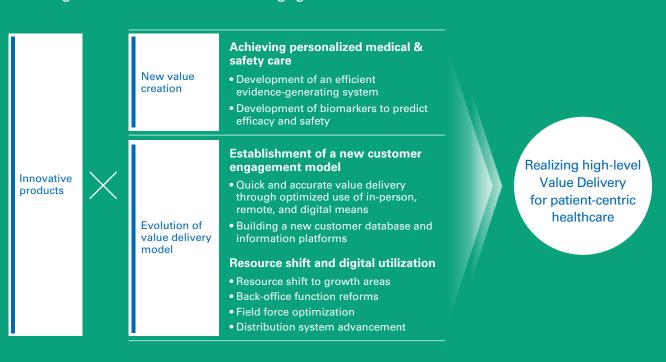
Currently, these technologies are in the final stages of technological development. Prototype equipment for the culture process was installed in 2020, and the scale-up study will start in 2021. We then plan to install prototype equipment for the purification processes in 2022 and test the linking of all the processes. We are making steady progress toward applying these technologies to actual production in the late 2020s.

# Efficiency of Antibody Production with Perfusion Culture (Green) and Total Titer Recovered (Blue)



# 4. Value Delivery

Achieving sophisticated Value Delivery with a limited number of exceptional talents by generating evidence for personalized healthcare (PHC) and building an innovative customer engagement model



## **Generating Evidence for PHC**

As a pioneer in PHC, Chugai has been working not only to develop and supply products but also to promote their use in cooperation with medical facilities and local governments. Under the previous mid-term business plan IBI 21, we focused on the promotion of gene panel testing and the development of genomic cancer medicine as a key strategy to advance PHC. In addition to continuing our efforts in these areas, we will generate high-level evidence to promote PHC through the comprehensive analysis and utilization of various databases and real-world data (RWD) accumulated through drug discovery and clinical development. We will also accelerate the development of biomarkers that accurately predict efficacy and safety for each patient to realize a new phase of PHC.

#### **Establishment of a New Customer Engagement Model**

Against the backdrop of the development of digital tools and the impact of the spread of COVID-19, there is a dramatic change in the nature of how we engage with healthcare

customers, such as physicians, pharmacists, and nurses. We aim to build a completely new customer engagement model that reflects these changes. Specifically, by optimizing the use of in-person, remote, and digital means and coordinating the sales, safety, and medical functions, which are our major strengths, we will build a solution system that accurately and promptly delivers information truly valuable to customers while maintaining a high level of expertise. To achieve this, we will integrate customer databases with information from various solutions and create a comprehensive interface that allows customer-centric marketing.

#### **Resource Shift and Digital Utilization**

We are planning a bold shift in resource allocation to new and growth areas as well as the optimal allocation of personnel and sites in line with future changes in our product portfolio. In addition, we will implement drastic reforms to our back-office operations, including digitalization, outsourcing, and consolidation of operations.

#### Case Studies

#### **Building System Infrastructure for Customer-Centric Marketing**

In order to respond flexibly to the needs of healthcare professionals, who are our customers, we have launched a cross-departmental project entitled 0C (Organic Communication), or Zero C, which aims to build an integrated interface to realize customer-focused marketing. This will allow management via an integrated database of many different categories of data, from employee activity records to market information on Chugai and competitors, customers, and areas. In this way, we will create a system to support business activities through access to a range of analyses and an

Al-based decision support engine. The system will be established as a platform to visualize data, improve the quality of sales data, and facilitate approaches to new customers for each person in charge of various touch points with customers, such as sales, medical affairs, drug safety, clinical development, and Foundation Medicine Unit (FMU).

In addition, we will use the information obtained in this way for marketing purposes, in online seminars, and on PLUS CHUGAI, Chugai's website for healthcare professionals (monthly average unique users: approx. 140,000). We will also integrate the information into MR and digital programs tailored to customer needs.



# 0C (Organic Communication)



## **Promote Advances in PHC**

PHC involves using a patient's genomic and other information to provide optimal treatments. This approach has substantial benefits for various stakeholders, in terms of quality of care and health economics, and is at the heart of Chugai's goal to achieving advanced and sustainable patient-centric healthcare. As a pioneer in this area, we are focusing our efforts on a new phase in PHC that can deliver optimal treatment for each individual patient, driven by advances in gene analysis and drug discovery technologies.

One core initiatives is our FMI business, which uses the technology of Foundation Medicine, Inc. (FMI), a member of the Roche Group, to promote cancer genomic medicine. In 2019, we launched

FoundationOne CDx Cancer Genomic Profile (F1CDx), a comprehensive cancer gene panel test, and have now obtained approval for its use as a companion diagnostic for Rozlytrek and various other drugs.

In March 2020, we filed a submission for the approval of FoundationOne Liquid CDx as a liquid biopsy test using blood samples, and approval was granted in March 2021. This will enable the test to be used in cases where cancer tissue is difficult to access for biopsy as well as for prognosis prediction and confirmation of post-treatment resistance, thereby supporting a wider range of treatment decisions. Chugai will continue to develop PHC through the adoption of comprehensive genomic profiling.



# 5. Foundation for Growth



# Strengthening the foundation for growth necessary to create innovation and evolve the value chain

People and • Thoroughly implement new HR system · Acquire highly specialized talent Organization New ways of working • Ongoing promotion of diversity and inclusion (D&I) • Create innovative new drugs using digital technology **Digital** • Streamline entire value chain • Strengthen digital infrastructure • Implementation of climate change countermeasures, use of **Environment** renewable/recycled resources, and biodiversity conservation • Acquire approaches for next-generation quality management Quality · Achieve high productivity Build capability and seek commercialization through verification and **Insight Business** expansion of insight-generating technologies

In parallel with the reforms of each value chain process, we will also work to strengthen our business foundation which supports the generation of innovation and the realization of our growth strategy, especially in the following five priority areas.

#### **People and Organization**

Through the operation of the new HR system launched in April 2020, we will work to upgrade our talent management, ensure the right person in the right place, and foster an organizational culture that encourages bold challenges. In addition, we will focus on acquiring, developing, and fulfilling highly specialized talent, such as data scientists and other digital and science talent, who are key to the execution of our strategy. We will make further progress with the D&I initiatives vital for innovation by instilling in employees the three actions of "communicate, discuss, and accept."

### **Digital**

We will promote digital transformation (DX) in each part of the value chain to improve efficiency. Among these, we will focus on the use of digital technologies to create innovative new drugs. We will work to build a digital foundation for both software and hardware in order to achieve this goal. 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.

#### **Environment**

We will push ahead with initiatives to achieve our mid-term environmental goals for 2030 that are based on materiality and external expectations and requirements. For environmental, social, and governance (ESG) issues, we will continue to upgrade our Group-wide initiatives and accelerate the sustainable development of Chugai and society.

We will strengthen the development and operation of new quality management methods that anticipate changing business processes, such as establishing a new quality assurance system suited to diverse technological advances and the challenge of new modalities, strengthening digital compliance, enhancing collaboration with external parties and developing the Chugai quality brand.

#### **Insight Business**

We will explore the commercialization of solutions for healthcare professionals and R&D support solutions based on various insights derived by accumulating and analyzing data obtained across the value chain as well as external data such as real-world data (RWD). In collaboration with Roche, we will expand our capabilities in data analysis and insight extraction, and verify technologies under various different use cases.

#### Case Studies

#### Transforming Working Practices as Part of the "New Normal"

Chugai has long promoted the effective use of work-from-home (WFH), but in addition to verifying the status of WFH under the measures to prevent COVID-19 infections, we have now designed new ways of working in the new normal in order to achieve Chugai's new growth strategy. These new working practices are designed to maintain or improve productivity, support quality communication and relationships, and achieve work-life synergies, while at the same time create a system that can flexibly adapt to the needs of the organization, job role, and work tasks as well as individual employee lifestyles.

In terms of detailed initiatives, the working practices encourage each workplace to independently manage whether employees come into the office or whether they work from home or use satellite offices. The system is also designed to improve individual and organizational productivity and to promote digitalization of work processes and the establishment of an IT environment suited to the Telework System. We also need to set up detailed performance-based review systems suited to teleworking, so we will provide

training for management skills to achieve this. At our Head Office, we plan to optimize floor space according to the percentage of employees coming into the office for work, and will implement other reforms at the same time to create working spaces suited to value creation through a sense of organizational unity and collaboration.

#### **Envisioned new ways of working**

Promote greater digitalization of work processes to achieve more flexible ways of working ("smart working") suited to the needs of the organization, job role, and work tasks, and improve productivity while also achieving work-life synergies with the goal of achieving continuous innovation

#### Measures to achieve new ways of working

- 1. Introduction of the Telework System utilizing WFH and satellite offices
- 2. Creation of an environment that maintains and improves productivity even with flexible ways of working
- 3. Development of staff performance evaluation and management systems suited to teleworking
- 4. Review of office plans and various rules in light of the introduction of the new Telework System

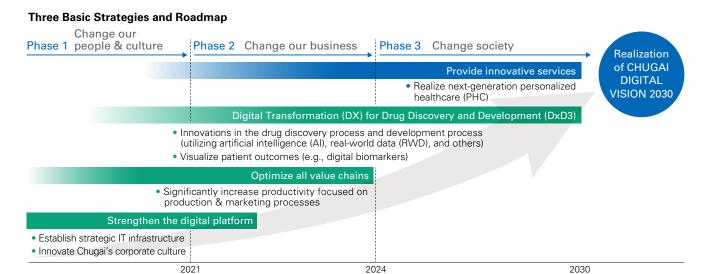
#### Overview of the Main DX Measures to Enhance Our Foundation for Growth

Foundations: Establish digital/ IT infrastructure	<ul> <li>Development of Chugai Scientific Infrastructure (CSI), an IT platform for securely using, moving, and storing large amounts of data, with the aim of promoting company-wide data utilization</li> <li>Digital transformation (DX) of manufacturing functions to realize digital plants, and establishment of digital infrastructure to support new operations</li> <li>Establishment of Digital Compliance Committee, formulation of rules and guidelines relating to the handling of human-derived data, and construction of systems capable of responding appropriately in line with risk</li> </ul>
Foundations: Reform awareness and culture	<ul> <li>Initiatives to transform awareness and culture in Chugai (Digital Leaders appointed in each division; events to share various departmental digital initiatives across the Company, including Digital Summit and the online event DIGITAL IT HEALTHCARE WEEK for internal and external audiences; information sharing via various in-house channels; support from the Digital &amp; IT Supervisory Division to help progress with all DX initiatives; etc.)</li> <li>Establishment of the Digital Innovation Lab (DIL) to incubate bottom-up ideas and support their realization, as well as fostering staff trial and error (DIL started operating in June 2020; approximately 150 ideas had been put</li> </ul>
Talent	<ul> <li>• Visualization of internal digital talent and skills, preparation of education systems to foster digital talent, and design/implement training programs</li> <li>• Enhancement of recruitment strategy to bring in external digital talent (use new recruitment methods, communication about in-house role models on the official channel on "note," a content platform that supports creators)</li> </ul>
Partnering	<ul> <li>Acceleration of external partnerships to make further progress in the various DX initiatives IBM Japan, Amazon Web Services, NTT DATA, Biofourmis, FRONTEO, Preferred Networks, LINE WORKS, Welby</li> <li>Launch of DigiTube online corporate briefing; held regularly, the briefing features presentations by tech companies on the latest technologies to inspire Chugai employees, regardless of their department or job role, and helps to facilitate business matching between employees and tech companies (presentations and technical materials from over 30 companies each year are available for all employees to access)</li> </ul>

# CHUGAI DIGITAL VISION 2030



Transform our business by using digital technologies to make Chugai a top innovator in the provision of society-changing healthcare solutions



#### Progress with CHUGAI DIGITAL VISION 2030

Chugai established the Digital Strategy Department in October 2019 to bring together all the digital initiatives underway at various departments and to plan and progress an optimized company-wide digital strategy. The Company then formulated CHUGAI DIGITAL VISION 2030 and a roadmap to achieve this.

We have defined three basic strategies to achieve this vision. First, we will reform our corporate culture and work to strengthen the digital platform by training and hiring more digital talent while also integrating and streamlining various types of data. As we build this infrastructure, we will optimize all value chains through the introduction of digital technologies and reforms to operational processes, with the goal of digital transformation (DX) for drug discovery and development through bold shifts in business resources. For drug discovery, we will improve our capabilities in AI, real-world data (RWD), and digital biomarkers (dBM) to realize unparalleled Digital Transformation for Drug Discovery and Development (DxD3) and promote advances in PHC.

We made steady progress in all these measures in 2020 and were proactive in communicating about our programs externally, such that Chugai started to be recognized externally for DX, including selection by the Ministry of Economy, Trade and Industry (METI) and the Tokyo Stock Exchange (TSE) as a DX Stock 2020 and a doubling in the number of job applications from digital talent.

We will actively allocate resources to these areas in the future and are developing new initiatives to be funded by aggressive investment, which will be positioned as Transformation in the digital and IT budget categories of Operation and Maintenance, Growth, and Transformation. The 2021 budget allocations for these categories are planned to be limited to approximately 50 percent for Operation and Maintenance, which generally tends to rise, with 25 percent for Growth and 25 percent for Transformation.

#### **Future Initiatives**

#### DX for drug discovery and development

▶ P63

Chugai is working on a wide range of initiatives, including the use of AI to improve the efficiency of antibody drug discovery processes, application of AI in pathology image analyses during pharmacology research, use of natural language processing technologies to improve literature search efficiency, and development of integrated databases. The Company is also developing dBM and using RWD in its development programs.

#### Optimize all value chains

▶ P65 ▶ P6

Chugai aims to develop digital plants where digital technologies transform production processes and human resources provide greater added value. The Company is also making progress with digital marketing programs and system infrastructure for customer-centric marketing.

#### Strengthen digital platforms

▶ P69

As well as building the infrastructure needed for greater data utilization internally and externally, Chugai is also stepping up the recruitment and training of digital talent. Through the Digital Innovation Lab (DIL), the Company is creating new projects, transforming the culture across the organization, and developing more collaborative projects with external partners.

# Mid-Term Environmental Goals 2030

## Background to the Setting of Mid-Term Environmental Goals 2030

Chugai set mid-term environmental goals for 2020 and made solid progress in initiatives to help protect the global environment. Looking ahead, we have decided to set new mid-term environmental goals that are more comprehensive and have a longer-term perspective, are consistent with our Material Issues, and reflect the ever-increasing expectations and demands of society and our conclusions following analysis of the previous mid-term environmental goals (see on the right). We conducted scenario analyses based on the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) as prior analysis before setting new goals.

#### Climate change countermeasures

- Climate change is an increasingly important global challenge.
   We need to develop higher-level initiatives and set targets with a longer-term view.
- We assume fluorocarbon regulations will be tightened further.

# Use of renewable/recycled resources and protection of biodiversity

- Expectations for more advanced environmental management, starting with prioritizing circular economies
- We recognize water as one of the most important resources and assume more emphasis will be placed on water risk management in the future.

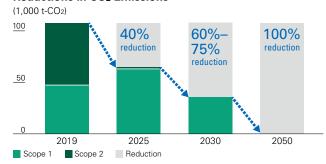
# Targets and Initiatives for Mid-Term Environmental Goals 2030

We have set 10 new mid-term environmental goals through to 2030 (up from four goals) that incorporate medium- and longer-term perspectives and are also consistent with materiality. The goals include water risk and chemical substance management. Many of the goals include a milestone in 2025 to be achieved on the way to reaching the goal in 2030. We have also set a long-term goal of zero CO<sub>2</sub> emissions by 2050, as we need large-scale and long-term initiatives if we are to combat climate change.

In terms of specific initiatives, for climate change we will work on achieving 100 percent use of sustainable electricity and are also investigating reducing direct CO<sub>2</sub> emissions due to fuel use (Scope 1<sup>1</sup>) and reducing energy use and improving efficiency through renovations and reforms to facilities and equipment. In terms of use of renewable/recycled resources,

we will accelerate efforts toward zero waste emissions and will also step up programs to reduce water consumption. For protection of biodiversity, we will implement stricter protocols on the management of hazardous chemical substances and design improved manufacturing processes.

#### Reductions in CO<sub>2</sub> Emissions



Material Issues	Item		KPI (Base year 2019)
	Scope 1+2 <sup>1</sup> CO <sub>2</sub> emissions	40% reduction by 2025	60–75% reduction by 2030 Zero emissions by 2050
Climate change	Scope 1+2 <sup>1</sup> energy consumption	5% reduction <sup>2</sup> by 2025	15% reduction <sup>2</sup> by 2030
countermeasures (Prevention of	Sustainable electricity ratio	100% by 2025	
global warming)	Fuel consumption by MR vehicles	35% reduction by 2025	75% reduction by 2030
	Halogenated hydrocarbons (Base year 2020)	25% reduction by 2025	100% reduction by 2030
Use of renewable/	Industrial waste reduction	5% reduction <sup>2</sup> by 2025	10% reduction <sup>2</sup> by 2030
recycled resources (Resource conservation,	Plastic waste reduction	5% reduction <sup>2</sup> by 2025	10% reduction <sup>2</sup> by 2030
waste management)	Water resource conservation (Water withdrawal)		15% reduction <sup>2</sup> by 2030
Protection of biodiversity (Reduction of	Chemical substance management (SVHCs³)	,	processes without using SVHC-listed chemicals are original candidate molecules by commercial productions.
environmental load)	Hazardous waste reduction	5% reduction <sup>2</sup> by 2025	10% reduction <sup>2</sup> by 2030

<sup>1.</sup> Scope 1: Direct emissions, Scope 2: Indirect emissions from the generation of purchased energy 2. Per total floor area (Excluding leased properties)

<sup>3.</sup> Substances of Very High Concern



We are building the foundation for sustainable growth through further refinements in our unique cash generation cycle and a balanced allocation of capital. In addition to increasing our economic value, we will also pursue ESG initiatives and other programs to create shared value with society.

#### **Global Growth by In-House Products Drove Earnings** to an All-Time High for Fourth Consecutive Year

In 2020, we maintained our growth momentum and reported earnings at an all-time high for the fourth consecutive year, beating our initial forecasts with revenues of ¥786.9 billion (up 14.7 percent year on year, 6.3 percent above forecast) and Core operating profit of ¥307.9 billion (up 36.9 percent, 12.0 percent above forecast).

The global spread of COVID-19, which we did not anticipate at the beginning of the year, was a headwind to our business but also brought unexpected opportunities.

Due to voluntary restraints on marketing activities and patient reluctance to keep medical appointments, we saw a significant slowdown in market penetration by new product Hemlibra and new indications for Tecentriq. On the other hand, demand increased for Actemra in the treatment of COVID-19 associated pneumonia, and export sales to Roche and royalty income rose unexpectedly. In terms of costs, our spending was down for research meetings, lectures, and travel, giving us the opportunity to invest in remote sales & marketing and work-from-home (WFH). As a result of the offsetting positive and negative effects, the impact on 2020 earnings overall was relatively limited.

The year 2021 got off to an extremely challenging start as the state of emergency was reinstated in January. With the government's implementation of off-year drug price revisions in April and increasing market penetration by generics, domestic sales revenues are expected to decline for the second year in a row. In overseas markets, conditions remain severe due to a reduction in the number of patients keeping medical appointments and increased pressure on drug costs in the wake of the COVID-19 pandemic, but we expect exports of our in-house global products and royalty income to continue to drive earnings. Overseas sales revenues, which command high profit margins, will likely account for over 50 percent of total revenues for the first time. Our operating profit ratio is now at a high level even compared with global companies, as the ratio of operating expenses to revenues is falling due to ongoing restructuring and productivity improvements. This fiscal year is expected to be another record year, with revenues of ¥800 billion (up 1.7 percent year on year) and Core operating profit of ¥320 billion (up 3.9 percent), aiming for a Core operating profit to revenues of 40 percent.

#### Fixed-Period Mid-Term Business Plan Completed in 2020

Mid-term business plan IBI 21 started in 2019 and was completed one year ahead of schedule.

Our initial financial target was a Core EPS CAGR of 7–9 percent, but this was raised to around 30 percent at the start of 2020 due to strong market penetration by Hemlibra and Tecentriq. We beat this revised target as well in the second year, and based on the steady progress with qualitative targets, we expected to surpass the initial quantitative and qualitative targets by a wide margin in the third year. Looking back on the previous mid-term business plan, IBI 18, we also significantly exceeded the targets over its three-year period. This experience presented us with the opportunity to reconsider our fixed-term plans. Considering the speed and quality of changes in the business environment and in technological innovation are different from the assumptions made at the time of formulating business plans, we concluded that new strategies and targets that look even further into the future were needed.

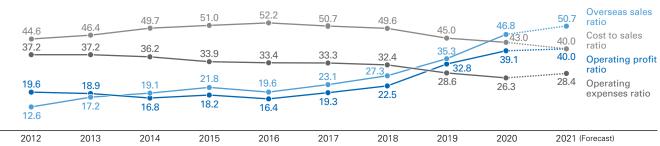
For all these reasons, we decided to complete IBI 21 after only two years, and also to stop formulating mid-term business plans that cover fixed periods. Instead, plans will now be backcasted from the year 2030, when we aim to become a top innovator in the healthcare industry, in order to decide what we need to achieve over the next few years. The timing of key milestones

will vary according to the issue or theme. We will summarize the plan as a schedule spanning a period of three to five years, revising this as needed based on the status of implementation and changes in the business environment. We believe that not only a bird's-eye view from above and a worm's-eye view from below, but also a fish-eye view is needed in order to give us the panoramic outlook to move freely with the flow.

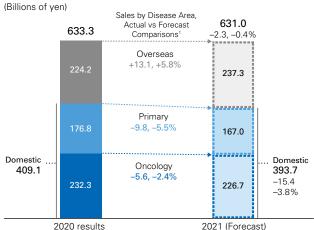
This means we will no longer release mid-term business plans that remain in place even though they contradict what is actually happening inside and outside the Company. Now we will manage according to plans that are constantly updated in an event-driven and agile manner. Our financial plans will also be designed according to multiple scenarios and updated as needed to reflect changing factors that have a financial impact. These changes first emerge in pre-financial indicators. More information on this topic is summarized in the section on the relationship between pre-financial indicators and financial results on pages 34–35. Note that our basic policy on information disclosure will remain unchanged. We still disclose pre-financial information, such as our direction, risk factors, and progress in R&D pipelines, as

#### **Earnings Structure**

(%)

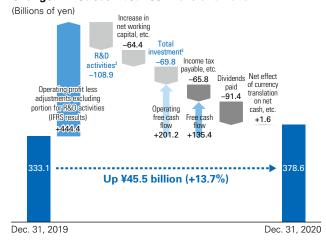


## 2021 Sales Forecast



 From 2021, sales for Foundation Medicine, which were included in "Oncology" and "Others" until 2020, will be included in "Oncology." Also, sales for products included in "Bone and Joint," "Renal Diseases," and "Others" until 2020, will be included in "Primary" from the forecast for 2021.

#### Change in Net Cash between 2019 and 2020



- R&D expenses based on IFRS results, less depreciation and impairment losses related to R&D
- Amount invested in property, plant and equipment, and intangible assets

well as detailed progress updates and financial forecasts for the next year. We will also increase opportunities for dialogue with stakeholders.

#### **Refining Our Business Model and Allocating Capital to Strategic Areas**

Chugai's business includes out-licensing, in which products from Chugai research are mainly delivered to the world through the Roche global network, and our own marketing operations, where we market in-house products and products in-licensed from Roche in Chugai sales territories (mainly Japan, South Korea, and Taiwan). By generating stable earnings through our own marketing operations and investing in the creation of innovative new drugs, we continue to expand our out-licensing business, allowing us to generate even more funding for innovation. This cash generation cycle is the business model we have built based on our strategic alliance with Roche.

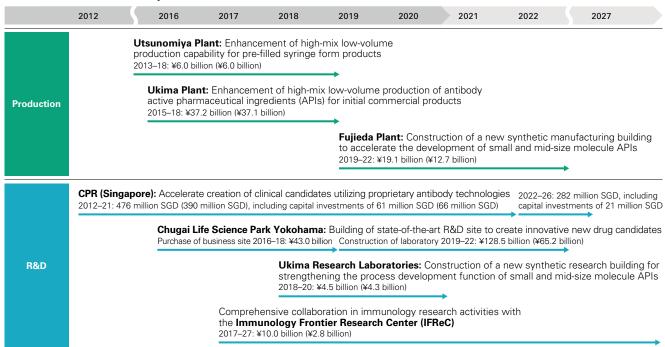
Strengthening this cash generation cycle even further is the key to our financial strategy. In out-licensing, we need to achieve global growth for products discovered in-house, including Hemlibra and Enspryng, and make progress with nemolizumab, crovalimab, and other development projects in order to achieve successive launches of new products. It is also essential to further enhance our drug discovery technologies, including the establishment of mid-size molecule technologies and expansion of antibody engineering technologies. To maintain the innovative drug discovery

capabilities we have developed thus far, it is vital that we pursue the Research & Early Development (RED) Shift, where we focus our limited resources in drug discovery, and Open Innovation, where we supplement any gaps in our business through in-licensing or outside partnering.

Thus far, we have pursued a program of cost optimization through a selection and concentration strategy, which included the transfer of long-listed products, the sale of or withdrawal from subsidiaries no longer compatible with our strategy, the outsourcing of packaging and logistics functions, and the consolidation of standard operations. Moving forward, we will make further improvements in efficiency and productivity in each function. In the production function, we aim to make operations more advanced and efficient by developing digital plants, starting with the UK3 project at the Ukima Plant.

Amid expectations that the domestic market will shrink, structural reforms in the marketing function, which is responsible for our own marketing business, is an urgent issue if we are to continue generating stable earnings. We will work to maintain productivity by building a new customer engagement model and reviewing sites, systems, and processes. For the R&D function, we will expand our digital platforms that can integrate and apply internal and external data, and develop next-generation laboratory automation that uses artificial intelligence (Al). We are ready to make a bold shift in capital allocation into the indispensable features of our

#### **Current Status / Plan for Major Investments**



Note: Figures in parentheses indicate cumulative amount at the end of December 2020

new growth strategy, namely enhancing RED functions, building digital platforms, and acquiring new technologies and functions from outside of Chugai.

Regarding shareholder returns, we have set a target payout ratio of around 45 percent on average based on Core EPS, with the aim of maintaining a stable dividend that can withstand short-term fluctuations in profit levels.

#### Greater Understanding through Dialogue and Improved Management Based on External Evaluations

As a listed company, one of our main responsibilities is to improve capital efficiency. In 2020, we maintained high capital efficiency with Core ROIC significantly higher than the weighted average cost of capital (WACC)\* at 37.3 percent.

Here, I would like to discuss the financial key performance indicators (KPIs) we consider important. The KPIs that we use as management indicators are revenues and Core operating profit over the short term, Core EPS growth rate over the medium term, and Core ROIC over the long term. While many companies use return on equity (ROE) as an indicator of capital efficiency, Chugai uses Core ROIC because we are subject to limitations on how we control total asset turnover and financial leverage as a large number of our products dominate the market and thus we have a social responsibility to constantly maintain stocks at a certain level. From the perspective of autonomy, we need to maintain Roche's

# **Changes in Dividends and Payout Ratio**

(Yen) 60.00 55.00 46.67 30.00 14 67 28.67 ..... 4.67 20.67 30.00 Year-end (Special) 25.00 Year-end (Regular) 16 00 Interim 10.33 9.67 2017 2018 2019 2020 2021 Payout ratio 5-year average 48.4% 48.6% 47.4% 44.9% 43.8%

Note: Chugai conducted a three-for-one stock split of common stock effective July 1, 2020. Dividends are calculated based on the assumption that the stock split was conducted at the beginning of 2017.

48.7%

45.8%

41.2%

44.7%

shareholding at a certain level. Therefore, to improve ROE, we must improve the profit margin. For these reasons, we have set Core EPS CAGR, which shows sustained growth in the margin, as our medium-term financial KPI. As a long-term indicator, we have started to manage capital efficiency using ROIC based on the belief that it is essential to quantify investment efficiency over the long term in the pharmaceutical business, where activities are conducted in timeframes of a decade or more. We have also introduced methods that take into account cost of capital in our internal business decision-making processes and mechanisms, including discounting present value with WACC when assessing the business feasibility of investments and development projects.

From the perspective of increasing corporate value, reducing the cost of capital and invested capital are important themes alongside increasing profits. Investment in digital transformation (DX) and environmental, social, and governance (ESG) initiatives may put pressure on profits over the short term, but they will also reduce cost of capital and invested capital in the future, so we need to implement and control such programs in an integrated fashion, while also monitoring priorities. For example, we were quick to set the challenging environmental goal of zero CO<sub>2</sub> emissions by 2050. To achieve this, we will need to make substantial investments in equipment, facilities, and technologies. But we believe that this will create a positive cycle whereby society recognizes Chugai as a corporate citizen working to address social issues and endorses these activities, resulting in an increase in Chugai's social value. Chugai has been solving unmet medical needs by delivering breakthrough medicines and services, but has also been committed to other issues, such as global environmental problems, and has actively been taking the lead to address such social issues. In 2020, Chugai was selected for the first time for inclusion in the Dow Jones Sustainability Indices (DJSI) World, which is the world's leading ESG index. We cannot continue these initiatives without the support and understanding of all stakeholders, and we thank you for this support.

In 2020, we found new ways to continue the dialogue with stakeholders as we had done before the pandemic. We developed various methods to communicate, including remote briefing sessions with analysts and investors and socially distanced meetings that were also broadcast live to provide specific information on financial results, new products, and initiatives including DX and ESG. We obtained numerous suggestions from such meetings. In 2021, we will continue to disclose information in a transparent and fair manner and create opportunities for two-way dialogue. We very much look forward to hearing your views.

\* 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.

# **Enhancement of Corporate Governance**

# Message from an Outside Director

Dr. Mariko Y Momoi Independent Outside Director

Professor Emeritus of Jichi Medical University Visiting Professor of School of Medicine, Shinshu University Regent of Tokyo Medical University (Part-time)



#### **Shaking Up Default Thinking**

I was appointed as an independent outside director in March 2020. I am a complete outsider in the world of corporate management and the pharmaceutical industry, but I appreciate that my role is that of an outsider, providing opinions from the perspective of medical science and a physician. People tend to make immediate judgments based on the "default settings" in their brains. As these default settings are developed through experience and intuition, when the defaults become assumptions, errors are more likely to come into play. The same is true for organizations. If the default settings of a group are uniform, unconscious assumptions can have far-reaching consequences and also make it difficult to change mindsets. This is precisely why diversity is so important in organizations. Chugai is a talented organization capable of shaking up such default thinking. I am convinced this is why the Company has achieved such outstanding results. Even though my comments at Board of Directors meetings and other events tend to be about elementary or even irrelevant matters, I believe that I am fulfilling my duties to help increase corporate value if these discussions can be used as a springboard to shake up customary ways of thinking.

#### **Three Issues That May Support Further Evolution**

Going forward, I would like to focus on three issues. The first issue is to enhance public awareness of Chugai's excellent corporate philosophy and culture. Chugai continues to take on the challenge of, and generate successes with, the discovery of innovative new drugs. However, as the products that Chugai creates are used in highly specialized medical treatment, the excellent corporate culture that produces them is not well known by the general public. By sharing its Envisioned Future as a top innovator more broadly with society, Chugai can promote (1) a better understanding of the needs of patients who hope for the development of new treatment methods, (2) information sharing with healthcare professionals in a wider range of therapeutic areas, and (3) the recruitment of talented employees looking to take on

these challenges. Such communication can be meaningful for a company as it helps to foster expectations from society.

The second issue I want to highlight is improving workplace happiness for all employees. The 2020 employee awareness survey showed positive results compared with global companies, but if Chugai is to progress further, it is important for employees to feel that problems are improving consistently. I hope to see and confirm that employee feedback is reflected in constant improvements such as efficient operations, information sharing beyond divisions and departments, necessary support, management of workloads to appropriate levels, and leadership development. I am particularly excited about the new TOP I 2030 growth strategy, and I think that sharing the excitement felt by all employees will be the foundation for further growth in corporate value.

The final issue is risk monitoring. When the new growth strategy was formulated, Chugai developed a Risk Appetite Statement and revised the risk map that extracts and visualizes risks from multiple perspectives. I look for Chugai to focus on responding rapidly to various risks.

Chugai is a company that conducts sound and ambitious management with determination and motivation, while sharing a clear vision with all employees. Not satisfied with its recent performance, Chugai has a strong sense of urgency from a long-term perspective and is determined to continue making rapid progress. At the same time, Chugai combines this outlook with a serious and steady approach, including careful risk assessment and sincere efforts to address internal and external feedback.

I will work to fulfill my role as an outside director, supporting Chugai in its goal of increasing corporate value even further for all stakeholders, including investors, shareholders, the medical community, employees, and patients.

#### Realization of Mission and Creation of Shared Value Relationship with Roche and Securing 2 4 Officer the Rights and Equality of Shareholders Remuneration Reinforcement of Emphasizing Linkage the PDCA Cycle with Performance 3 and Stock Price Introduction of Outside Perspectives 1 A Governance Structure Supporting Chugai's Unique Business Model

# 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 this shared value, Chugai considers it important to establish and evolve its unique system of corporate governance, which is an integral part of management. We reflect this approach by identifying five priority issues.

- 1 A Governance Structure Supporting Chugai's Unique Business Model—a prerequisite for all that follows. It is essential for value creation. Under its strategic alliance with Roche, one of the world's largest pharmaceutical companies, Chugai is a member of the Roche Group, but at the same time maintains autonomy and management independence as a separate listed company. Chugai pursues management that fulfills the mandate of its 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.

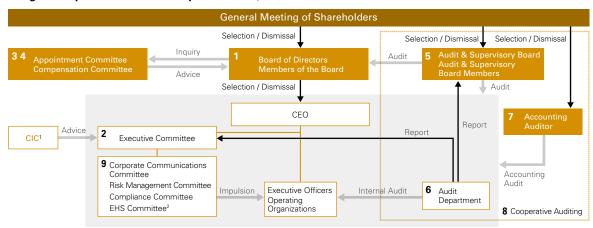
- Introduction of Outside Perspectives—important for ensuring a stakeholder viewpoint and objectivity in order to create shared value with stakeholders under this unique business model.
- 4 Relationship with Roche and Securing the Rights and Equality of Shareholders—a priority issue for properly ensuring 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 (TSE)'s Corporate Governance Code. The item indicated below 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.



#### Chugai's Corporate Governance System (As of April 1, 2021)



- 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 environment, health, and safety (EHS) activities for the Chugai Group.
- 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 2020
- 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: 14 members (3 directors, 10 executive officers (excluding directors), 1 head of division)
- Convened: 32 times in 2020
- 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 2020
- 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 2020

#### 5 Audit & Supervisory Board / 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. The Office of Audit & Supervisory Board Members ensures the independence and enhances the auditing functions of Audit & Supervisory Board members

- 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 2020
- 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.

#### 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 Compliance Committee reinforces the PDCA cycle for compliance activities and monitors the implementation of countermeasures and the status for particular items: and 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. Collectively referred to as the corporate management committees.

# 1 A Governance Structure Supporting Chugai's Unique Business Model

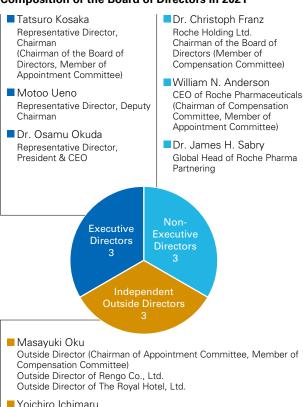
In order to promote Chugai's unique business model while ensuring its effectiveness, we separate management decision-making (Board of Directors) and business execution (Executive Committee and others), thereby expediting business execution and clarifying executive responsibility.

#### **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,

#### Composition of the Board of Directors in 2021



Outside Director (Member of Appointment Committee)

Visiting Professor of School of Medicine, Shinshu University

Outside Director of Seino Holdings Co., Ltd.

Professor Emeritus of Jichi Medical University

Regent of Tokyo Medical University (Part-time)

Dr. Mariko Y Momoi Outside Director 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.

#### **Results and Progress in 2020**

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 (Dr. Osamu Okuda, Dr. Mariko Y Momoi, and Kenichi Masuda were newly appointed). Dr. 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.

Regarding the appointment of representative directors, by resolution of the Board of Directors following the General Meeting of Shareholders held on March 30, 2020, former President Tatsuro Kosaka became Representative Director, Chairman & Chief Executive Officer (CEO), while former Executive Vice President Dr. Osamu Okuda was appointed Representative Director, President & Chief Operating Officer (COO). Additionally, by resolution of the Board of Directors meeting held on February 4, 2021, Dr. Osamu Okuda was appointed CEO effective March 23, 2021. Tatsuro Kosaka as Representative Director and Chairman retains the position of Chairman of the Board of Directors.

These changes were agreed upon by the Appointment Committee, which is chaired by an outside director, on the basis of ongoing discussions and consultations on the succession plan. This is based on the belief that it is important to realize a smooth generational change in the management team for sustainable development and growth, and to further increase corporate value. Going forward, the Appointment Committee

intends to continue with the formulation and discussion of successor development plans.

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.

## Message from the Chairman of the Appointment Committee

The succession planning process for developing and selecting the next CEO functioned well this time, but now we need to develop the next generation of leaders.



Masayuki Oku Independent Outside Director Chairman of Appointment Committee

Chugai's Appointment Committee deliberates and reports to the Board of Directors on the selection of director candidates and succession plans for or dismissal of executive directors, including the CEO, as well as the status of talent within the pool of Chugai employees. Input from external consultants may also be considered, particularly for the selection of top executives. The committee also discusses reports on the main operating systems in business execution, including its executive officers. As well as these committee-based activities, members of the Appointment Committee work to get to know potential candidates for leadership and executive roles from multiple perspectives, in terms of what they say or how they conduct themselves, as well as through exchanges of opinions and discussions at social gatherings and various meetings, including those of the Board of Directors, Annual General Manager / Manager Meeting, and Executive Study Groups.

To select and develop successors for management roles, we focus on two perspectives in particular.

The first perspective is the continued evolution of our distinctive business model concerning our unique strategic alliance with Roche. Companies often talk about win-win relationships, but they are not easy to build. Chugai's management team must understand the essence and the practicalities of Roche's thoughts and ideas, and we think it is important that successors for executive roles have experience in this regard, for example, through collaborating with or working in management roles at Roche. The same is true for the next generation of directors and senior management. During my career in business management, I was able to gain experience in developing strategic alliances with external companies. This experience showed me that successful partnerships are based on mutual and in-depth understanding at all levels.

The other perspective is diversity. As Chugai accelerates programs to promote diversity in terms of gender or nationality, the Company's thinking on the composition of directors will change according to the needs of the industry or business characteristics. It is important to develop and steadfastly execute succession plans through deliberations over the future management of the Company and the type of management team required.

In March 2021, Dr. Osamu Okuda stepped into the role of CEO after he was appointed as Representative Director and President the previous year. We believe we achieved a seamless transfer of leadership and were able to provide exactly the right development program for the succession. Our planned (strategic) succession management process succeeded because it allowed Dr. Okuda the opportunity to experience various aspects of management, including involvement in strategy formulation, business management, and negotiating with Roche.

As a listed company, we need healthy succession in our top executive team to enable the Company to continuously innovate and reward our shareholders. However, we do not necessarily know exactly when a change of leadership will happen. I liken company management to a never-ending relay race. During a relay, each stage presents different challenges in terms of distance or terrain, and we need to choose the best person for that particular stage, someone who can carry the baton forward and then pass it on. Company management is the same. The business environment, growth phase, or challenges facing the Company at the time will be decisive factors when making decisions on who should fill leadership positions and how long they should serve.

Looking ahead, therefore, we now need to focus on the post-Okuda era, developing leaders for the future. It is often said that you need to start thinking about the next successor as soon as an executive takes over the top role. As president. Dr. Okuda was responsible for defining the top innovator vision and the 10-year value creation strategy. We need to identify the best candidates for future executive roles and develop them through exposure to various opportunities. In an increasingly uncertain future, the Appointment Committee will play an even more important role with a greater focus on objectivity, transparency, and risk perspectives. We will create more diverse and multifaceted opportunities for members of the committee to come into contact with potential leadership candidates in natural and unforced settings and be even more proactive in our contributions to the development of management successors.

# **Principal Matters Deliberated by the Board of Directors**

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

# Principal Matters Deliberated by the Executive Committee and Corporate Management Committees (2020)

Executive Committee	<ul> <li>Management policy, medium- to long-term strategy, and other key policies</li> <li>Medium- to long-term and annual business plans</li> <li>Key policies relating to company-wide business execution</li> <li>Policy on issues of management strategy</li> <li>Key matters in company-wide control and coordination</li> <li>Key policy matters relating to HR development, appointment, individual personnel matters, and allocation</li> <li>Matters relating to organizational performance evaluation systems</li> <li>Other key matters relating to general corporate management</li> </ul>
Corporate Communications Committee	Formulation of policy on corporate information disclosure (company-wide communications) to internal and external stakeholders     Decision on corporate communications strategy and policy on risks impacting corporate value and reputation
Risk Management Committee	<ul> <li>Deliberation and proposal of risk management policy</li> <li>Maintenance and monitoring of risk management system</li> <li>Submissions and reports on risk management to the Board of Directors and Executive Committee</li> <li>Deliberation and decision on the establishment of risk response subcommittees and the Emergency Headquarters</li> </ul>
Compliance Committee*	<ul> <li>Formulation and evaluation of key measures relating to compliance promotion and monitoring of their progress</li> <li>Assessment of compliance risk and formulation of countermeasures</li> <li>Analysis of cause of compliance infringements or other compliance issues and exploration of measures to prevent recurrence (in cooperation with the Risk Management Committee)</li> <li>Revision of compliance-related regulations</li> </ul>
EHS Committee	Key policies and measures relating to environmental protection and health and safety activities

<sup>\*</sup> Made up of the Corporate Meeting, Healthcare Meeting, and GxP Meeting

# 2 Reinforcement of the PDCA Cycle (Items Revised in 2020)

Chugai has focused on evaluation of the effectiveness of the Board of Directors and improvement activities based on evaluation results since 2015

#### **Results and Progress in 2020**

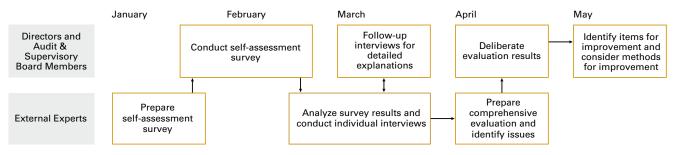
Effectiveness evaluation is carried out every year in February and March in the form of a self-assessment survey for those currently serving directors and Audit & Supervisory Board members who were in office during the applicable period. The results are discussed following a report from the Secretariat of the Board of Directors. Up to 2018, the Secretariat prepared the survey, collated the responses, and presented a report to the Board of Directors after having the results aggregated, evaluated, and analyzed by external experts. Starting with the 2019 effectiveness evaluation, to further enhance outside perspectives and objectivity, we changed to a method under which the secretariat functions are taken over by external experts, who formulate the survey items and analyze the grounds for self-assessment, the rationality of the logic leading to the self-assessment results, and other matters. They then make a comprehensive evaluation after conducting individual interviews if necessary, and report issues and propose effective countermeasures to the Board of Directors

In response to the analysis results received for 2019, we are considering implementation going forward of the improvement initiatives indicated below.

Regarding the Board of Directors' supervision of transactions with the Company's parent company, since it is important to deepen outside officers' understanding, including of basic transaction agreements with the parent company, the Company will take measures to provide further information through liaison meetings for outside officers, and other such opportunities.

With regard to the supervision of Group companies and enhancement of Group internal control by the Company, to enhance the corporate governance system of both domestic

#### Process for Evaluating the Effectiveness of the Board of Directors



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

Applicable year	Main items for improvement	Main new initiatives implemented after analysis and evaluation
2015	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
2016	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)
2017	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
2018	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
2019	Oversight of transactions with the parent company     Enhanced Group company oversight and Group internal control	Conducted briefings through liaison meetings for outside officers to enhance understanding of the content of the basic agreement with the parent company     Presented regular and timely reports on the internal control status of overseas subsidiaries at Board of Directors meetings

and overseas subsidiaries and the internal control system as a group, the Board of Directors will supervise the Group based on continuous and timely reports received through the enhanced monitoring system established in 2019 by amending the system for management of overseas subsidiaries, in addition to regular reports on the internal control system and risk management. The Board of Directors will continue its discussions based on the results of the evaluation described above and endeavor thereby to further improve its effectiveness.

# 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 also considers it important to reflect outside perspectives through dialogue with shareholders, investors, and other stakeholders. Accordingly, the Company will focus on active dialogue as well as analysis and reporting to the Board of Directors of insights and other results emerging from the dialogue.

#### 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. The CIC is composed of 10 members including women, nine of whom are non-Japanese nationals.

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

Secretarial Office staff provide support for outside directors. Managers including the head of the Corporate Planning

#### Expertise and Experience of Directors and Audit & Supervisory Board Members (As of April 1, 2021)

				Expertise	e and experier	nce expected	of directors ar	d Audit & Sup	ervisory Board	members
	Positions, Responsibilities	Name	Roles	Corporate management	R&D	Sales, Marketing	Finance, Accounting, Taxation	Legal, Risk management	Medical science, Pharmaceutical sciences	International experience
Executive Directors	Representative Director, Chairman In charge of External Affairs Dept.	Tatsuro Kosaka	Chairman of the Board of Directors Appointment Committee	•	•	•				•
	Representative Director, Deputy Chairman In charge of Sustainability Dept., Audit Dept.	Motoo Ueno		•	•			•		•
	Representative Director, President & CEO	Dr. Osamu Okuda	Appointment Committee	•	•	•			•	•
	Outside Director*	Masayuki Oku	Chairman of Appointment Committee, Compensation Committee	•		•	•	•		•
	Outside Director*	Yoichiro Ichimaru	Appointment Committee	•		•		•		
Non- Executive	Outside Director*	Dr. Mariko Y Momoi							•	•
Directors	Director	Dr. Christoph Franz	Compensation Committee	•						•
	Director	William N. Anderson	Appointment Committee, Chairman of Compensation Committee	•		•				•
	Director	Dr. James H. Sabry		•	•				•	•
	Full-Time Audit & Supervisory Board Member	Atsushi Sato						•		
Audit &	Full-Time Audit & Supervisory Board Member	Dr. Yoshiaki Ohashi			•			•	•	•
Supervi- sory Board	Outside Audit & Supervisory Board Member*	Takaaki Nimura					•			•
Members	Outside Audit & Supervisory Board Member*	Dr. Yuko Maeda		•	•					
	Outside Audit & Supervisory Board Member*	Kenichi Masuda						•		•

<sup>\*</sup> Designated as an independent officer pursuant to the regulations of Tokyo Stock Exchange, Inc., to which notification has been made.

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 takes advantage of opportunities to provide advance explanation.

#### **Results and Progress in 2020**

The CIC had scheduled a plenary session in Tokyo in October 2020, but has postponed the event in view of the COVID-19 pandemic.

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.

We held ESG meetings and a range of other meetings, such as individual briefings and events for investors and analysts, with the aim of reflecting outside perspectives through dialogue with stakeholders. Through these initiatives, we disclosed new information and engaged in dialogue on issues including sustainability-related governance systems, the relationship between material issues and increase in corporate value, and our perception of issues during and after the COVID-19 pandemic. We also held the pharmaceutical industry's first briefing dedicated to the subject of digital transformation (DX). Additionally, to gauge the expectations and demands of society and identify issues for Chugai to address, we carried out a gap analysis against ESG global indices. As a result of PDCA activities ongoing since 2018, Chugai was selected for the first time as a component of the DJSI World index, the worldwide version of the Dow Jones Sustainability Indices (DJSI), a respected set of ESG indicators covering global markets.

# 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 TSE.\*

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 TSE—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 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. Accordingly, recognizing that business plans are a commitment to shareholders, we will engage in timely, appropriate, and fair information disclosure activities in accordance with laws and regulations. As one aspect of ensuring transparency, we will also provide easy access to the information we disclose by making it available in Japanese and English.

# 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

To reach a wide range of stakeholders, we send out press releases and hold various types of information meetings for the media. We also use the website and a variety of other tools to disseminate information.

\* The TSE requires delisting if the ratio of tradeable shares to listed shares is less than 5 percent.

#### **Results and Progress in 2020**

In 2020, we worked to maintain opportunities for dialogue with shareholders and investors in the context of the COVID-19 pandemic by making flexible use of in-person, remote, and combined formats depending on the scale and purpose of the event.

#### Performance in 2020

- Number of media and IR information events: 27
- Number of investors and security analysts attending meetings worldwide: 385
- Number of briefings for individual investors and shareholders: 8
- Number of attendees at the General Meeting of Shareholders: 46
- Grand Prize, Nikkei Annual Report Awards 2020
- Best IR Award from Japan Investor Relations Association for the first time
- 2nd Place, 2020 Awards for Excellence in Corporate Disclosure, Pharmaceuticals Category
- 2020 All-Japan Executive Team Rankings, Institutional Investor magazine: Best IR Team: Rank 1 (buy side) Best CFO: Rank 3 (sell/buy side combined; buy side)

## Message from the Roche Group CEO

A passion for transforming the lives of patients through breakthrough science and innovation is the foundation of our personalized healthcare solutions. This approach creates value for all stakeholders.



Dr. Severin Schwan Roche Group CEO

Everything we do at Roche is driven by our passion to find solutions to unmet medical needs and to make a significant impact on the life of people facing serious diseases. With Chugai, we share a common purpose and values. They are the bedrock of our strategic alliance. The result is a unique business model that leverages the strengths of both companies to bolster the creation and delivery of medically differentiated products. Chugai brings Roche's novel medicines to patients in Japan, whilst Roche's global organization brings Chugai's breakthrough medicines such

as Actemra, Alecensa, and Hemlibra to patients across the world. It is exciting that Enspryng, a new groundbreaking medicine to treat a rare autoimmune disease (NMOSD), is poised to be the next global medicine designed by Chugai, and has already been approved in the United States and other countries.

Staying innovative means exploring the unknown and having the courage to scout for new challenges and ideas. These are distinct qualities I experience when I meet colleagues at Chugai. For instance, I am excited to see how Chugai is expanding its drug discovery modalities with next-generation antibodies and a mid-size molecule platform. Together with world-leading science, top-notch IT, and digital science are key capabilities for the current era of DX. They promise to reshape the entire value chain for discovering, creating and delivering healthcare solutions, and they will enable even more benefits to society. Of course, success will require tremendous changes. However, I am convinced that Chugai is on the right path with CHUGAI DIGITAL VISION 2030

and the initiatives for new partnerships, business models, and ways of working.

Chugai is also passionate about enhancing long-term stakeholder value by thoroughly integrating ESG aspects into corporate strategy. That is why in 2020 Chugai was selected for the first time as one of only eight companies in the pharmaceutical sector of DJSI World. Roche and Chugai, ranking first and third, respectively, are true leaders in corporate sustainability. Through our win-win partnership, Chuqai and Roche will continue to maximize value for all stakeholders-and hence also our shareholders.

The new management team with Tatsuro Kosaka as Chairman and Dr. Osamu Okuda as President & CEO has positioned the company well to execute its new growth strategy over the next 10 years to become a top innovator in global healthcare by 2030. Together we will continue to create and deliver breakthrough innovations that bring new hope to patients worldwide.

# 5 Officer Remuneration Emphasizing Linkage with Performance and Stock Price

Chugai has designed its remuneration plan for directors and Audit & Supervisory Board members to attract outstanding people to put our corporate philosophy into practice 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.

Bonuses, which are a short-term incentive, are determined by multiplying the standard amount set for each position by an evaluation coefficient reflecting an overall evaluation of the degree of achievement of Company and individual performance targets based on the published forecasts for the relevant fiscal year. The indicators used for the evaluation of

Company performance are Core operating profit, revenues, R&D performance, and the status of achievement of company-wide tasks for the relevant fiscal year, while those used for individual performance evaluation are the status of achievement of measures to meet performance targets and ESG-related objectives, etc., in the operational areas for which the individual is responsible. 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 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.



Notice of Convocation of the 110th Annual General Meeting of Shareholders (page 21)

https://www.chugai-pharm.co.jp/english/ir/share/agm/files/ 210317eChugai\_110thAGM\_Convo.pdf#page=22

# System for Remuneration of Directors and Audit & Supervisory Board Members

Type of remuneration			Executive Non-executive directors Supervisory directors (including outside directors) Board members			Payment criteria	Payment method
Fixed Regular Compensation	Fixed Regular Regular compensation		•	•	•	Paid according to position and other factors	Monthly (Cash)
	Bonuses		•	_	_	Paid according to performance in each fiscal year	Yearly (Cash)
Performance- Based	Long-term incentive (Stock-based compensation)	Tenure-based restricted stock	•	_	_	Paid according to fixed length of service	Yearly (Common stock)
Remuneration		Performance-based restricted stock	•	_	_	Paid according to performance over fixed period in addition to above	Yearly (Common stock)

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

Type of Remuneration		Indicators and evaluation methods				
Bonuses		<ul> <li>Comprehensive evaluation is based on degree of achievement of factors including Core operating profit, revenues, R&amp;D performance, and company-wide tasks in the relevant fiscal year.</li> <li>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.</li> </ul>				
	Tenure-based	Continuous service during the transfer restriction period				
Restricted Stock Compensation	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 2020: Amount of Remuneration Paid to Directors and Audit & Supervisory Board Members

	T . I	Total amour					
Position	Total remuneration, etc. (Millions of yen)	Regular compensation	Bonuses	Restricted stock compensation Performance- Tenure-based based		Number of eligible officers	
Directors (Excluding Outside Directors)	458	199	121	55	84	4	
Outside Directors	41	41	_	_	_	4	
Total	499	361		138		8	
Audit & Supervisory Board Members (Excluding Outside Audit & Supervisory Board Members)	63	63	_	_	_	2	
Outside Audit & Supervisory Board Members	36	36	_	_	_	4	
Total	99	9	99	-	_	6	

Notes: 1. Amounts are rounded to the nearest million yen.

- 2. The table above includes two directors and one Audit & Supervisory Board member who retired during 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.

#### Results in 2020: Amount of Remuneration Paid to Representative Directors

	Total co	Consolidated			
Name	Regular	Bonuses	Restricted stock	remuneration total	
	compensation	Donuses	Tenure-based	Performance-based	(Millions of yen)
Tatsuro Kosaka	71	72	26	41	210
Motoo Ueno	58	21	15	25	119
Dr. Osamu Okuda	40	27	8	9	84

Notes: 1. Amounts are rounded to the nearest million yen.

- 2. Figures show the total amount of remuneration, etc., for representative directors.
- 3. Other than the representative directors in the table above, no director or Audit & Supervisory Board member received total remuneration of more than ¥100 million.

#### 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 March 2020, in response to the issue by the Ministry of Health, Labour and Welfare (MHLW) of the notification "Key points to note for pharmaceutical manufacturers and distributors when providing information on prescription pharmaceuticals in response to patient inquiries," we established guidelines for information provision activities to the public, including patients and their families, based on the Chugai core value of a patient-centric approach.

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, in the Compliance Committee, a corporate management committee, thereby creating a compliance system linked more directly to management. At the same time, we established functions in the Sustainability Department, Quality & Regulatory Compliance Unit, to monitor, lead, and support compliance within 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 Chuqai 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/

#### IT Security and Information Control Initiatives to Accelerate DX

Chugai, which uses a variety of IT systems, regards risks relating to IT and information as major risks. These include system malfunctions and the leakage of critical confidential information relating to personal data and IP rights. Chugai has established and disseminated related rules, conducts employee education, and takes safeguarding measures and other precautionary actions. Our policy of reinforcing these measures going forward is stated in the "Major Risks and Countermeasures" section (page 54).

Meanwhile, the acceleration of digital transformation (DX) that comes with the advance of the digital society and the implementation of CHUGAI DIGITAL VISION 2030 will further expand the range of risks to be dealt with through IT security and information control. This means that improvement of security management capabilities across all departments is an urgent task. In response, in January 2021 we formulated CHUGAI CYBER SECURITY VISION 2030, a mid- to long-term vision for cybersecurity built around our concept of developing as an advanced cybersecurity company to support our ambition to become a top innovator in the healthcare industry. The vision formulates strategic measures from the three perspectives of organizational operation, human resources and corporate culture, and technology, with milestones marking the way to 2030.

As part of the new cybersecurity system, we have established the Information Security Committee to plan, implement, and monitor countermeasures, while separate security countermeasures consist of PDCA cycle implementation by the Digital & IT Supervisory Division, General Affairs Department, Legal Department, and the other individual corporate organizations.

#### Risk Management

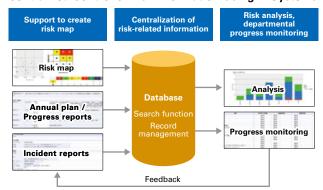
#### Advanced Risk Management through ERM

Enterprise risk management (ERM) is an approach to managing risk aimed at maximizing corporate value by visualizing all risk relating to business activities and managing it in an integrated framework. The Chugai Group has an established practice of ERM that identifies and evaluates risk by division and monitors the status of implementation of countermeasures. However, to realize more advanced risk management, we have introduced and operated a new ERM framework from 2021 that integrates strategy-related risk management. Specifically, we have formulated the Risk Appetite Statement to clarify policy on risk preferences with the aim of creating a healthy risk culture. We divide risks to be addressed on a company-wide basis into strategic risk (risk inherent in strategic decision-making and risk that hinders strategy execution) and operational risk (risk that hinders smooth business operations). On this basis, we will create a company-wide risk map that systematizes these risks by identifying, classifying, and visualizing them in a centralized fashion for company-wide sharing and discussion. This will not only promote effective and efficient risk management but also strengthen accountability to external stakeholders.

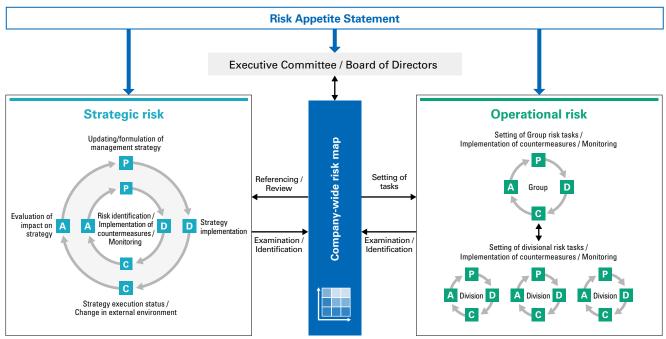
### **Using IT Systems to Boost Risk Management Efficiency**

To promote more efficient identification, analysis, and feedback of company-wide risk information, Chugai developed an original risk management system and implemented it globally. Using the database for centralized management, divisions can record their risk maps, annual risk response plans, and incident reports. This enables us to analyze risks for the Group as a whole, and monitor countermeasures at each division.

#### **Centralized Control of Risk Information Using IT Systems**



# **Operational Outline of ERM**



#### **Risk Appetite Statement**

Chugai's Mission Statement is the basis of the business activities we pursue to create shared value with society and increase corporate value. In these business activities, the Chugai Group regards risk as any phenomenon that hinders the achievement of management goals and the execution of strategy.

To support appropriate strategic decision-making and smooth business operations, we have formulated the Risk Appetite Statement that sets out our policy in response to risk. It is intended not only to promote a healthy risk culture but also to serve as a comprehensive basis for the judgments and actions of individual employees.

#### Chugai's Risk Appetite Statement (Summary)

#### Risk associated with pursuit of innovation

- Pursuit of innovation is the value in our existence and the source of our growth.
- To become a top innovator in the healthcare industry by pursuing cutting-edge science and technology and digital innovation, at the same time as putting in place the appropriate safeguards, we will accept risk in a bold spirit of challenge to pursue opportunities to generate innovation.

#### Risk of compliance infringement

 Based on the belief that "corporate ethics take priority over profit," we will not only respect laws and regulations but also ensure that our judgments and actions are firmly grounded in social values, ethics, and fair dealing, and will <u>tolerate no</u> <u>risk of infringing on compliance.</u>

# Risk that hinders product safety and efficacy, quality assurance, and stable supply

- Product efficacy and safety as well as quality assurance are our foremost priorities.
- Mindful that our products and the pursuit of innovation carry the inherent risk of causing unexpected side effects, and taking due account of economic viability, we will work to avoid and reduce risk that hinders product safety and efficacy, quality assurance, and stable supply.

#### Risk to social responsibility as a corporate citizen

• In answer to the question of how Chugai as a company can help address the issues facing local communities and global society, we will cooperate and collaborate with a wide range of stakeholders to promote environmental protection and respect for human rights in all aspects of our business activities, working in this way to reduce the risk of loss of public trust.

# Directors / Audit & Supervisory Board Members (As of April 1, 2021)

#### **Representative Directors**



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

#### Executive Director

(Shares of the Company owned: 129,700 shares)

1976 Joined the Company

1995 Deputy President of Chugai Pharma Europe Ltd. (U.K.)

2000 Head of Business Strategy Planning Office

2002 Vice President, Head of Corporate Planning Dept.

2004 Senior Vice President, Head 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. 2018 Representative Director, President & CEO 2020 Representative Director, Chairman & CEO

2021 Representative Director, Chairman (to present)



Motoo Ueno

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

(Shares of the Company owned: 2,409,100 shares)

1984 Joined the Company

1991 General Manager of London Representative Office

1993 Director

1994 Director, Head of Medical Information Div.

1995 Director, Head of Clinical Research & Development Div.

1996 Director, Deputy Head of Research & Development Div.

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 & CEO

#### Executive Director

(Shares of the Company owned: 44,387 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 Head of Oncology Unit, Marketing & Sales Div. of the Company

2014 Executive Officer, Head of Oncology Unit, Marketing & Sales Div. of the Company

2015 Executive Officer, Head of Corporate Planning Dept. of the Company

2017 Executive Vice President, Head of Corporate Planning Dept.

of the Company

2018 Executive Vice President, Co-Head of Project & Lifecycle Management Unit

2020 Representative Director, President & COO 2021 Representative Director, President & CEO (to present)

#### **Non-Executive Directors**













**Audit & Supervisory Board Members** 











#### **Non-Executive Directors**

1 Masavuki Oku Outside Independe

(Shares of the Company owned: 1,000 shares) Outside Director of Rengo Co., Ltd. Outside Director of The Royal Hotel, Ltd. Non-Executive Director of The Bank of East Asia 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 1999 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)

Non-Executive Director of The Bank of East Asia (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 Outside Independent

Outside Director of Seino Holdings Co., Ltd.

1971 Joined Toyota Motor Sales Co., Ltd. 2001 Member of the Board of Directors of Toyota Motor Corporation ("TMC")

1 Oyota Motor Corporation (1 Mic )
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.
2019 Outside Director of Seino Holdings Co., Ltd. (to present)

2014 Director of Japanese Medical Specialty Board (part-time)

3 Dr. Mariko Y Momoi Outside Independent

Professor Emeritus of Jichi Medical University Visiting Professor of School of Medicine, Shinshu University Regent of Tokyo Medical University (part-time)

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

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 Atsushi Sato (Full-time)

1981 Joined the Company

1981 Joined the Company
 2009 Head of Risk Management & Compliance Dept.
 2011 Head of Corporate Social Responsibility Dept.
 2015 Head of Corporate Social Responsibility Dept.
 and General Affairs Dept.
 Head of Corporate Social Responsibility Dept.

2016 Associate Vice President, Head of Corporate Social Responsibility Dept.

2019 Associate Vice President

Audit & Supervisory Board Member (to present)

8 Dr. Yoshiaki Ohashi (Full-time)

(Shares of the Company owned: 22,940 shares)

(Shares of the Company owned: 2.942 shares)

1988 Joined the Company 2004 Department Manager, Quality & Regulatory Compliance Dept. 2009 Department Manager, Drug Safety Coordination Dept. 2013 Head of Drug Safety Div. and Department Manager of Drug Safety Coordination Dept.

2015 Vice President, Head of Drug Safety Div.
Vice President, Head of Quality & Regulatory Compliance Unit, and Head of Drug Safety Div.
2018 Senior Vice President, Head of Quality & Regulatory Compliance Unit and Head of Drug Safety Div.
2021 Senior Vice President
Audit & Supervisory Board Member (to present)

9 Takaaki Nimura Outside Independent

Representative of Nimura Certified Public Accountant Office

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 Shiruwa & 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 Outside Independent

Director, CellBank Corp. External Director, Kosé Corporation Auditor (part-time), Japan Agency for Marine-Earth Science and Technology
Executive Vice President (part-time), Kyushu University

1984 Joined Bridgestone Corporation

1998 CFO of BTR Power Systems Japan 2001 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 Visiting Professor of Tokyo Medical and Dental University 2011 Specially Appointed Professor of Kyoto Prefectural University of Medicine

2013 Executive Officer of Bridgestone Corporation

2014 Auditor (part-time) 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)

(to present)

2020 External Director, KOSÉ Corporation (to present)
Executive Vice President, Kyushu University (part-time)
(to present)

11 Kenichi Masuda Outside Independent

Partner of Anderson Möri & Tomotsune Outside Director of Bridgestone Corporation
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

1988 Registered as an attorney-at-law (Daini Tokyo Bar Association)
Joined Anderson Möri & Tomotsune
1993 Registered as an attorney-at-law in the state of New York
1997 Partner of Anderson Möri & 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) 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

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

Note: Outside Audit & Supervisory Board members do not own Company shares.

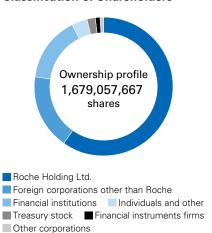
# Shareholder Information (As of December 31, 2020)

#### **Major Shareholders**

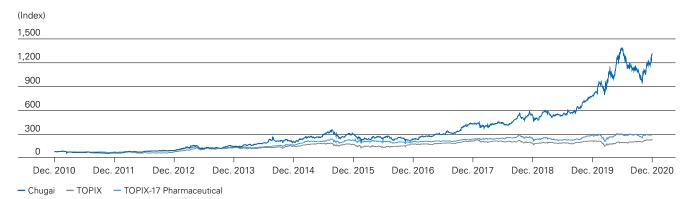
Name	Number of Shares Held (Thousands)	Percentage of Voting Rights (%)
Roche Holding Ltd.	1,005,670	61.18
The Master Trust Bank of Japan, Ltd. (Trust Account)	105,907	6.44
JP MORGAN CHASE BANK 385632	60,658	3.69
Custody Bank of Japan, Ltd. (Trust Account)	48,548	2.95
Custody Bank of Japan, Ltd. (Trust Account 7)	18,546	1.12
SSBTC CLIENT OMNIBUS ACCOUNT	14,518	0.88
STATE STREET BANK WEST CLIENT - TREATY 505234	14,460	0.87
STATE STREET BANK AND TRUST COMPANY 505001	12,283	0.74
Custody Bank of Japan, Ltd. (Trust Account 5)	9,930	0.60
Custody Bank of Japan, Ltd. (Security Investment Trust Account)	9,849	0.59

Note: The Company holds 35,186,586 shares of treasury stock, but is excluded from the 10 major shareholders listed in the table above.

#### Classification of Shareholders



#### 10-Year Total Shareholder Return (TSR)



	Last 1 year	Last 3 years		Last 5 years		Last 10 years	
	TSR	TSR	Annualized TSR	TSR Annualized TSR		TSR	Annualized TSR
Chugai	65.3%	197.5%	46.0%	316.1%	38.5%	1,219.4%	33.2%
TOPIX	7.4%	6.6%	3.2%	30.7%	6.4%	149.9%	11.3%
TOPIX-17 Pharmaceutical	4.4%	21.6%	7.4%	26.9%	5.6%	212.4%	13.2%

Note: In the above graphs and tables, the Chugai closing price and benchmark indexes as of December 30, 2010, are fixed at 100 and the figures for ROI assume re-investment of the dividends. The benchmark indexes used are the Tokyo Stock Price Index (TOPIX) and TOPIX-17 Pharmaceutical.

#### **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 (Times) 10.00 9.23 8.00 6.46 6.00 4.62 4.56 4.00 2.00 0.00 2016 2017 2018 2019 2020

#### **Dividend Yield** Dividends per share / Year-end share price

(%) 2.50 2.00 1.50 1.39 1.35 1.00 1.00 0.50 0.00 2016 2017 2018 2019 2020

#### Corporate Overview (As of December 31, 2020)

#### Company Name

Chugai Pharmaceutical Co., Ltd.

Year of Foundation

1925

Year of Establishment

1943

#### **Head Office**

2-1-1 Nihonbashi-Muromachi, Chuo-ku, Tokyo 103-8324, Japan Tel: +81-(0)3-3281-6611 (main switchboard)

Stated Capital ¥73,202 million

Number of Employees 7,555 (Consolidated)

Number of Shares Issued of Common Stock 1,679,057,667

Number of Shareholders 34,921

#### 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

#### 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.



Sustainability website

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

# Chugai Pharmaceutical website and social media



Corporate website

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



Twitter

https://twitter.com/chugai\_cc ID @chugai\_cc



YouTube

https://www.youtube.com/chugaijp

#### **External Evaluation of Chugai's ESG Initiatives**

Selected for the first time in the DJSI World, a global ESG investment index

Member o

#### Dow Jones Sustainability Indices

Powered by the S&P Global CSA

Award of AA rating, which covers the top 9% of pharmaceutical companies worldwide



Selected as a constituent in the FTSE4Good Index Series for the 18th consecutive year



Listed for All Four ESG Indices used by the Government Pension Investment Fund of Japan



FTSE Blossom Japan



2020 CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN)

2020 CONSTITUENT MSCI JAPAN ESG SELECT LEADERS INDEX









In 2020, Chugai Pharmaceutical Co., Ltd. received a rating of AA (on a scale of AAA-CCC) in the MSCI ESG Ratings assessment. The inclusion of Chugai Pharmaceutical Co., Ltd. in any MSCI index, and the use of MSCI logos, trademarks, service marks or index names herein, do not constitute a sponsorship, endorsement or promotion of Chugai Pharmaceutical Co., Ltd. by MSCI or any of its affiliates. The MSCI indices are the exclusive property of MSCI. MSCI and the MSCI index names and logos are trademarks or service marks of MSCI or its affiliates.

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.

#### **Inquiries on This Annual Report:**

Investor Relations Group, Corporate Communications Dept.

Tel: +81-(0)3-3273-0554 Fax: +81-(0)3-3281-6607 E-mail: ir@chugai-pharm.co.jp

Innovation all for the patients

