

Our History and Shared Value

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

Turning Point 1

Shift to Prescription Pharmaceuticals

1960s

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

Main Shared Value

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



Turning Point 2

Focus on Biopharmaceuticals

1980s

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

Main Shared Value

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



Turning Point 3

Strategic Alliance with Roche

Since 2000s

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

Main Shared Value

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



Turning Point 4

Promoting the Adoption and Advancement of PHC

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

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

Examples of Initiatives to Promote Adoption of PHC

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

Examples of Initiatives to Promote Advances in PHC

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

Turning Point 4

Promotion of PHC

Since 2000s

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

Main Shared Value

Patients: Administration of drugs only when they are expected to be effective; improved quality of life; reduced burden

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



Turning Point 5

Launch of Therapeutic Antibody and Continuous Creation of Innovative Drugs

Since 2000s

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

Main Shared Value

Patients: Superior efficacy and safety; groundbreaking outcomes

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



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

Turning Point 6

Commitment to Realizing Advanced and Sustainable Patient-Centric Healthcare

Since 2019

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

Shared Value from Realizing Advanced and Sustainable Patient-Centric Healthcare

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

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



Turning Point 5

Breakthrough Therapy Designations

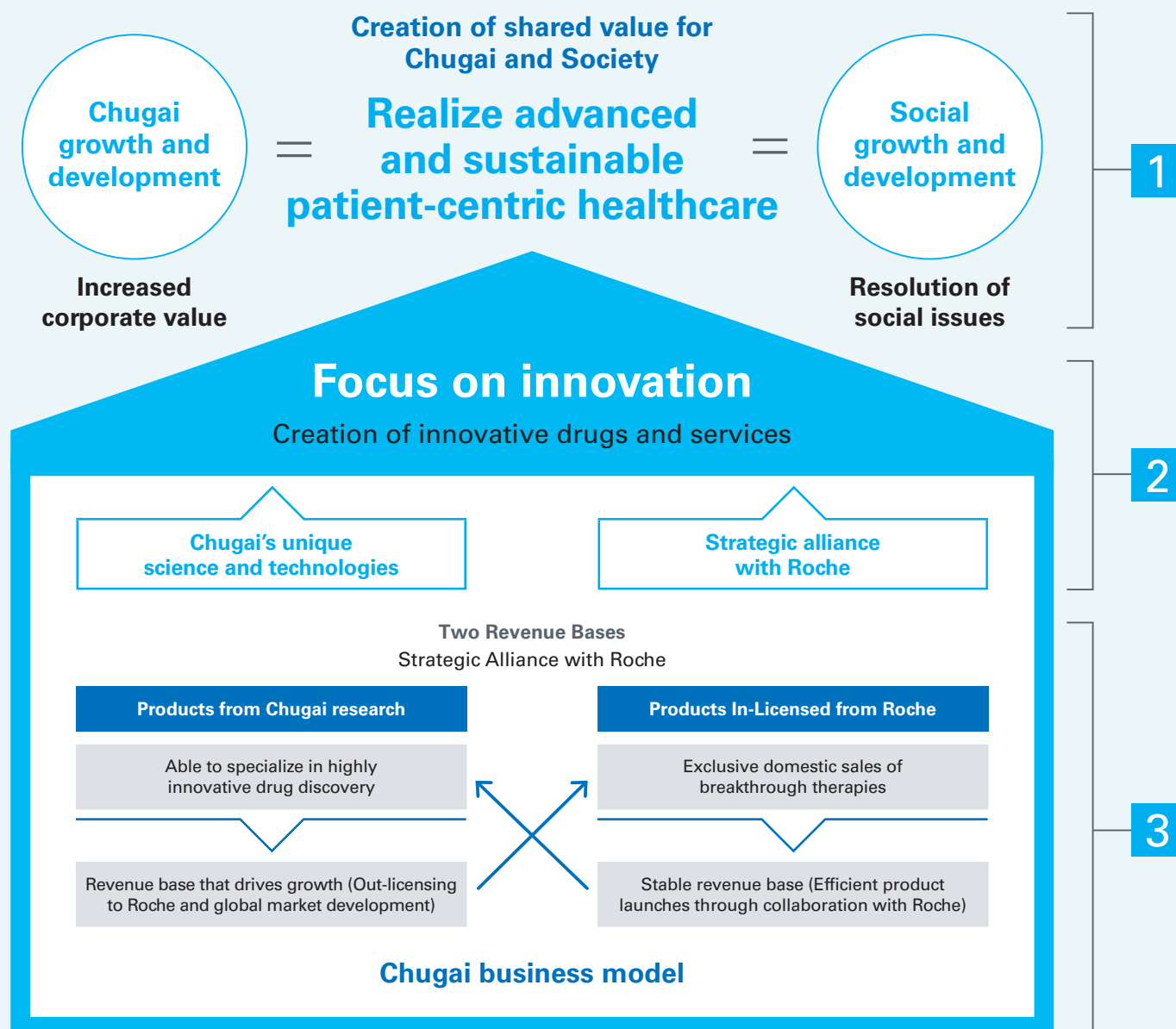
The breakthrough therapy designation of the U.S. FDA is aimed at expediting the development and review of drugs for the treatment of severe or life-threatening diseases or symptoms. A drug must be highly innovative to receive the designation, but receiving it is valuable for various reasons. For example,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

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

Chugai Products That Received Breakthrough Therapy Designation

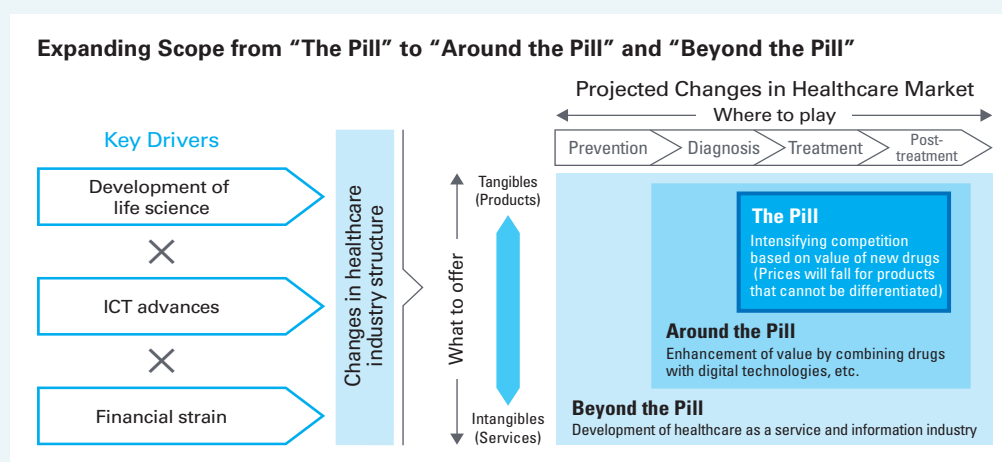
Jun. 2013	Alecensa (treatment of people with ALK-positive metastatic NSCLC whose disease has progressed on crizotinib)
Jun. 2015	Actemra (systemic sclerosis)
Sep. 2015	Hemlibra (people 12 years of age or older with hemophilia A with factor VIII inhibitors)
Sep. 2016	Alecensa (first-line treatment of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

Value Creation Model



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

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



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

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



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

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

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

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

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

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▶ See “Analysis of Value Provided” on page 14.

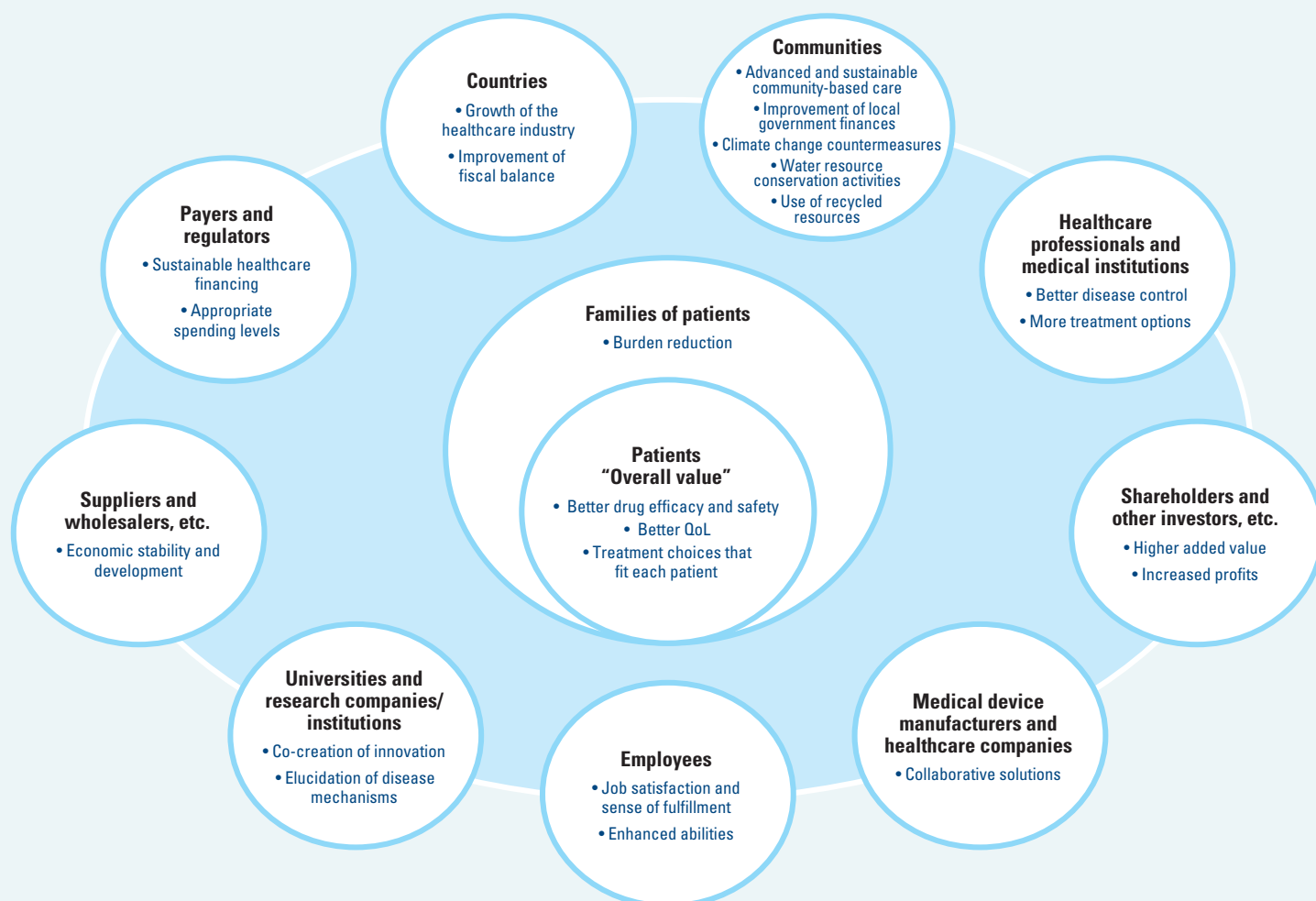
2

▶ See “Examination of Innovation” on page 16.

3

▶ See “Analysis of Business Model” on page 18.

1 Analysis of Value Provided



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

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

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

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

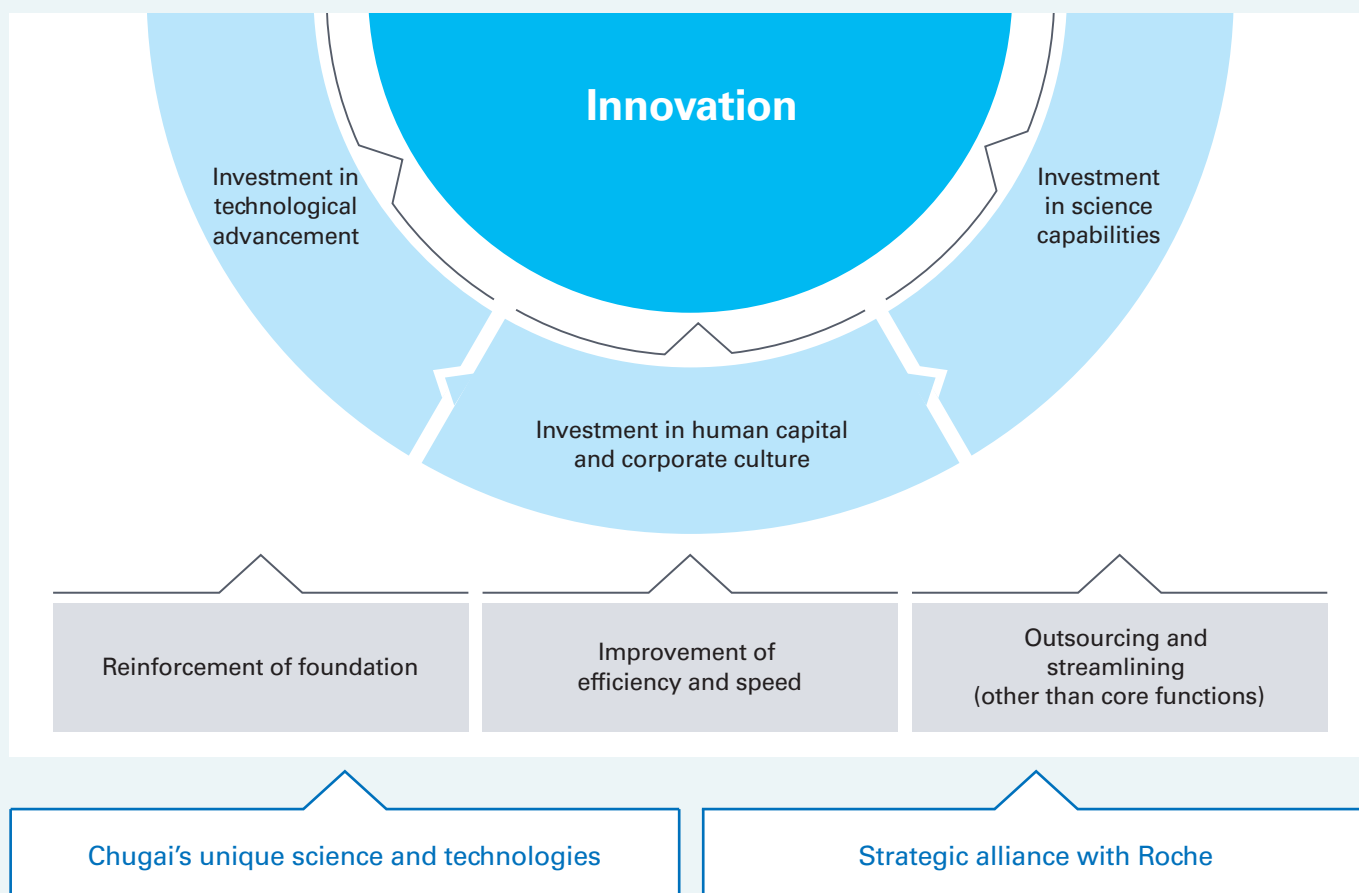
Statistics for Key Global Chugai Products (including cooperation with Roche)

<p>Actemra</p> <p>Total of more than 1,000,000 patients treated</p> <p>Approved in over 110 countries</p>	<p>Alcensa</p> <p>Approved in over 85 countries</p>	<p>Hemlibra</p> <p>Total of more than 6,000 patients treated</p> <p>Approved in over 90 countries</p>
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Value Shared with Stakeholders and Key Value Indicators

Stakeholder	Shared Value	Value Indicators	
		Indicators Used by Chugai	External Indicators
Patients	<ul style="list-style-type: none"> Better drug efficacy and safety Better QoL Treatment choices that fit each patient 	<ul style="list-style-type: none"> Number of new products launched and additional indications Number of safety information reports Number of development projects and products based on PHC 	<ul style="list-style-type: none"> Treatment outcomes in each disease area Treatment adherence rate Medication and post-treatment care costs
Families of patients	<ul style="list-style-type: none"> Burden reduction 	<ul style="list-style-type: none"> Number of development projects and products based on PHC 	<ul style="list-style-type: none"> Total cost of care for patients
Healthcare professionals and medical institutions	<ul style="list-style-type: none"> Better disease control More treatment options 	<ul style="list-style-type: none"> Number of new products launched and additional indications 	<ul style="list-style-type: none"> Treatment outcomes in each disease area Number of standard of care guidelines
Communities	<ul style="list-style-type: none"> Advanced and sustainable community-based care Improvement of local government finances Climate change countermeasures Water resource conservation activities Use of recycled resources 	<ul style="list-style-type: none"> Number of liaison activities Energy consumption Eliminate use of specific fluorocarbons Waste recycling ratio 	<ul style="list-style-type: none"> Treatment adherence rate Drug costs in hospital market Environmental-related assessments
Countries	<ul style="list-style-type: none"> Growth of the healthcare industry Improvement of fiscal balance 	<ul style="list-style-type: none"> Revenues Income taxes paid 	<ul style="list-style-type: none"> Growth rate of healthcare industry Taxable capacity of the industry
Payers and regulators	<ul style="list-style-type: none"> Sustainable healthcare financing Appropriate spending levels 	<ul style="list-style-type: none"> Number of new products launched and additional indications Number of development projects and products based on PHC 	<ul style="list-style-type: none"> Health insurance costs
Universities and research companies/institutions	<ul style="list-style-type: none"> Co-creation of innovation Elucidation of disease mechanisms 	<ul style="list-style-type: none"> Number of joint research projects Number of research agreements/alliances 	<ul style="list-style-type: none"> Number of clinical studies in main disease areas
Suppliers and wholesalers, etc.	<ul style="list-style-type: none"> Economic stability and development 	<ul style="list-style-type: none"> Sales Number of risk evaluations 	<ul style="list-style-type: none"> Growth rate of healthcare industry
Medical device manufacturers and healthcare companies	<ul style="list-style-type: none"> Collaborative solutions 	<ul style="list-style-type: none"> Number of cooperative solution development projects 	<ul style="list-style-type: none"> Growth rate of healthcare industry
Employees	<ul style="list-style-type: none"> Job satisfaction and sense of fulfillment Enhanced abilities 	<ul style="list-style-type: none"> Employee awareness surveys Productivity indicators 	<ul style="list-style-type: none"> Diversity and inclusion-related indices
Shareholders and other investors, etc.	<ul style="list-style-type: none"> Higher added value Increased profits 	<ul style="list-style-type: none"> Core EPS CAGR Payout ratio 	<ul style="list-style-type: none"> ESG rating Market capitalization

2 Examination of Innovation



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

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

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

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

As for investment in science capabilities, main areas of focus will include research in pathology and the visualization of value. In addition to Chugai's own research, our comprehensive collaboration agreement with IFReC and other open innovation with academia will be essential. Resource investment in this area will encompass not only research and development but also analysis of real-world data³ and epidemiological demonstration of product value.

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

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

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

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

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

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

Example 1: Development Background of Switch Antibody™

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

► See “Focus 1: Evolution of Antibody Engineering Technologies” on page 50.

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



Creation of ideas and hypotheses



Verification and discovery through testing



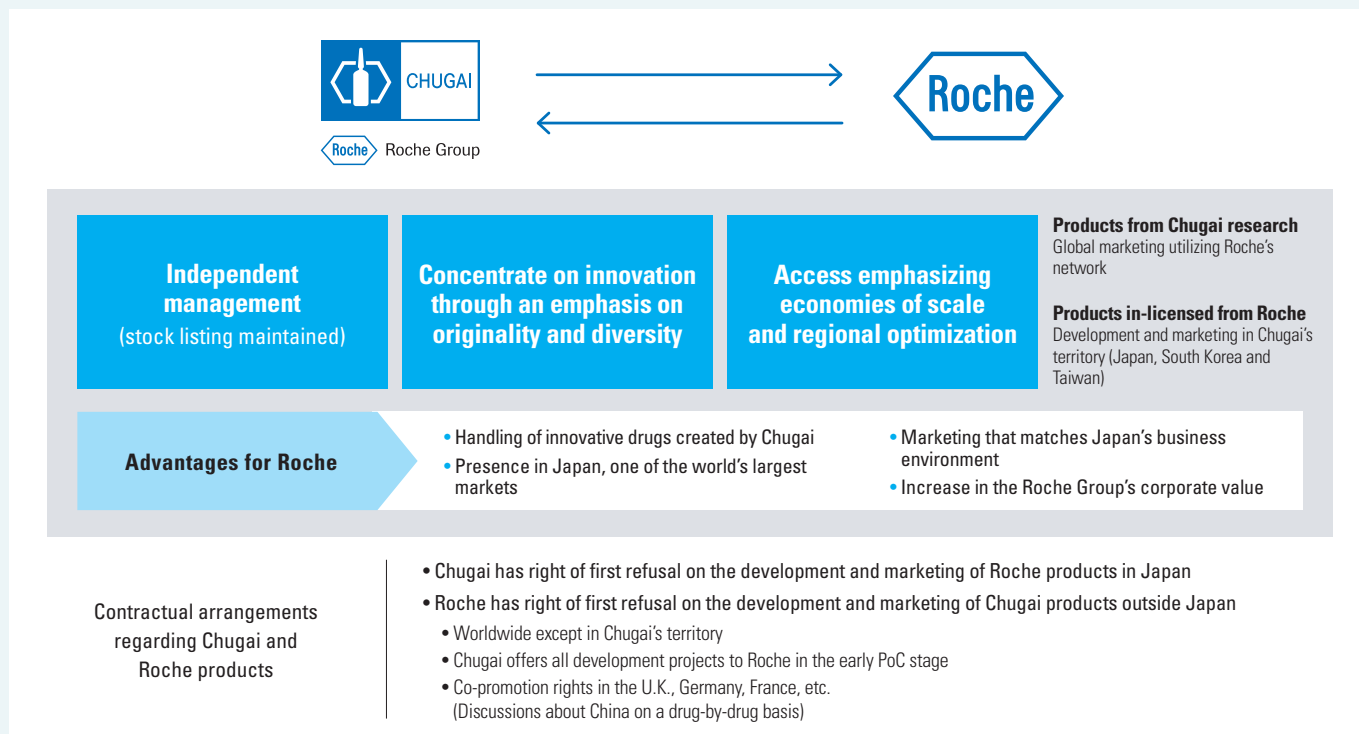
Creation of groundbreaking new drugs based on original discoveries and inventions

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

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

3 Analysis of Business Model

Win-Win Relationship with Roche



Features and Outcomes by Business Model Function

Area/Function	Features of Business Model	Outcomes of Relationship and Cooperation with Roche
Management	<ul style="list-style-type: none"> • Stock listing maintained by guaranteeing independence • Minority interests ensured • Management with a broad, long-term view 	<ul style="list-style-type: none"> • Basic Agreement emphasizes Chugai's management independence and maintenance of stock listing. • Executive directors, independent outside directors, and directors concurrently sitting on Roche's Board of Directors each comprise one-third of Chugai's Board of Directors. • Joint committees with Roche and close consultation between senior managers take place routinely. Chugai and Roche share and confirm each other's mission, values and direction.
Research 	<ul style="list-style-type: none"> • Concentration on innovation through independent decision-making • Efficient research activities • Acceleration of efforts driven by friendly rivalry within the Group 	<ul style="list-style-type: none"> • Activities are based on Chugai's independent decision-making, including selection of research projects and investment of resources. • Chugai can use Roche's research infrastructure, including its large, high-quality compound library. • In the Roche Group, a culture of friendly competition between the research divisions of each company provides mutual motivation.
Clinical Development 	<ul style="list-style-type: none"> • Optimal timing of collaboration with Roche • Efficient and rapid global marketing utilizing the Roche Group's infrastructure • Access to latest market information globally 	<ul style="list-style-type: none"> • While Roche has right of first refusal on the global development of Chugai products, Chugai has exclusive development and marketing rights to Roche products in Japan. • Out-licensing of products from Chugai research is immediately offered to Roche upon achievement of early PoC (changed in 2014). This has enabled faster development by reducing "white space" in the development process. • Participation in global studies conducted by Roche for in-licensed and out-licensed products that extend worldwide. Chugai manages clinical trials in Japan. • Chugai is establishing its own independent global development system in order to quickly achieve early PoC.
Pharmaceutical Technology and Production 	<ul style="list-style-type: none"> • Optimization of global production system • Conformance with the world's most advanced management standards • Information-sharing in the areas of supply chain management and environment, health and safety (EHS) 	<ul style="list-style-type: none"> • In principle, products from Chugai research are manufactured by Chugai and exported to Roche, but for Actemra, technology has been transferred to Roche Group production bases. • Roche, which manufactures and markets products worldwide, shares its knowledge on the latest GxP compliance. • In addition to incorporating Roche's expertise in supplier due diligence and management, Chugai and Roche keep each other informed about EHS management of production bases.
Marketing/ Medical Affairs/ Drug Safety 	<ul style="list-style-type: none"> • Provision of solutions tailored to regional characteristics • Sharing of various information with Roche and establishment of common infrastructure for safety information 	<ul style="list-style-type: none"> • Chugai provides solutions in each territory with a focus on local healthcare systems and regional characteristics. • However, when necessary Chugai and Roche share information and cooperate across regions in marketing strategy, generation of evidence and other matters for each product. • Safety information on each product is collected and analyzed in real time in cooperation with Roche.

Chugai's Business Model

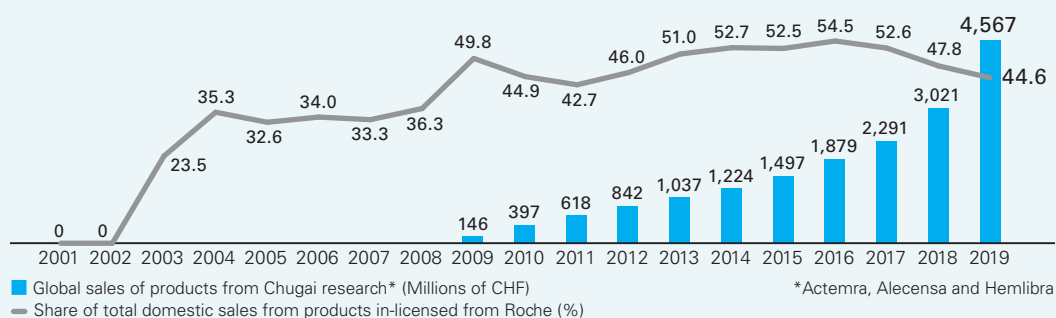
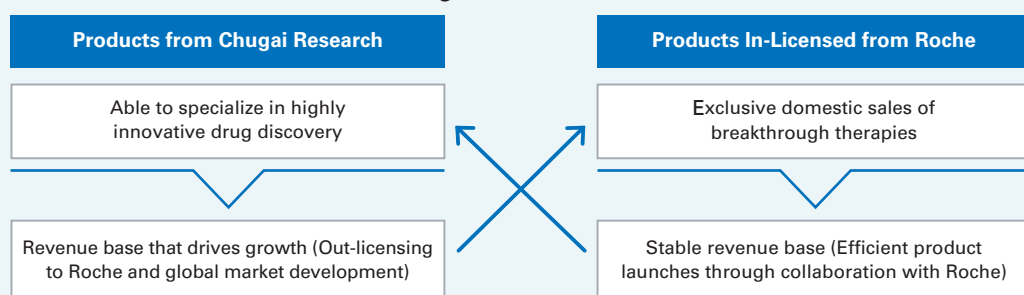
Chugai's business model, in which Chugai is a member of the Roche Group while maintaining autonomy and management independence, allows us to concentrate on innovation through an emphasis on originality and diversity, thereby contributing to the enhancement of Chugai's corporate value as well as the growth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

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

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

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

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







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

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

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

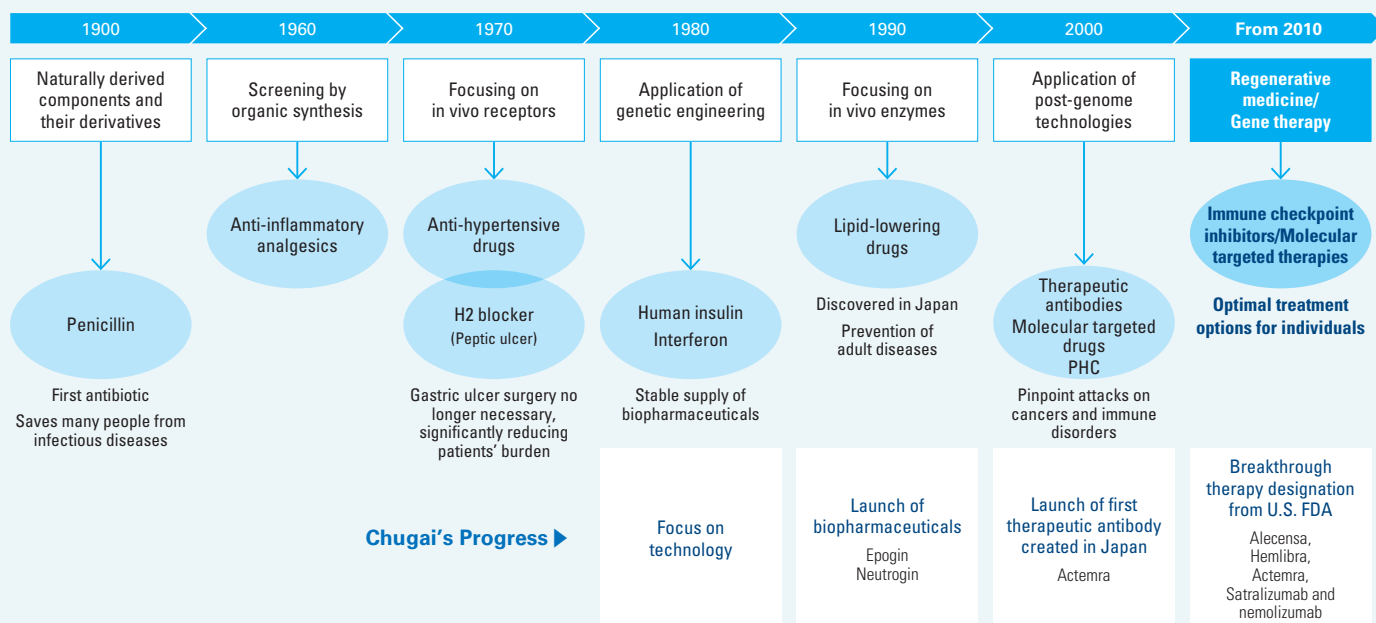
Chugai's Unique Strengths

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

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

For Reference: The Pharmaceutical Industry and Chugai's Business

Evolution of Drug Therapy



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

In recent years, further advances have been made in the treatment of cancer, which will affect almost one of every two people in developed countries at some point in their lives. Immune checkpoint inhibitors, a new cancer immunotherapy, are a prime example. These drugs target the signals produced by cancerous tissues that block the immune system's activity. By inhibiting these "brake" signals, immune checkpoint inhibitors allow the immune system to function normally so they can attack the cancer cells. Another promising new trend in cancer treatment is cancer genomic profiling. Cancer treatments have typically been classified according to the organ where the cancer occurs (lung, stomach, etc.) or the tissue type (adenocarcinoma, squamous cell carcinoma, etc.), but as genetic mutations have become better understood, treatment

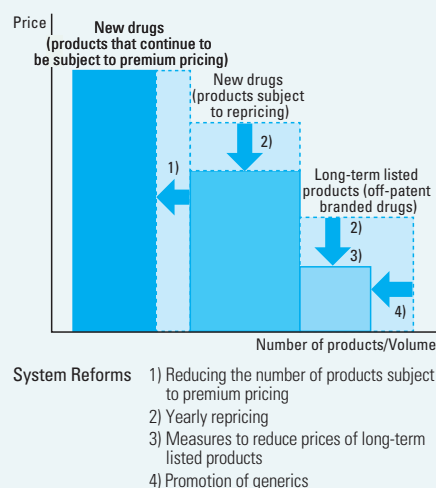
classification has extended beyond conventional classification. Selecting treatments according to the genetic mutation pattern (tumor-agnostic treatment) has gained wider acceptance. This approach, combined with the development of next-generation sequencers and other technologies that make it possible to read large quantities of gene sequences rapidly, enables the genetic profiles of patients to be comprehensively analyzed, which is expected to lead to more advanced PHC.

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

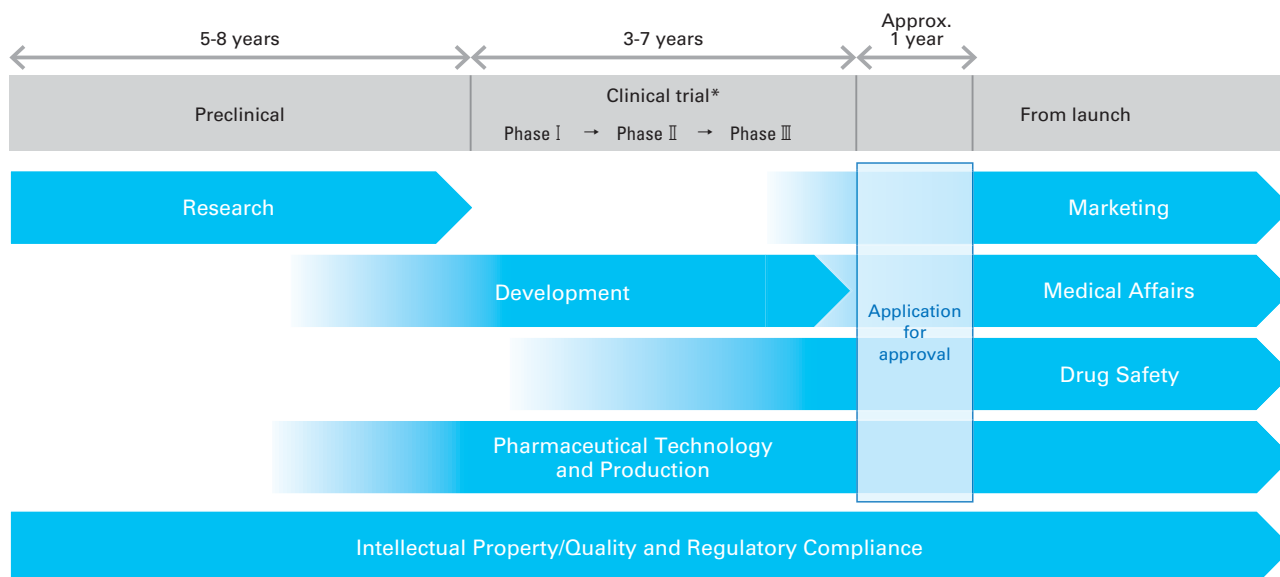
Although innovative drugs are being created, the drug pricing system is a serious risk for the future of the pharmaceutical industry, particularly in Japan. In Japan, fundamental reforms were made to the NHI drug pricing system in 2018 as a measure to curb

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

Impact of Fundamental Reforms of Drug Pricing System



Chugai's Business Process



To provide innovative drugs, Chugai conducts its business largely according to the flow in the diagram above. Research encompasses work from searching for target molecules to selection and optimization of drug candidates. Development consists of conducting clinical trials to prove the efficacy and safety of drug candidates based on the evidence obtained in research, as well as activities to obtain the necessary data for regulatory approval of drugs. Pharmaceutical Technology and Production involves the establishment of production processes for the drug candidates selected in research, as well as work to expedite commercialization and stable supply of high-quality products. Marketing entails the provision of solutions by sharing information with healthcare professionals and acting as a liaison between healthcare facilities. Medical Affairs involves generating and disseminating scientific evidence for products after they have been launched. Drug Safety encompasses the collection, evaluation, and timely

and appropriate provision of safety data to help ensure the proper use of drugs. In addition, we have built a system for providing sophisticated solutions according to regional characteristics through the appropriate division of labor and collaboration among Marketing, Medical Affairs and Drug Safety operations. Activities related to all of these processes are the functions of Intellectual Property and Quality and Regulatory Compliance.

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

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

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

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

Chugai's System for Providing Solutions in Japan

