

# History of Daiichi Sankyo—Path to the Merger

Daiichi Sankyo was born out of the merger of Sankyo Co., Ltd., and Daiichi Pharmaceutical Co., Ltd., two drug discovery-oriented companies with histories spanning roughly a century.

From the 1980s onward, both companies proceeded to expand their operations globally while developing and launching new products. *Pravastatin*, *levofloxacin* and *olmesartan* became blockbuster drugs\* on the global market.

\* New drugs whose annual peak sales exceed ¥100 billion (or \$1 billion).

## History of Sankyo

Sankyo started its journey by commercializing compounds created through its fermentation, extraction of biological materials from plants and animals, and other biotechnologies such as *taka-diastase*, *adrenaline* and *orizanin*. In the years that followed, it built upon its biotechnology research to create numerous antibiotic drugs. Another innovative pharmaceutical developed by applying Sankyo's biological fermentation technologies was *pravastatin*, a early statin compound that was created by Sankyo and that revolutionized medicines in the world as an antihyperlipidemic agent. As for organic synthesis technologies, this company created *loxoprofen* and *olmesartan*, both best-in-class drugs.



### 1899

Founded as Sankyo Shoten through a joint investment by businessmen Matasaku Shiobara (pictured to the left), Shotaro Nishimura, and Genjiro Fukui and launched digestive enzyme *taka-diastase*



### 1902

Launched *adrenalin* (Product name: Adrenalin), the world's first adrenal cortex hormone agent to be extracted successfully



### 1910

Dr. Umetaro Suzuki, who became Sankyo's scientific adviser, made the world's first discovery of vitamin B1 (*orizanin*) in rice bran and established a foundation for the theory of vitamins



### 1913

Changed company name from Sankyo Shoten to Sankyo Co., Ltd., and appointed Dr. Jokichi Takamine as its first president



### 1951

Launched *Lulu* cold medicine



### 1986

Launched *loxoprofen* (Product name: *Loxonin*), an anti-inflammatory analgesic

### 1989

Launched *pravastatin* (Product name: *Mevalotin*), a globally groundbreaking antihyperlipidemic agent



### 2002

Launched global product *olmesartan* (Product names: *Olmetec* and *Benicar*), an antihypertensive agent (Japanese launch took place in 2004)

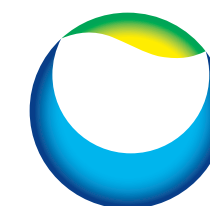


### 2005

Daiichi Sankyo Co., Ltd., established by joint holding company of Sankyo Co., Ltd. and Daiichi Pharmaceutical Co., Ltd.

### 2007

Start of new Daiichi Sankyo Group



Daiichi-Sankyo

## History of Daiichi Pharmaceutical

Daiichi Pharmaceutical began its advance by using its organic synthesis technologies to realize the domestic production of *salvarsan*, a pioneering chemotherapeutic drug. This company also commercialized *tranexamic acid*, which is once again garnering attention for its antiplasmin effects (hemostasis and anti-inflammatory effects), and succeeded in developing and launching *ticlopidine*, which opened the door for antiplatelet therapies in the cardiovascular field. *Levofloxacin*, which could be seen as a masterpiece in the field of synthetic antibacterial agents, left a mark on the history of not only Japan but also the entire world with its broad spectrum of antibacterial activity.



### 1915

Founded as Arsemin Shokai by Dr. Katsuyaemon Keimatsu and realized domestic production of *salvarsan*, a treatment for syphilis, which was a common disease in Japan at that time



### 1918

Changed company name to Daiichi Pharmaceutical Co., Ltd., and appointed Seinosuke Shibata as its first president



### 1921

Launched *adrenaline* (Product name: *Bosmin*), a vasoconstriction, hemostasis, and asthma medicine that became its longest-lasting product



### 1965

Launched *tranexamic acid* (Product name: *Transamin*), an antiplasmin medicine



### 1981

Launched *ticlopidine* (Product name: *Panaldine*), an antiplatelet product



### 1993

Launched *levofloxacin* (Product name: *Cravit*), a broad-spectrum oral antibacterial agent



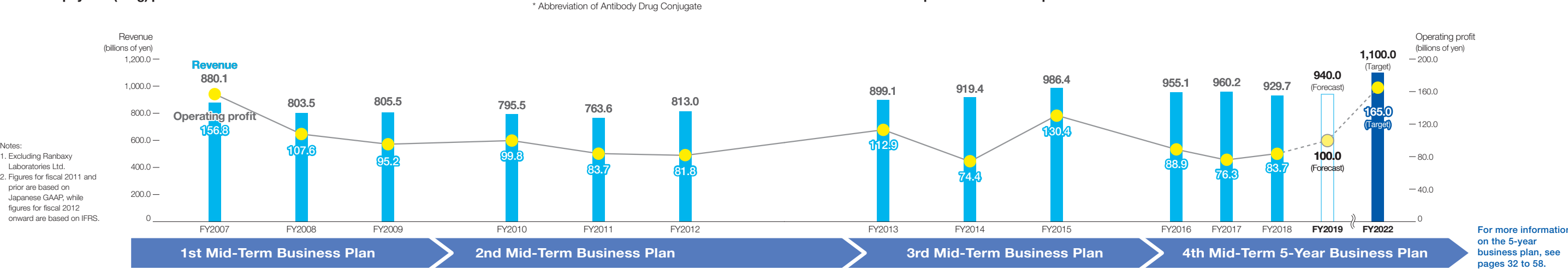
### 1985

Launched *ofloxacin* (Product name: *Tarivid*), a broad-spectrum oral antibacterial agent

History of Daiichi Sankyo — Road After the Merger

Carrying on the century-long strength in science & technology forged by its predecessors, Daiichi Sankyo continues its quest to create innovative pharmaceuticals. We have been successful in growing *olmesartan* and *edoxaban*, the fruits of our predecessors' efforts and expertise in science & technology, into major global products. The ADC\* franchise that will be key to the future of Daiichi Sankyo is also built upon these strengths, using the biotechnologies of Sankyo in the antibody portion of these drugs and the synthesis technologies of Daiichi Pharmaceutical in the linker and payload (drug) portions.

We are finally ready to file an NDA in fiscal 2019 for *DS-8201*, the first entry in our ADC franchise. We have also entered into an agreement with AstraZeneca for collaborating in global development and commercialization. This collaboration will accelerate and expand development as well as help achieve early market penetration, allowing us to deliver *DS-8201* to more patients even quicker. Furthermore, as well as accelerating the process of building a structure for our oncology business in the global market, we will also allocate resources to other projects and accelerate the pace of their development.



Overview of initiatives under mid-term business plans		1st Mid-Term Business Plan	2nd Mid-Term Business Plan	3rd Mid-Term Business Plan	4th Mid-Term 5-Year Business Plan
Launches of new products		<div>Japan</div> Loxonin Tape <div>US</div> AZOR <div>US</div> Effient <div>Europe</div> Sevikar <div>Europe</div> Efient	<div>Japan</div> Loxonin Gel <div>Japan</div> Rezaltas <div>Japan</div> Inavir <div>Japan</div> NEXIUM <div>Japan</div> Memaery <div>Japan</div> LIXIANA <div>Japan</div> RANMARK <div>Japan</div> TENELIA <div>US</div> TRIBENZOR <div>Europe</div> Sevikar HCT	<div>Japan</div> PRALIA <div>Japan</div> Efient <div>US</div> Injectafer <div>US</div> SAVAYSA <div>US</div> MOVANTIK <div>Europe</div> LIXIANA	<div>Japan</div> VIMPAT <div>Japan</div> CANALIA <div>Japan</div> Tarlige <div>Japan</div> MINNEBRO <div>US</div> MorphaBond
Important management decisions	In-licensed products	<div>Japan</div> Denosumab <div>US</div> Tivantinib (Development discontinued) <div>Europe</div> Tivantinib (Development discontinued)	<div>Japan</div> NEXIUM	<div>US</div> CL-108 (License returned) <div>Japan</div> VIMPAT, FluMist <div>Global</div> TS23 (License returned)	<div>Japan</div> Heartcel <div>Japan</div> Nine biosimilars <div>Japan</div> Axi-Cel® <div>Japan</div> Four authorized generics <div>US</div> MorphaBond <div>US</div> RoxyBond <div>Europe</div> Antihyperlipidemic agent
	Acquisition	<div>Europe</div> U3 Pharma GmbH <div>Global</div> Ranbaxy Laboratories Ltd. <div>US</div> Pharma-Force, Inc.	<div>US</div> Bethlehem Plant, Plexxikon Inc.	<div>US</div> Ambit Biosciences Corp. <div>Japan</div> Im Co., Ltd.	
	Business expansion Restructuring Others	<div>Europe</div> Expansion in Turkey and Ireland <div>US</div> Expansion in Puerto Rico	<div>Japan</div> Start of generic business <div>Japan</div> Start of vaccine business <div>Japan</div> Closure of Osaka Plant <div>Japan</div> Sale of Shizuoka Plant	<div>Japan</div> Sale of Akita Plant <div>Japan</div> <div>US</div> <div>Europe</div> Restructuring in Japan, the United States, and Europe <div>Global</div> Divestment of Ranbaxy to Sun Pharmaceutical Industries Ltd. <div>Global</div> Completion of sale of Sun Pharmaceutical shares	<div>Japan</div> Sale of 41 long-listed products <div>Japan</div> Decision to sell the Takatsuki Plant of Daiichi Sankyo Protopharma Co., Ltd. <div>Japan</div> Decision to close the Hiratsuka Plant of DSCP <div>Europe</div> <div>US</div> Restructuring of operations in Europe and the United States <div>US</div> Sale of Bethlehem Plant (US) of Daiichi Sankyo, Inc. <div>Global</div> Decision to close four R&D bases <div>Global</div> Collaboration with AstraZeneca for <i>DS-8201</i>
ESG		<div>G</div> Set the term of Board Members as one year, four out of 10 Board Members are Outside Members <div>G</div> Established Nomination Committee and Compensation Committee <div>G</div> Established Audit & Supervisory Board (two out of four Members of the Audit & Supervisory Board are Outside Members) <div>G</div> Introduced Corporate Officer System <div>E S G</div> First time for inclusion in FTSE4Good*1; inclusion continues thereafter <div>E S G</div> First time for inclusion in Dow Jones Sustainability Indices*2 (Asia Pacific); inclusion continues thereafter	<div>E S G</div> Revision of DAIICHI SANKYO Group Corporate Conduct Charter <div>E S</div> Participation in United Nations Global Compact <div>S</div> Started "Daiichi Sankyo Presents Family Ties Theater" program <div>S</div> Establishment of Daiichi Sankyo Kusuri Museum <div>S</div> Launch of mobile healthcare field clinic services in developing countries	<div>G</div> Formulated specific criteria on the judgment of independence of outside board members <div>G</div> Implemented and achieved compliance with all principles of Japan's Corporate Governance Code <div>S</div> Participation in the Global Health Innovative Technology (GHIT) Fund <div>S</div> Receipt of first-prize UCDA Award 2015*3 for Daiichi Sankyo's Value Report 2015 <div>S</div> Establishment of Daiichi Sankyo Group Individual Conduct Principles	<div>G</div> Selected as the winner of the Corporate Governance of the Year® 2017*4 <div>E S G</div> Included for two consecutive years (2017, 2018) in Dow Jones Sustainability Indices (World Index) <div>E S G</div> Receipt of a prize for excellence in the Nikkei Annual Report Awards for Value Report 2018 <div>S</div> Acquired the Highest Grade of Eruboshi Certification (2018), certified in the White 500 (2018), and acquired Platinum Kurumin certification (2019)

2025 Vision

Global Pharma Innovator with Competitive Advantage in Oncology

\*1 Index compiled by FTSE Russell evaluating companies' engagement in Corporate Social Responsibility activities  
\*2 Index compiled by S&P Dow Jones Indices LLC and RobecoSAM AG recognizing companies that exhibit sustainability  
\*3 Award for communication design  
\*4 An award for companies hosted by the Japan Association of Corporate Directors, which supports corporations that have achieved and maintained medium-to-long-term growth

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Daiichi Sankyo Group Value Report 2019 20



# Medium-to-Long-Term Initiatives and Challenges

Daiichi Sankyo is working to enhance our long-term corporate value, as well as to engage in medium-to-long-term initiatives and challenges in order to realize a sustainable society.

We have positioned the constant creation of innovative pharmaceuticals and the provision of pharmaceuticals addressing diverse medical needs as the basis for our value creation and have been delivering values to society by committing ourselves to solving issues on sustainability, including social and environmental problems, through our corporate activities.

We will explain the following eight issues that Daiichi Sankyo should address in its corporate activities on a medium-to-long-term basis.

### Promoting Environmental Management

P22

Daiichi Sankyo Group recognizes, with great importance, environmental issues such as global warming or extreme weather which have impacts on our work and life, and we also understand that these issues are risks that may affect long-term business itself. We work to promote environmental management based on this understanding, and we believe that doing so contributes to a sustainable society and helps build long-term foundations for corporate growth.

### Corporate Governance Aimed at Fulfilling Our Mission

P61

Daiichi Sankyo Group is working to secure legal compliance and management transparency, and to strengthen the oversight of management and the conduct of operations in addition to creating a management structure that can respond speedily and flexibly to changes in the business environment. We are promoting a corporate governance structure aimed at fulfilling our mission.

### Promoting Compliance Management

P23

At Daiichi Sankyo Group, we recognize that thorough compliance is essential for maintaining and improving our corporate value over the long term. We remain compliant with all relevant laws and regulations and manage compliance with a strong focus on ensuring the highest level of ethics and social consciousness, which we believe is essential for a life science-oriented company.

### Promoting the Success and Development of a Diverse Range of Human Resources Who Can Produce Competitive Advantages

P24

In order to achieve sustainable business activities, it is essential to promote the success and development of a diverse range of human resources. Based on Daiichi Sankyo Group's Human Resources Management Philosophy, we respect the diversity of each and every employee, and we aim to achieve mutual growth between employees and the company in order to produce competitive advantages.

### Creating Innovative Pharmaceuticals

P25

Daiichi Sankyo Group is united to create innovative pharmaceuticals and resolve the social issue of overcoming illnesses. To meet patients' unmet medical needs, our diverse global members are united to enhance our science & technology, with the aim of delivering innovative pharmaceuticals to help treat as many people as possible, as quickly as possible.

### Improving Access to Healthcare

P26

Within Daiichi Sankyo Group, we work to address access to healthcare issues including unmet medical needs (UMN) regarding diseases for which an effective method of treatment does not exist, and access barriers to healthcare caused by social factors such as public health, education and income inequality.

### Providing the Highest Quality Medical Information

P27

Pharmaceuticals are crucial for the life of each and every patient. As such, it is vital to create and convey high-quality information, so that patients can use pharmaceuticals correctly. Within Daiichi Sankyo Group, we continually establish high-quality information and deliver this information in an appropriate manner, thereby promoting the proper use of our pharmaceuticals and enhancing their product value (contribution to patient treatment in the medical field).

### Providing a Stable Supply of Top-Quality Pharmaceutical Products

P28

Pharmaceutical companies have an imperative mission to provide high-quality pharmaceuticals in an appropriate and stable manner. As we at Daiichi Sankyo Group work to expand our product lineup to meet demand for a high level of manufacturing technologies, we strive to fulfill this mission by continually providing high-quality pharmaceuticals to the world in a stable manner over a long-term period, even in the event of an earthquake or other emergency.

## Promoting Environmental Management

### Basic Policy

Daiichi Sankyo Group recognizes, with great importance, environmental issues such as global warming or extreme weather which have impacts on our work and life, and we also understand that these issues are risks that may affect long-term business itself. We work to promote environmental management based on this understanding, and we believe that doing so contributes to a sustainable society and helps build long-term foundations for corporate growth.

### Introduction of Our Initiatives

**Expressing Agreement with the Recommendations of the TCFD (Task Force on Climate-related Financial Disclosures)**

In April 2019, Daiichi Sankyo Group was the first pharmaceutical company in Japan to express support for the TCFD\* recommendation, which were formulated to encourage companies to disclose information about the risks and opportunities presented by climate change in business activities.

We see "Climate Action," Goal 13 in the SDGs (Sustainable Development Goals), to be an important issue within environmental management, and we are actively engaged in initiatives to independently disclose climate-related financial information in line with the recommendations of the TCFD and in response to requests from stakeholders.



\* TCFD (Task Force on Climate-related Financial Disclosures): This task force was established in December 2015 by the FSB (Financial Stability Board). The FSB is an international organization joined by central banks and financial regulators from the major powers.

**Building a System to Secure the Reliability of Environmental Performance Data**

We recognize actions to secure the reliability of environmental performance data, including climate change, to be the most crucial issue within environmental management. As such, we have gained third-party certification in order to enhance the reliability of our data.

We have built a system that can collate all applicable data with external evidence such as electricity and gas meter readings. We received a high evaluation from the third-party certification body for this system as it ensures the accuracy of data.



Third party certificate

Other initiatives: Structure for promoting environmental management; response to water risks; effective use of resources; control of chemical substances; initiatives for biodiversity conservation. The Company updates its corporate website with information regularly.

[https://www.daiichisankyo.com/about\\_us/responsibility/csr/business/environment/index.html](https://www.daiichisankyo.com/about_us/responsibility/csr/business/environment/index.html)

We have also issued an environmental data book that focuses on disclosing environmental performance data, with the aim of providing information related to the environment.

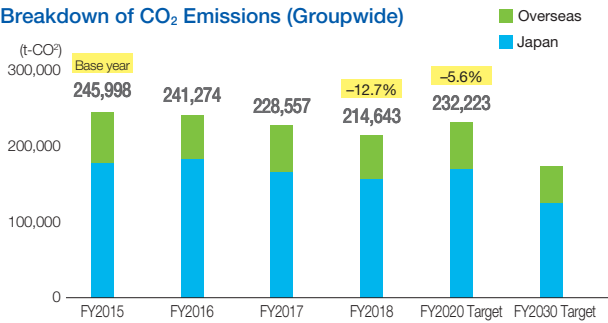
**Setting a Target to Reduce CO<sub>2</sub> (by 27% Compared to 2015) with Consideration for Long-Term Goals**

We have set a target at Daiichi Sankyo Group to reduce greenhouse gases, and this target has been approved by the Science Based Targets initiative (SBTi)\*. Our target to reduce greenhouse gases emitted through business activities at the Group falls in line with the necessary degree of reduction for keeping the average increase in global temperature below 2°C.

CO<sub>2</sub> emissions target for fiscal 2020:  
5.6% reduction from fiscal 2015

In fiscal 2018, we achieved a 12.7% reduction of CO<sub>2</sub> emissions from fiscal 2015, meaning that we have gone beyond our target for fiscal 2020. We will continue to engage in initiatives for CO<sub>2</sub> reduction in consideration of long-term goals in 2030.

\* Science Based Targets initiative (SBTi): An international initiative that encourages companies to set CO<sub>2</sub> reduction targets based on scientific evidence in order to help accomplish the goal of the Paris Agreement of keeping the average increase in global temperature below 2°C.



Medium-to-Long-Term Initiatives and Challenges

Promoting Compliance Management

Basic Policy

At Daiichi Sankyo Group, we recognize that thorough compliance is essential for maintaining and improving our corporate value over the long term. We remain compliant with all relevant laws and regulations and manage compliance with a strong focus on ensuring the highest level of ethics and social consciousness, which we believe is essential for a life science-oriented company.

Introduction of Our Initiatives

Entrenching Compliance Awareness Among Employees

Daiichi Sankyo Group companies have developed compliance conduct standards in their respective regions based on the Daiichi Sankyo Group Corporate Conduct Charter and the Daiichi Sankyo Group Individual Conduct Principles. Compliance officers at each company send out messages and carry out other activities in order to entrench awareness of these standards among all employees, including executive officers.

At the beginning of fiscal year 2018, we adopted a “Blue Tree” symbol as our Groupwide compliance logo. This logo is utilized to “brand” compliance-related materials and activities, and serves as a reminder of the importance of compliance to employees.



Revising and Enforcing the Daiichi Sankyo Group Global Marketing Code of Conduct

We established a Global Marketing Code of Conduct on October 1, 2016, with the aim of maintaining high standards in interactions with healthcare professionals, medical institutions and patient organizations, as well as in the promotion of pharmaceutical products. This Code of Conduct is applicable to, and enforced throughout, Daiichi Sankyo Group companies. In January 2019 the Code was updated to incorporate revisions made to the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Practice that address the prohibition of providing gifts and promotional aids to healthcare professionals. We promote appropriate marketing activities based on this Code.

Establishing the Daiichi Sankyo Group Global AntiBribery & Anti-Corruption Policy

The laws and regulations that pertain to bribery and other forms of corruption in countries around the world are growing stricter with each coming year. Thus, it is becoming increasingly important for companies with global operations to implement initiatives for the prevention of bribery and other forms of corruption.

We established the Daiichi Sankyo Group Global Anti-Bribery & Anti-Corruption Policy in October 2017, which includes details such as prohibiting cash payments to government officials and healthcare professionals. We are working to bolster our corporate structure by conducting measures in a focused manner, taking special measures against bribery and other unwanted activities in business in high-risk countries.

Respecting Human Rights in Accordance with the UN Guiding Principles on Business and Human Rights

As a pharmaceutical company that operates businesses around the globe, Daiichi Sankyo Group promotes business activities that consider the human rights of a diverse range of stakeholders. Examples include, a focus on ethics in R&D, as addressed in the Declaration of Helsinki; showing respect for the human rights of people within the supply chain; and providing a workplace environment where employees can work easily without harassment or discrimination. Based on the UN Guiding Principles on Business and Human Rights, we began to build a structure for human rights due diligence at all of our companies in fiscal 2019 so that the issues regarding human rights can be understood on a global scale.

Promoting the Success and Development of a Diverse Range of Human Resources Who Can Produce Competitive Advantages

Basic Policy

In order to achieve sustainable business activities, it is essential to promote the success and development of a diverse range of human resources. Based on Daiichi Sankyo Group's Human Resources Management Philosophy, we respect the diversity of each and every employee, and we aim to achieve mutual growth between employees and the company in order to produce competitive advantages.

Introduction of Our Initiatives

Promoting Diversity and Inclusion

Within Daiichi Sankyo Group, we engage in initiatives to foster a culture of actively accepting all employees with a wide range of diverse characteristics depending on each type of job position, including varied specialties, mindsets, values, and lifestyles, in addition to nationality, gender, age, and other attributes; and also a culture of respecting one another in order that all employees can exercise their abilities to the greatest extent possible. In addition to achieving diversity within the Group, through acquiring talent from outside and promoting the Global Management Structure, we realize a form of management where a wide range of employees can achieve success through their individual differences and strengths, working beyond national and organizational boundaries. (E.g.: Daiichi Sankyo conducts training programs about Diversity Management for employees who have been newly appointed to management positions. A total of 134 people participated in fiscal 2018)

Promoting Group Talent Management

Within Daiichi Sankyo Group, we aim for optimal human resources to achieve success as leaders, regardless of their nationality, gender, or age. To this end, we actively promote and acquire human resources with a broad range of experience from both inside and outside the Group, and we promote Group talent management with a primary focus on continually producing quality leaders in future generations. In particular, we have identified global key positions that are vital for realizing our Vision and 5-year business plan, and we are effectively promoting leadership development activities through training programs, opportunities, and positions that allow for further growth among successor candidates. We have also been actively providing opportunities for global business experience (international assignment and overseas study programs), to allow future leaders to expand their knowledge and comprehend global business. As of April 2019, 99 individuals are engaged in work outside of Japan.

Focusing Efforts on Strengthened Fields to Realize Our 2025 Vision: the COF Project

The COF (Create Our Future) Project started in 2017 with the aim of achieving our 2025 Vision of becoming a “Global Pharma Innovator with competitive advantage in oncology,” by taking the talented people who are the source of our competitiveness and allocating them to strengthened fields where they can maximize their ability. Apart from seeking to actively allocate personnel to our oncology business and other strengthened fields, we work to achieve mutual growth between employees and the company, using our internal portal to send out information needed to make career choices, including information on job positions and organizations as “Career Path Models.” We strive to foster an organizational culture in all business areas and functions within the company for developing an independent mindset regarding career development, so that we can continue to undertake even greater challenges than before.

COF Project Overview

Employees' endeavors and successes equate to the Company's growth and development



Other initiatives: Compliance system; sustainable procurement; information security; R&D ethics. The Company updates its corporate website with information regularly. [https://www.daiichisankyo.com/about\\_us/responsibility/csr/business/fair/index.html](https://www.daiichisankyo.com/about_us/responsibility/csr/business/fair/index.html)



Other initiatives: Promotion of occupational health and safety; signing of a Statement of Support for the Women's Empowerment Principles (WEPS). The Company updates its corporate website with information regularly. [https://www.daiichisankyo.com/about\\_us/responsibility/csr/business/human/index.html](https://www.daiichisankyo.com/about_us/responsibility/csr/business/human/index.html)



## Medium-to-Long-Term Initiatives and Challenges

### ■ Creating Innovative Pharmaceuticals

#### Basic Policy

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#### Introduction of Initiatives

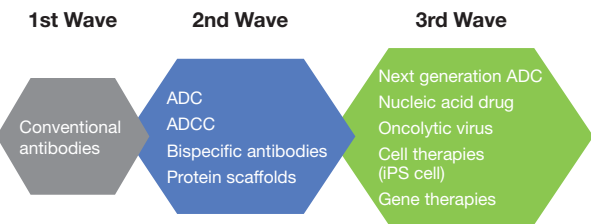
##### Mid-to-long-term Initiatives in R&D

Since its founding, Daiichi Sankyo has been focusing on expanding its business through in-house drug discovery. In-house drug discovery that lead to business expansion requires researchers with a high degree of specialization and expertise based on a wealth of experience. Researchers at Daiichi Sankyo are involved in many projects through various opportunities and have acquired the ability to deliver a message that draws people around us. Our researchers deepen their awareness of diverse experiences and create a network of global researchers by studying at leading universities and laboratories in and outside Japan. Such experience leads to the development of researchers with far-sightedness in identifying future directions, creating a culture that allows researchers to conduct research activities as they wish according to their interests and based on science without fear of failure.

The path to drug discovery is not seamless, rather it is a series of challenges and these challenges lead to the discovery of *DS-8201* and other medicines in the ADC franchise. We will continue creating innovative pharmaceuticals through such experience.

##### New Modalities

Daiichi Sankyo has been advancing research on modalities in which, in addition to small molecules and *DS-8201* in the ADC franchise, we conduct research of next generation ADC, bispecific antibodies, nucleic acid drugs, oncolytic viruses, cell therapy (including iPS cells), gene therapy, and so on. Through such research, we have been advancing multi-modality strategies to select the optimal forms of modality for drug discovery targets or find the diseases on which the characteristics of these modalities are best utilized.



##### Maximizing Created Value

With the aim of obtaining approval and launching new drug candidates as quickly as possible, we have been evolving our R&D process. To strengthen the creation of cancer treatment medicines, in particular, we have combined oncology field research and development into one sub unit. Also, in collaboration with Medical Affairs and Global Marketing, we make decisions swiftly and optimize resource allocation. Furthermore, in an attempt to strengthen our translational research\*, we have built and started the operation of a platform that enables us to make the most of our clinical data. Going forward, we will store and utilize data from other institutions working in our joint research. Using knowledge obtained from this database, we will develop companion diagnostics and conduct small-scale clinical trials with high success rates. Storing data through this platform also enables us to react immediately and appropriately upon obtaining new scientific knowledge.

In clinical development, we develop clinical trial plans, taking into account the specialty of the doctor and medical institution based on the characteristics of the project as well as from a global viewpoint. Thus, we conducted the phase 1 study for *DS-8201* in Japan ahead of other countries. Meanwhile, we collaborate with major laboratories in the U.S. that have a wealth of experience and expertise in the field of oncology and authentic academia with a track record of success to introduce different types of know-how on the development of pharmaceuticals for cancers.

Furthermore, we continue to create information by collecting real world data to increase product value, and also strive to advance highly sophisticated manufacturing technologies such as ADC, enhance the product supply system, and strengthen the quality assurance system on a global basis. Throughout the entire process for creating pharmaceutical products, we also solidify the intellectual property strategy covering technology and use.

\* Translational research: the research, method, and process of deepening the understanding of diseases, drug interaction mechanisms, and so on through the mutual use of information and other materials from clinical and non-clinical studies.

### ■ Improving Access to Healthcare

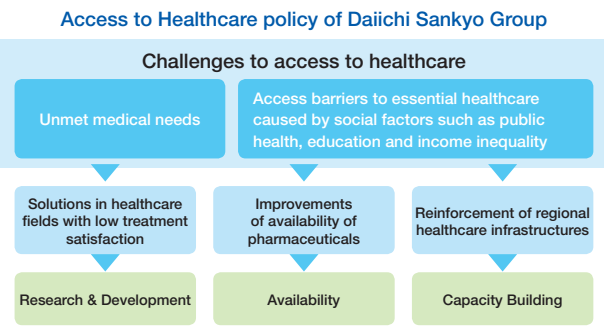
#### Basic Policy

Within Daiichi Sankyo Group, we work to address access to healthcare issues including unmet medical needs (UMN) regarding diseases for which an effective method of treatment does not exist, and access barriers to healthcare caused by social factors such as public health, education and income inequality.

#### Introduction of Our Initiatives

##### Establishing the Access to Healthcare Policy of Daiichi Sankyo Group

We established Access to Healthcare policy of Daiichi Sankyo Group in 2018 in order to eliminate access barriers to healthcare within developing countries and all other regions around the world. We work to address access to healthcare challenges in the following three activity areas: “Research & Development”, “Availability”, and “Capacity Building”.



##### Initiatives Targeting Rare Diseases (Research & Development)

There is a continually high level of UMN regarding rare diseases with a small number of patients and with no established method of treatment. Within Daiichi Sankyo Group, we actively undertake initiatives to develop pharmaceuticals for these rare diseases with significant social needs.

Disease	Drug name
Atypical hyperphenylalaninemia	<i>Biopten</i>
Severe spastic paralysis	<i>Gabalon</i> intrathecal injection
Toxic methemoglobinemia	<i>Methylene Blue</i>
Acute myeloid leukemia	<i>Quizartinib</i>
Tenosynovial giant cell tumor	<i>Pexidartinib</i>
Glioblastoma	<i>DS-1647 (G47Δ)*</i>
Duchenne muscular dystrophy	<i>DS-5141*</i>
Large B Cell Lymphoma	<i>Axi-Cel®*</i>

\* under development

##### Global Market Access & Pricing (Availability)

In order to contribute to patients’ good health by providing pharmaceuticals, Daiichi Sankyo Group launched the Global Market Access & Pricing Department in April 2017 with the aim of more reliably delivering the pharmaceuticals needed by each patient at a reasonable price. We strive to improve patients’ access to pharmaceuticals while giving consideration to the appropriate market access from early stages in clinical trials. This is achieved by setting appropriate prices for pharmaceuticals based on their value and in consideration of healthcare systems, income levels, and other environmental differences within each country and region.

##### Participating in the Global Health Innovative Technology (GHIT) Fund (Capacity Building)

The Global Health Innovative Technology (GHIT) Fund\* aims to achieve drug discovery for combating infectious diseases in developing countries. Daiichi Sankyo Group has contributed to the Fund since its establishment. We are also promoting collaboration research with the GHIT Fund by providing our compound library (consisting of small molecules and natural substances) in a screening program to explore candidate compounds to treat malaria, tuberculosis and neglected tropical diseases (NTDs), namely leishmaniasis and Chagas disease.

\* Global Health Innovative Technology (GHIT) Fund: It was established in 2013 through a public-private partnership originating in Japan, and is supported by the government of Japan, six pharmaceutical companies, and the Bill & Melinda Gates Foundation.



Other initiatives: Participating in Access Accelerated; vaccine production technology transfer for Vietnam. The Company updates its corporate website with information regularly. [https://www.daiichisankyo.com/about\\_us/responsibility/csr/business/medical/index.html](https://www.daiichisankyo.com/about_us/responsibility/csr/business/medical/index.html)

Medium-to-Long-Term Initiatives and Challenges

■ Providing the Highest Quality Medical Information

Basic Policy

Pharmaceuticals are crucial for the life of each and every patient. As such, it is vital to create and convey high-quality information, so that patients can use pharmaceuticals correctly. Within Daiichi Sankyo Group, we continually establish high-quality information and deliver this information in an appropriate manner, thereby promoting the proper use of our pharmaceuticals and enhancing their product value (contribution to patient treatment in the medical field).

Introduction of Our Initiatives

Developing Pharmaceuticals Based on Statistical Evidence

In order to receive approval for a pharmaceutical, it is necessary to verify its efficacy and safety through clinical studies carried out appropriately and scientifically. At Daiichi Sankyo Group, we include statistical experts in the project team as we develop the optimal plan for conducting an objective evaluation, enabling us to carry out high-quality pharmaceutical development.

Managing Safety Information and Promoting Proper Use

We collect safety management information (such as information on adverse events) globally, use this information to conduct objective assessments, review, and analysis, and then we provide the results to the front line of medical field in order to promote the proper use of pharmaceuticals. In addition, we strive to minimize the safety risk for patients by conducting training for all employees every year about safety management information, as well as by thoroughly enforcing safety management activities.

Generate Information (Evidence) Through Clinical Research and Other Activities

The Medical Affairs Division works to generate new evidence through clinical research, so that our products can contribute even more toward the treatment of patients. We design trials that closely follow the actual conditions of patient treatment by using real-world database\*, and we deliver information about the evidence gained in these studies through academic meetings, conferences, and other similar events.

\* A database containing data that originates from real-life activities in diagnosis and treatment, such as data on medical fee payment requests, medical records, and checkup data

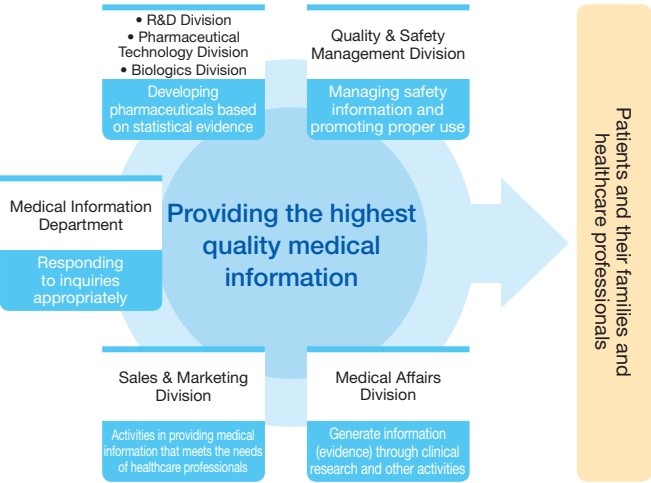
Activities in Providing Medical Information that Meets the Needs of Healthcare Professionals

With changes in the environment such as integrated community medical systems in Japan, the needs of healthcare professionals are changing all the time. Our marketing division engages in activities to provide medical information through a wide range of methods, including lectures, web seminars, and websites on the Internet. Apart from providing information, MRs play an important role in gathering and reporting information on safety. We also aim to enhance the level of specialized knowledge among MRs by implementing an MR qualification system and reinforcing our training programs.

Responding to Inquiries Appropriately

The Medical Information Department in Japan receives about 10 thousand inquiries each month from healthcare professionals and patients. The department has secured the leading rank\* in all surveyed categories, including “Ease in Getting through when Calling by Phone,” “Swift Responses,” “Good Collaboration with MRs,” and “Attitude and Politeness of Staff.” The department started running a system using AI from April 2018, enabling optimal information to be delivered even more quickly.

\* Survey of pharmacists in health insurance pharmacies conducted by an outside research company



■ Providing a Stable Supply of Top-Quality Pharmaceutical Products

Basic Policy

Pharmaceutical companies have an imperative mission to provide high-quality pharmaceuticals in an appropriate and stable manner. As we at Daiichi Sankyo Group work to expand our product lineup to meet demand for a high level of manufacturing technologies, we strive to fulfill this mission by continually providing high-quality pharmaceuticals to the world in a stable manner over a long-term period, even in the event of an earthquake or other emergency.

Introduction of Our Initiatives

Developing Manufacturing Processes

We develop manufacturing processes before receiving approval so that the new drugs created through R&D can be produced in a high-quality, stable, and efficient manner. In addition, we transfer the developed manufacturing process to global commercial production.

Manufacturing and Supply Systems (Supply Chain Management)

At Daiichi Sankyo Group, we have constructed flexible and efficient manufacturing and supply systems (supply chains) that integrate two main groups of functions: systematic manufacturing functions that involve collaborating with global manufacturing bases and procuring raw materials stably; and logistics functions for shipping swiftly and reliably after receiving an order. Unlike traditional small molecule drugs, *DS-8201* and other antibody drugs present technical hurdles including the optimization of production cells for manufacturing. In addition, the process of creating an antibody drug conjugate (ADC) by conjugating an antibody with a drug payload requires advanced technological capabilities, such as for conjugating the payload (drug) with a linker and then lyophilizing to produce a formulation. We strive to build efficient manufacturing and supply systems using new facilities and technologies, and we aim to undertake new

challenges every day to achieve innovative technologies as well as to develop manufacturing and supply systems for innovative pharmaceuticals.

Quality Assurance at a Global Standard

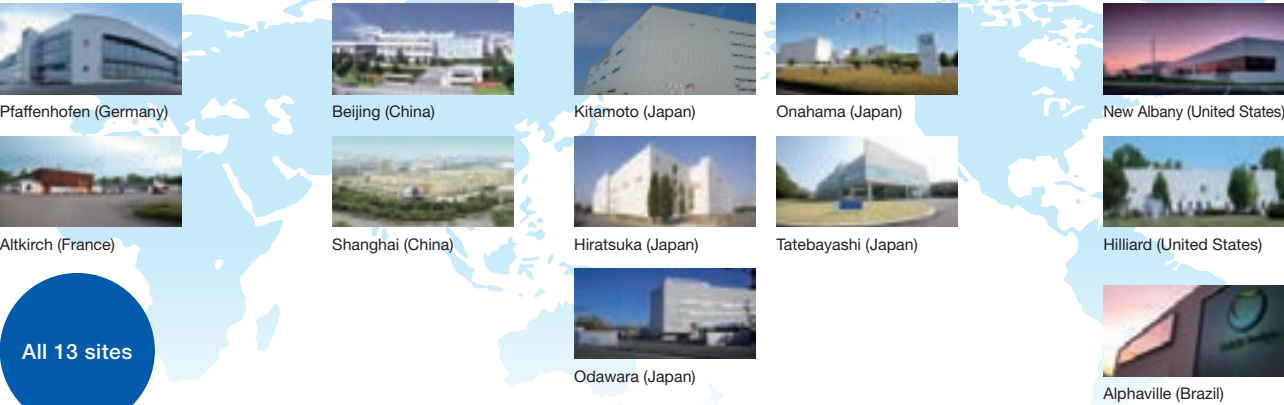
At Daiichi Sankyo Group, we guarantee the quality of our products in adherence with GMP (Good Manufacturing Practice: rules on managing the production and quality of pharmaceuticals), whereby we use a scientifically backed method of managing all processes, from receiving raw materials to manufacturing and shipping products. We collaborate with many global suppliers in order to maintain and enhance our global level of quality assurance.

Systems for Achieving Stable Supply During Emergencies

Daiichi Sankyo Group has a business continuity plan (BCP) in preparation for four major threats to business continuity: natural disasters, facility accidents, pandemic influenza and other infectious diseases, and system failures. Based on this plan, systems are in place to quickly restore operations in the event of an emergency and to ensure a steady supply of pharmaceutical products with assured quality to help support the continued provision of medical services.

For details, refer to page 74.

Daiichi Sankyo Group's production sites (as of October 2019)





# Daiichi Sankyo's Strengths

Carrying on the century-long strength in science & technology forged by its predecessors, Daiichi Sankyo continues its quest to create innovative pharmaceuticals.

Moreover, with a robust, global pool of talent and global management, we will utilize our strong presence in Japan so as to continue our earnest and trustworthy activities.

## Science & Technology

### Strong R&D DNA Cultivated Over Years of Operation as a Drug Discovery-Oriented Company

The roots of Daiichi Sankyo's R&D DNA can be traced back to the founding of the company. Our journey began with the extraction of *adrenaline*, the discovery of *orizantin* and the domestic production of *salvarsan*. Ever since then, we have aimed to be a drug discovery-oriented company originating from Japan and we have focused on in-house drug discovery. We have also gone on to create and deliver innovative products that have had a global impact such as *pravastatin*, *levofloxacin*, *olmesartan*, and *edoxaban* to patients around the world. Utilizing this strong R&D DNA, honed and cultivated over years of operation, Daiichi Sankyo is committed to the development of innovative pharmaceuticals that will change SOC\*.

\* SOC (Standard of Care): Universally applied best treatment practice in today's medical science

### Superior Pharmaceutical and Technological Capabilities for Creating Innovative Pharmaceuticals

#### Daiichi Sankyo's Proprietary Antibody Drug Conjugate (ADC) Technologies

DS-8201 was created through Daiichi Sankyo's proprietary science and technology. The antibody portion of this drug was created by applying the antibody research and protein engineering capability of the former Sankyo, while the drug payload and linker were born out of the research capabilities of the former Daiichi Pharmaceutical. Our ADC project started in 2010 by examining the merits and issues regarding the preceding ADC. In order to solve these issues regarding the preceding ADC, our researchers screened and optimized over several hundred combinations of antibodies, linkers, and payloads to ultimately produce the technology we have now. Daiichi Sankyo ADC has been established as a platform technology where a payload and linker can be combined with many different antibodies, and we are currently developing seven ADC projects.

### Diverse Modality Technologies

Daiichi Sankyo is working on the development of innovative modality technologies for the creation of innovative pharmaceuticals. Diverse modality technologies, such as next-generation ADC, nucleic acid drugs, oncolytic viruses, cell therapy, and gene therapy are utilized to broaden the possibilities for drug development.

### Powerful Research Engines

Many Nobel laureates have come from Japan to date, and Japan has shown the world its high standard of research. At Daiichi Sankyo, we hire many talented researchers from excellent universities in Japan every year from a wide range of fields, including pharmacology, medicinal chemistry, pharmacokinetics, toxicology and pharmaceutical technology. Additionally we strive to improve the scientific level of research employees after joining the company, sending many of them to study at overseas universities and prestigious research

institutions. These researchers take part in cross-functional project teams together with the development division, the pharmaceutical technology division, the marketing division, conducting research every day in order to create new drugs.

### Strong Ties with Leading-Edge Academic Institutions (Open Innovation Activities)

At Daiichi Sankyo, we strive to conduct research and development on pharmaceuticals that will change SOC, the universally applied best treatment practice in today's medical science. We have utilized collaborations with various organizations, including those in academia, so as to achieve many drug discovery targets, as well as to acquire and enhance drug discovery technologies. In fiscal 2018, we fostered multiple new collaborations in Japan and overseas, engaging in initiatives to bolster our pipeline by incorporating leading-edge science into the Company.

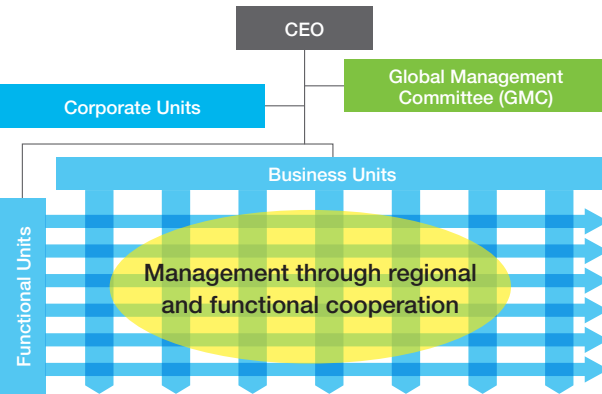
## Global Organization & Talent

### Global Management System Uniting Intellects from Around the World

#### Global Management Committee and Global Matrix Management Facilitating Swift and Accurate Decision-Making

In order to conduct swift and accurate management and decision-making from a global perspective, we established the Global Management Committee (GMC). Led by the CEO and joined by the head of each unit, the GMC is the highest-ranking committee structure within Daiichi Sankyo. Business units that focus on each region and functional units that focus on global value chain functions (including R&D, Pharmaceutical Technology, and Supply Chain) collaborate to conduct management and hold discussions in the GMC in order to maximize value creation across the entire Group.

For details, refer to page 77.



### Global R&D Structure Enabling Swift Decision-Making

GEMRAD\*, the decision-making body for global R&D projects, is composed of senior members from the R&D Unit, the Pharmaceutical Technology Unit, the Biologics Unit, Global Marketing, the Business Development Unit, and other departments. The multifunctional memberships allow GEMRAD to make decisions based on active discussions with a global perspective and comprehensive assessments covering science and business.

\* Global Executive Meeting for Research and Development

### Robust, Global Pool of Talent

#### Proactive Employment of Global Talent from Around the World

We employ many highly-talented individuals with diverse backgrounds in Japan and across the globe and we enhance our global organization and talent while working to achieve synergy by having such talent from around the world work together.

### Human Resources Development Programs Taking Advantage of Global Experience

In human resources development, Daiichi Sankyo identifies positions that are key to the accomplishment of its management vision and the goals of its mid-term business plan on a global basis, and nurtures people by assigning them duties with challenging goals or difficult tasks or by relocating them overseas. As such, we proactively promote global talent management that offers opportunities for further contributions.

### Assigning Human Resources to Strengthened Fields in a Concentrated Manner: COF Project

The Create our Future (COF) Project started in 2017, with the aim of assigning Daiichi Sankyo's human resources to strengthened fields that focus on oncology at appropriate times and in an appropriate manner, as well as to promote the maximum possible success of each and every employee.

For details, refer to page 24.

## Presence in Japan

### No.1 in Terms of Pharmaceutical Revenue in Japan



By continually launching and expanding the sales of proprietary developed products, Daiichi Sankyo works to grow the innovative pharmaceuticals\* business. At the same time, we utilize Daiichi Sankyo's superb sales capabilities to acquire licenses for promising products developed elsewhere in order to sustain a virtuous cycle that drives further growth. Through this process, we maintain the No.1 place in terms of pharmaceutical revenue in Japan.

\* Pharmaceuticals protected during the exclusivity period granted by reexamination period and patents

### No.1 MR Evaluation



We have developed activities according to the various needs of each healthcare professional with a multichannel approach\*<sup>1</sup> led by MRs. With regard to MR evaluation, we have been ranked highly not just for our knowledge and information, but also in terms of human nature and responsiveness. As a result, we are comprehensively ranked No.1.\*<sup>2</sup>

\*<sup>1</sup> Utilizing lectures, web seminars, Internet and other methods, principally conducted by MRs

\*<sup>2</sup> Conducted by ANTERIO Inc.

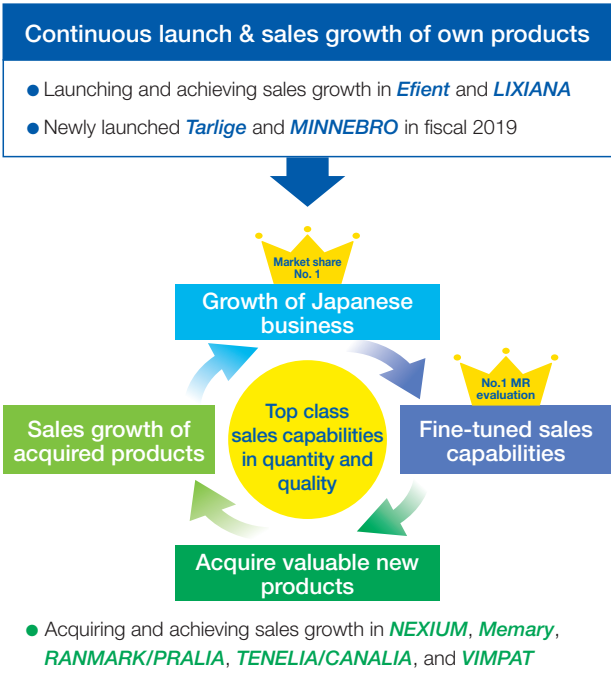
### Comprehensive Training Programs



In order to maintain our superb sales capabilities, we have developed comprehensive training programs for MRs, and all MRs have passed the certificate test for nine consecutive years.

### Four Businesses Responding to Diverse Medical Needs

By leveraging the strength of its innovative pharmaceutical business, Daiichi Sankyo engages in generic business, vaccine business, and OTC-related business in Japan. As the No.1 company in Japan in both name and practice, Daiichi Sankyo addresses a wide range of medical needs related to areas such as treatment, reduction of medical costs, prevention, and self-medication, making comprehensive contributions to medicine in Japan.



● Acquiring and achieving sales growth in *NEXIUM*, *Memary*, *RANMARK/PRALIA*, *TENELIA/CANALIA*, and *VIMPAT*

# 2025 Vision

Daiichi Sankyo set out our 2025 Vision of becoming a “Global Pharma Innovator with Competitive Advantage in Oncology.” The vision for Daiichi Sankyo in 2025 entails the Company having a specialty area centered on oncology as the core business, having enriched regional value products aligned with the regional market, and having innovative products and pipelines changing SOC in each market. At the same time, the Company aims to realize shareholders’ value through highly efficient management.



## Why Oncology?

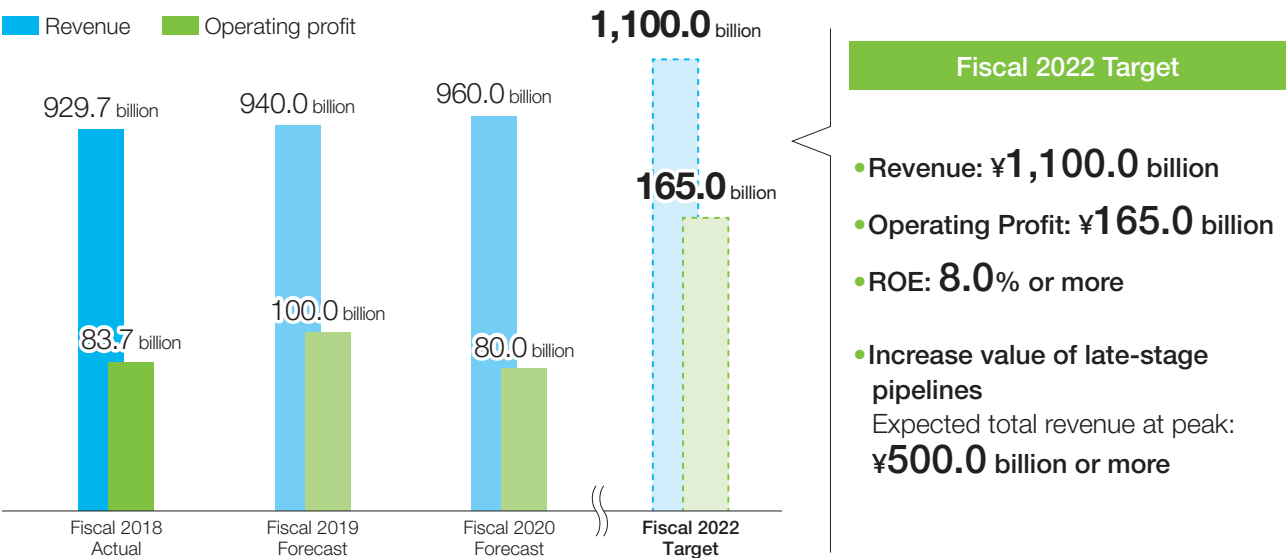
In recent years, new therapeutic drugs and therapies such as cancer immunotherapy and cell therapy have been developed. However, to overcome cancer, there is still a need for more effective and safer drugs and therapies in areas where unmet medical needs are still high. In fiscal 2019, we anticipate the launch of the first oncology product after integration, and we believe that we will be able to establish a core business for cancer, with the *DS-8201* of in-house developed products as the leading source of many promising drugs.

Our group is steadily advancing into our 2025 vision, “Global Pharma Innovator with Competitive Advantage in Oncology.”

# 5-Year Business Plan Overview and Progress

The 5-year business plan covers the period from fiscal 2016 to fiscal 2020, which has been positioned as a period for transformation leading up to the 2025 Vision. However, we made revisions to some targets in October 2018, owing to a wide range of environmental changes. Currently, we are studying new targets in light of our strategic alliance with AstraZeneca.

For details, refer to page 33.



## Six Strategic Targets for Accomplishing Our Performance Targets

<b>Grow Edoxaban</b>	<b>Grow as the No. 1 Company in Japan</b>	<b>Expand U.S. Businesses</b>
<b>Achievements and Progress</b>	<b>Achievements and Progress</b>	<b>Achievements and Progress</b>
<ul style="list-style-type: none"><li>Expanded global revenue (fiscal 2018 revenue: ¥117.7 billion)</li><li>Ranked No.1 in market share within Japan (as of 4th quarter, fiscal 2018)</li><li>Significantly expanded the market share in many countries within Europe and Asia</li></ul>	<ul style="list-style-type: none"><li>Ranked No.1 in market share of domestic ethical drugs for three consecutive years</li><li>Ranked No.1 in MR evaluation for seven consecutive years</li><li>Continually launching new products (<i>Tarlige</i> and <i>MINNEBRO</i>)</li></ul>	<ul style="list-style-type: none"><li>Expanded American Regent business (fiscal 2018 revenue: ¥117.8 billion)</li><li>Expanded <i>Injectafer</i> revenue (fiscal 2018 revenue: ¥44.2 billion)</li><li>Re-examined strategy for the pain franchise of Daiichi Sankyo, Inc.</li></ul>
<b>Establish Oncology Business</b>	<b>Continuously Generate Innovative New Medicine changing Standard of Care (SOC)</b>	<b>Enhance Profit Generation Capabilities</b>
<b>Achievements and Progress</b>	<b>Achievements and Progress</b>	<b>Achievements and Progress</b>
<ul style="list-style-type: none"><li>Accumulated promising clinical data on <i>DS-8201</i> and working ahead of schedule for the target date to submit an application for approval</li><li>Presented positive clinical data on <i>U3-1402</i> and <i>DS-1062</i></li><li>Submitted an NDA for <i>Quizartinib</i> and <i>Pexidartinib</i></li></ul>	<ul style="list-style-type: none"><li>Ventured into many different modalities</li><li><i>DS-1647</i> (oncolytic virus) NDA submitting planned</li><li>Progressed on open innovation</li></ul>	<ul style="list-style-type: none"><li>Optimized Sales &amp; Marketing structure in the U.S. and EU (total 550 position cuts in fiscal 2016 and 2017)</li><li>Optimized global R&amp;D structure (four locations closed)</li><li>Optimized global manufacturing structure (two locations closed and decided to sell one location)</li></ul>

## Growth Investments and Shareholder Returns

<b>Prioritize growth investments while also enhancing shareholder returns</b>	<b>Achievements and Progress</b>
<ul style="list-style-type: none"><li>Reduced cross-shareholding shares (33 different stocks for a total amount of ¥46.0 billion over three-year period)</li><li>Sold properties (¥25.0 billion over three-year period)</li><li>Gain on sales of business transfers (¥6.3 billion)</li></ul>	<ul style="list-style-type: none"><li>Issued super-long-term unsecured corporate bonds (¥100.0 billion)</li><li>Acquired own shares (¥100.0 billion over three-year period)</li><li>Maintained a total return ratio of 100% or more (114.8% over three-year period)</li></ul>



# Message from the CFO

I would like to begin by thanking all of our stakeholders for the ongoing support to Daiichi Sankyo.

Along with the explanation of our 5-year business plan, reasons for its revision, and its current state, I would like to introduce examples of specific initiatives I am working on to improve the corporate value as CFO.



**Toshiaki Sai**  
Representative Director, Member of the Board, Executive Vice President and CFO

## 5-Year Business Plan, Reasons for Its Revision, and Its Current State

### 1. 5-Year Business Plan (Presented in March 2016)

Since the development of 5-year business plan (fiscal 2016 to 2020) in March 2016, we are committed to establish a foundation for sustainable growth mainly consisting of the achievement of six strategic targets to transform ourselves along our 2025 Vision of becoming a “Global Pharma Innovator with competitive advantage in oncology.” Daiichi Sankyo has set revenue of ¥1,100.0 billion, operating profit of ¥165.0 billion, and return on equity (ROE) of more than 8% for fiscal 2020 as key numerical targets. In addition, for fiscal 2020, we aim to have three to five late-stage pipeline products that can be launched within the next five years with the potential to generate annual revenue exceeding ¥100.0 billion each at peak.

#### Establish Foundation for Sustainable Growth (Six Strategic Targets)

- Grow *Edoxaban*
- Grow as No. 1 Company in Japan
- Expand U.S. Business
- Establish Oncology Business
- Continuously Generate Innovative Medicine Changing Standard of Care (SOC)\*
- Enhance Profit Generation Capabilities

\* Broadly applied best treatment practice in today's medical science

### 2. Revision of Targets (Presented in October 2018)

In October 2018, we revised the 5-year business plan. Although *edoxaban*, an oral anticoagulant that is one of our global mainstay products, strongly increased its market share in Japan and Europe, achievement of the targets initially set for fiscal 2020 has become challenging. This is due to the sense of uncertainty over future growth

of Japan business as result of a radical reform of the NHI drug price system in the country, the unsuccessful development of new drugs in the U.S. pain business, and so on.

On the other hand, we decided to expand our investments to maximize the potential for our ADC franchise with *DS-8201* listed first, and based on several strong data for the ADC franchise.

Accordingly, we decided to delay our initial fiscal 2020 target (revenue of ¥1,100.0 billion, operating

profit of ¥165.0 billion, and return on equity (ROE) of more than 8%) for two years to fiscal 2022.

Meanwhile, as for returns to shareholders, we have decided to maintain the initial commitment calling for a total return ratio of 100% or more until 2022.

As for our oncology business, we decided to set a revenue target of ¥500 billion in fiscal 2025, exceeding the initial target of ¥300 billion by increasing and focusing our investment in the oncology business.



### 3. Revision Based on Impact of Strategic Alliance with AstraZeneca

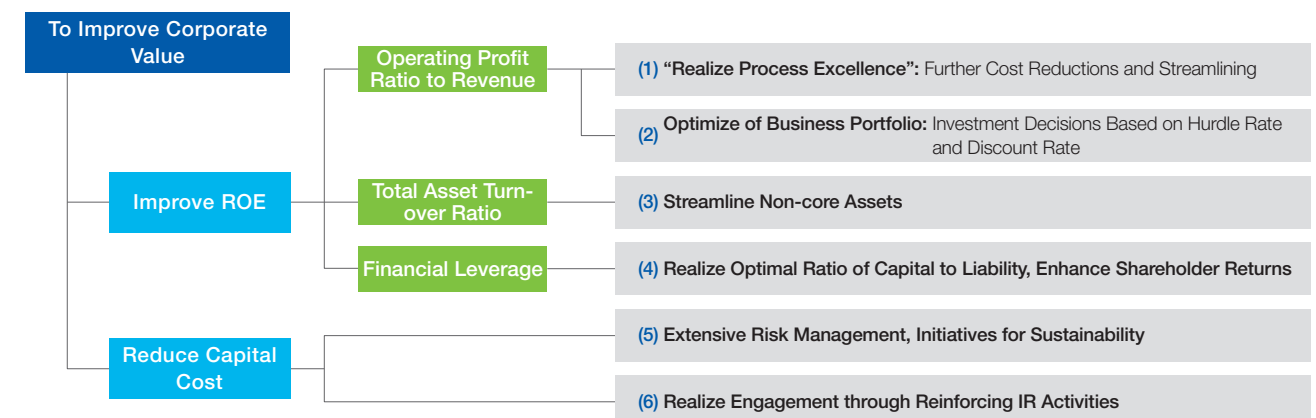
After the revision of numerical targets for the current 5-year business plan in October 2018, Daiichi Sankyo decided to form strategic alliance with AstraZeneca for *DS-8201* in March 2019. Currently, we are having discussion with AstraZeneca on the details of the

development and commercialization plan. Once we reach agreement, we will present Daiichi Sankyo's updated numerical targets including revised resource allocation for the other development projects such as *U3-1402*.

## Examples of Initiatives for Improving Corporate Value

Here, I will explain our specific ROE improvement and capital cost reduction initiatives as part of our

initiatives for improving corporate value, following (1) to (6) in the figure below.



Message from the CFO



(1) Realize Process Excellence

In order to improve the profit ratio as well as expand sales, we have taken steps to achieve further cost reductions and to streamline Daiichi Sankyo Group through activities called “Realize Process Excellence.” Major initiatives include enhancement of the procurement function and optimization of operating structures for manufacturing, marketing & sales, and R&D. Concerning the optimization of operating structures, in the past three years to fiscal 2018 since the start of

the current 5-year business plan, we have sold, closed, or transferred three sites within our supply chain organization, and closed four sites within our R&D organization. We have also implemented optimization within our marketing & sales organization in Europe and the United States. We will further accelerate initiatives to enhance profit generation capabilities in the future.

(2) Optimize Business Portfolio

In terms of investment, our focus is to optimize business portfolio by reinforcing financial investment decisions with capital cost in mind and taking synergies into consideration. When making investment decisions for the business or capital expenditure, which has significant impact on future profit, we will support such decision through reading the future business environment, vision, and strategy, and by setting the hurdle rate, discount rate and other factors in response to market and business risks.

We assumed our cost of shareholders’ equity to be approximately 6% and set forth the goal of more than 8% ROE, which is approximately 2% above the cost. Although we anticipate the WACC, the weighted average of our cost of shareholders’ equity and cost of debt, to be 5 to 6%, we use an 8% hurdle rate for investment decisions, by adding 2 to 3% to the WACC. In addition, we make investment decisions based on discount rate for each region that takes into account the characteristics of each market.

(3) Streamline Non-core Assets

We streamline non-core assets through pursuing optimization in assets and enhancing our total asset turnover ratio, while working to create free cash that will lead to improvement of corporate value. With regard to assets including real estate, we implement liquidation of non-core assets at the appropriate timing while considering not only the necessity of the assets for business activities and the ability to be replaced, but also life-cycle costs (maintenance costs needed to maintain functions subject to deterioration and renovation costs required to improve performance) and business continuity plans (BCPs). We sold real estate worth ¥11.0 billion in fiscal 2018 and ¥25.0 billion in total so far. In fiscal 2019, we also sold our Nihonbashi Building.

Sankyo’s policy of not holding listed stocks, except in cases where holding such stocks will maintain or strengthen long-term business relationship and contribute to improving our corporate value. We sold 10 stock brands for a total amount of ¥14.3 billion in fiscal 2018, and an aggregated total of 33 stock brands for a total of ¥46.0 billion so far. We will pursue further cost reductions in the future to achieve an appropriate level of capital efficiency.

In order to make prioritized investment of resources in the field of oncology, we decided to sell some of the long-listed products in Japan and recorded ¥6.3 billion in fiscal 2018. Going forward, we will continue to review our business portfolio to streamline our assets.

As a rule, we are aggressively streamlining cross-shareholdings in accordance with Daiichi

		(Billions of yen)			
		FY2016 Results	FY2017 Results	FY2018 Results	Total
Sale of properties	Sales proceeds	3.2	10.7	11.0	25.0
	Gain on sales	0.8	7.6	9.0	17.5
Reduce cross-shareholding shares	Number of stock brands	14 brands	9 brands	10 brands	Aggregated total of 33 brands
	Sales proceeds	17.3	14.4	14.3	46.0
	Gain on sales*	9.3	9.8	10.6	29.7
Gain on sales of business transfer	Gain on sales	-	-	(transferring long-listed products) 6.3	6.3

\* Booked in other comprehensive income  
Gain on sales of Takatsuki Plant transfer (¥19.0 billion) and Nihonbashi building (¥10.6 billion) will be booked in FY2019



(4) Realize Optimal Ratio of Capital to Liability, Enhance Shareholder Returns

In order to support sufficient investment to develop oncology projects including *DS-8201*, we will work to streamline our assets as well as to maintain our strong financial base. With the current equity ratio of

around 60% as a guide, Daiichi Sankyo will continue to pay stable dividends and flexibly implement share buy-back.

(5) Extensive Risk Management, Initiatives for Sustainability

Extensive risk management and initiatives for ESG are crucial in order to eliminate the risk of declining corporate value. As for extensive risk management, I oversee group-wide risk management as the CFO and risk management officer. I operate the risk management system in conjunction with an annual cycle for formulating and implementing business plans. Based on assessment of impact and the likelihood of occurrence, risks with the potential to significantly impact the management of the Company are identified through the Global Management Committee Meeting and the Board Meeting. Risk response measures are enacted as well as corrected and revised as necessary.

With regard to sustainability, Daiichi Sankyo Group also works to address many issues relative to CSR in addition to mid-to-long-term initiatives and challenges. We also engage in proactive disclosure of ESG information to reduce the risk from the viewpoint of investors. We have been selected for various ESG indices including the “DJSI World Index,” in which, we have been selected in the pharmaceutical sector for the first time as a Japanese company and also for two consecutive years.

For details, refer to page 96.

For details, refer to page 73.

(6) Realize Engagement through Reinforcing IR Activities

Engagement means having conversation with purpose, and we will foster mutual understanding and increase transparency, and thus further improve corporate value through healthy discussions between investors and our management team. In the distribution of IR information, we disclose information in a timely manner while giving consideration to transparency and fairness, and we endeavor to undertake IR activities to narrow the gap between the corporate value envisioned by people inside and outside of the Company. Following the recent enhancement of our

pipelines in particular, we have set up meetings and conference calls aimed at investors after presentations at major scientific conferences in the U.S. and Europe for better and deeper understanding among investors. In addition, we conduct more than 350 interviews with investors annually, including ten international road shows a year (interviews with international investors). As CFO, I myself engage by proactively holding conversations with investors and analysts, to realize engagement.

In Closing

Daiichi Sankyo Group aims to realize its 2025 Vision of striving to become a “Global Pharma Innovator with competitive advantage in oncology.” In light of the strong progress in oncology development with focus on ADC, we formed a strategic alliance with AstraZeneca for *DS-8201*, which is our first ADC project, in March 2019 and have been making steady progress indevelopment. From a mid-term perspective, prior investment in preparation for the launch of oncology products is anticipated in each region. With respect to business

development, demand for funds is expected to increase further to obtain pipelines, products, and businesses that meet the strategy. In addition, strategic investment from a long-term perspective is also essential. As such, I understand the role of CFO is extremely significant. Going forward, I will continue to improve corporate value by enhancing shareholder returns while paying attention to the balance between investment and profitability.



5-Year Business Plan Overview and Progress: Grow *Edoxaban*

Strategic  
Target

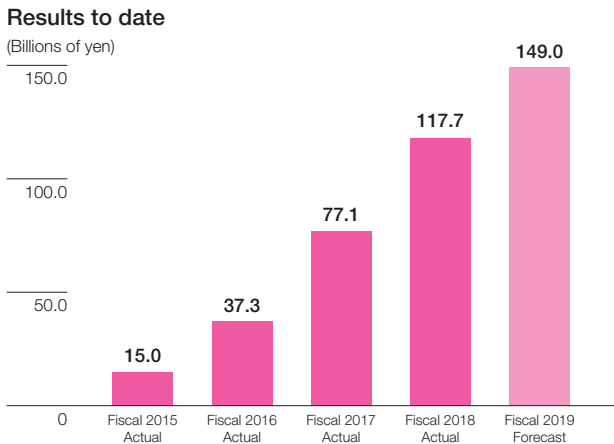
Grow *Edoxaban* Brand name: *LIXIANA* (Japan, Europe, Asia), *SAVAYSA* (U.S.)

*Edoxaban*, direct oral anticoagulant (DOAC) is a mainstay product in place of *olmesartan*, a treatment for hypertension that has expired exclusivity. Since it's marketed, the Company has steadily expanded its market share, particularly in Japan, Europe, and Asia. Going forward, we will strengthen our initiatives for life-cycle management and further raise awareness of product information. We also aim to maximize product value by successfully marketing this product in China.

*Edoxaban*'s "Edo" means that this product was born from a research institute in Tokyo. As the only made-in-Japan product in this area, we are reminded of the desire to save patients not only in Japan but also around the world.

1 5-Year business plan

The annual global revenue of *edoxaban* has steadily increased from ¥37.3 billion in fiscal 2016 to ¥77.1 billion in fiscal 2017 and ¥117.7 billion in fiscal 2018. We forecast ¥149 billion in revenue in fiscal 2019 that will be more than the initial target for fiscal 2020, ¥120 billion ahead of schedule. *Edoxaban* is growing at a much faster pace than the initial expectation.

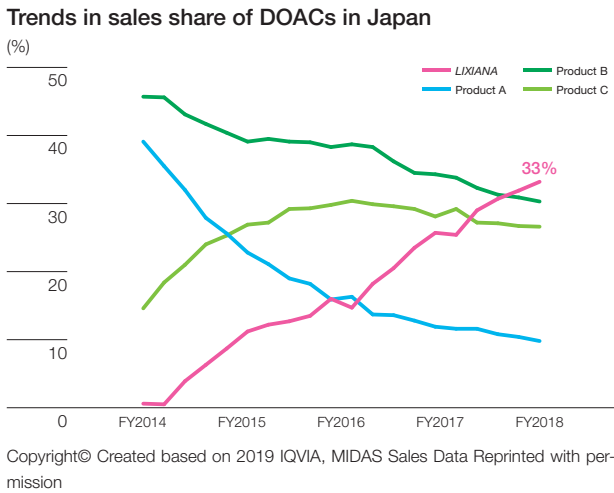


2 Progress to date

(1) Growth in Japan

Since the third quarter of fiscal 2018, we have become the No. 1 share in Japan by leveraging our product characteristics of once-daily administration and high levels of safety, as well as our high-quality marketing capabilities, which have been highly evaluated by external organizations.

Going forward, we will promote OD tablet (orally disintegrating tablet) by leveraging its strength, which is highly appreciated by doctors, saying that it is especially easy for elderly patients to take. Penetrating new evidence obtained from life-cycle management, we will try to make sure that doctors and patients will feel more reassured by anticoagulant therapy with *edoxaban*.



**Solubility of tablet**

Slow	Rapid
Conventional tablet	OD tablet
taken by water	dissolved rapidly by oral saliva

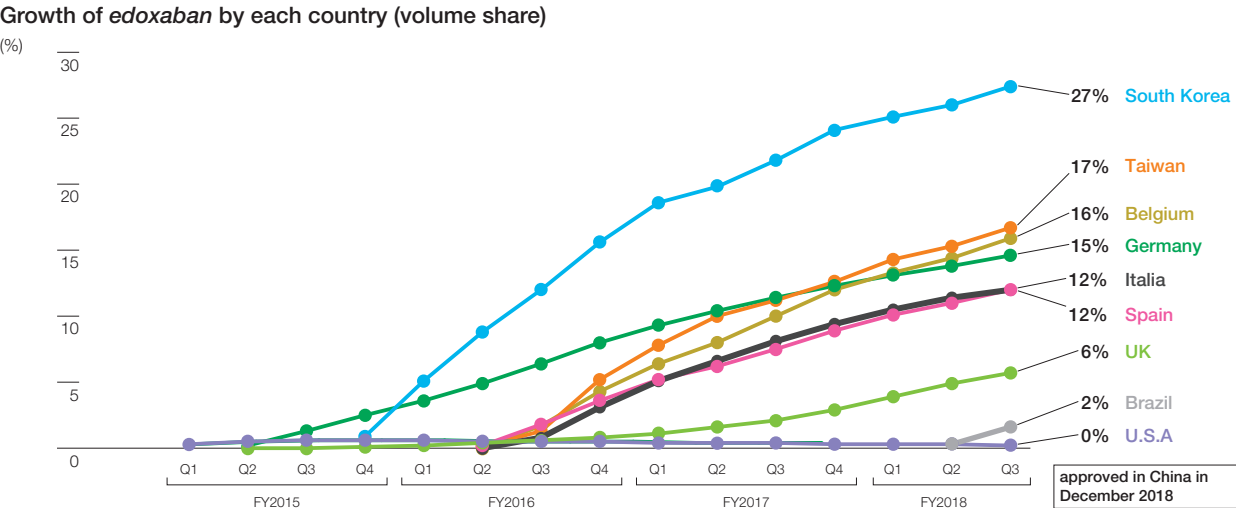
**Process of dissolving**

Sett 1 tablet on the mesh to evaluate disintegrability, using an injection barrel, drip refined water of 37 ± 2°C on the upper side of the tablet and measure the dissolving time

(2) Growth in each country

Since it's marketed, steadily increasing the number of countries in which *edoxaban* has been marketed, it has been on the market in more than 30 countries and regions globally. In addition to steady growth in Asian region like South Korea and Taiwan, as well as in

European region like Belgium and Germany, it was marketed in Brazil in August 2018 and was approved in China in December 2018. Going forward, we aim to achieve further growth by successfully marketing it in China.



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(3) Life-cycle management initiatives

Currently, we are engaged in many clinical studies and lifecycle management activities, collectively referred to as EDOSURE\*<sup>1</sup> that create data on how *edoxaban* is used in clinical settings.

The efficacy and safety data for patients undergoing catheter ablation\*<sup>2</sup> was presented in a Late Breaking Session of the European Heart Rhythm Association (EHRA) in March 2019.



\*1 Derived from two words, *edoxaban* and Assurance. It signifies our hope that doctors and patients will feel more reassured by anticoagulant therapy with *edoxaban*.

\*2 A procedure used to ablate abnormal electrical pathways in the heart tissue by inserting a thin tube (catheter) through the blood vessels to the heart in order to restore normal rhythm of the heart of patients with AF.

**What are direct oral anticoagulants?**

A blood clot usually forms to stop bleeding and will eventually dissolve and shrink. However, should a blood clot grow larger rather than dissolving, and consequently come to block a blood vessel, it could result in a lack of blood flow to areas of the body beyond the clot, potentially even leading to the death of the tissue therein. This condition is known as thrombosis.

*Warfarin* has long been the standard treatment to prevent blood clots. However, there are many restrictions to which attention needs to be paid when using *warfarin* such as periodic monitoring with blood tests,

**COLUMN**

a variety of drug interactions, and dietary restrictions. Direct oral anticoagulants including *edoxaban* have been developed to significantly improve the inconvenience of *warfarin* as mentioned above.

Diagram illustrating the effect of a direct oral anticoagulant on a venous thrombus (blood clot). The diagram shows a cross-section of a blood vessel with a thrombus (clot) blocking the flow of blood. A direct oral anticoagulant is shown acting on the clot, leading to its dissolution and the restoration of blood flow.

## 5-Year Business Plan Overview and Progress: Grow as the No.1 Company in Japan

## Strategic Target

## Grow as the No.1 Company in Japan

Japan is an important market for the Daiichi Sankyo Group in terms of its revenue generated on a regional basis. We aim to grow as the No.1 company in Japan in name and substance alike. To such ends, we will leverage the strengths of our innovative pharmaceuticals\* business, while precisely addressing various social and medical needs such as prevention, self-medication and medical treatment, with the innovative business as well as our vaccines, generics and OTC drug businesses.

\* Pharmaceuticals still protected by the exclusivity period granted by patents

## 1 5-Year business plan

In addition to *LIXIANA*, an anticoagulant developed for the global market, the innovative pharmaceuticals business is developing its operations centered around six major products: *NEXIUM*, an ulcer treatment; *Memary*, an Alzheimer's disease treatment; *PRALIA*, a treatment for osteoporosis that prevents the progression of bone erosion associated with rheumatoid arthritis; *RANMARK*, a treatment for bone complications caused by bone metastasis from tumors; *Efient*, an antiplatelet agent; and *TENELIA*, a type 2 diabetes mellitus treatment.

Of these, *NEXIUM*, *Memary*, *PRALIA*\* and *RANMARK* have achieved the No.1 shares in their respective markets.

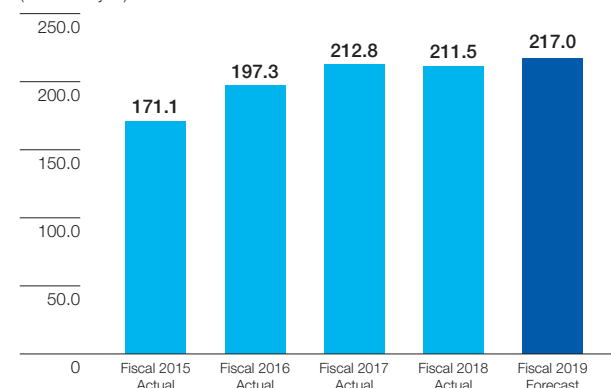
\* No. 1 in the bone resorption inhibitor market

Total revenue from the six major products has steadily expanded, from ¥197.3 billion in fiscal 2016 to ¥212.8 billion in fiscal 2017. However, in fiscal 2018, revenue remained almost unchanged at ¥211.5 billion, due to factors such as significant reduction in the drug price of *NEXIUM*, which are more severe than expected at the time of the 4th mid-term business plan announcement.

In fiscal 2019, revenue are expected to increase y-o-y to ¥217.0 billion, despite the impact of the drug price revision. Although the market environment is becoming increasingly challenging, we will leverage our extensive product portfolio and excellent sales capabilities to achieve our fiscal 2020 target of ¥243 billion in revenue.



Results to date  
(Billions of yen)



(Total of the 6 products above, including the impact of NHI drug price revisions.)

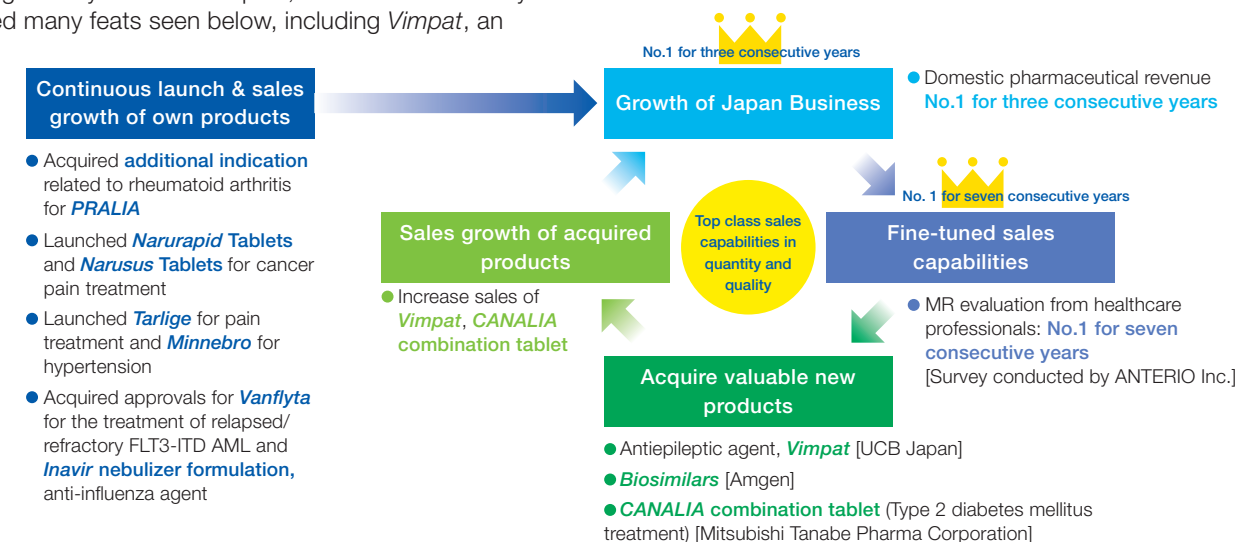
## 2 Progress to date

By continually launching and expanding sales of proprietary developed products, we grew the innovative pharmaceuticals business. At the same time, we utilize the Company's superb sales capabilities to acquire licenses for promising products in order to sustain a virtuous cycle driving further growth. Through these efforts, we are working to strengthen Daiichi Sankyo's presence in Japan.

During the 5-year business plan, we have successfully achieved many feats seen below, including *Vimpat*, an

epileptic agent, and *CANALIA* combination tablet, a treatment for type 2 diabetes mellitus, growing with a sales revenue target of ¥10 billion or more for fiscal 2019. Furthermore Daiichi Sankyo has ranked No.1 both in MR evaluation\*, which is an important foundation for sustainable growth, for seven consecutive years, and in revenue from pharmaceutical products in Japan for three consecutive years.

\* Based on survey conducted by ANTERIO Inc.



In fiscal 2019, we will add to our product portfolio our in-house developed drugs, *Tarlige* for pain treatment and *Minnebro* for hypertension, and *Vanflyta*, a promising new cancer product. We will aim to quickly nurture these new products.

Through aggressive in-licensing activities, we will win promising in-licensing products to overcome the challenging market environment.

*Tarlige* for pain treatment, Launched in Apr. 2019



*Minnebro* for hypertension, Launched in May 2019



*Vanflyta* for the treatment of relapsed/refractory FLT3-ITD AML, Approved in Jun. 2019



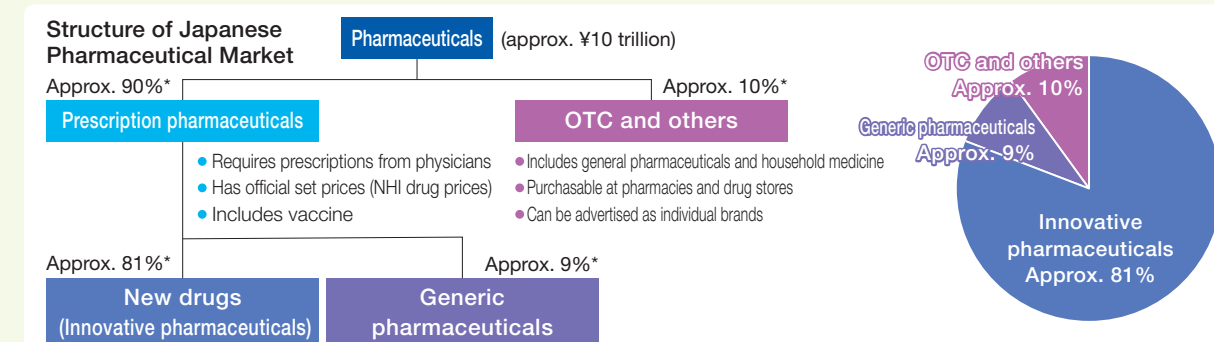
## COLUMN

## Pharmaceutical Market in Japan

The pharmaceutical market in Japan is worth approximately ¥10 trillion, of which approximately 90% is comprised of prescription pharmaceuticals that require prescriptions from physicians with the remainder of the market being accounted for by general pharmaceuticals and other over-the-counter (OTC) drugs that can be

freely purchased in pharmacies and drug stores. Moreover, the use of generic drugs has been increasing in the prescription pharmaceutical market, and these drugs have recently come to represent about 73% of the market on a sales-volume basis\* in September 2018.

\* Generic drugs ÷ (original drugs for which generic drugs have been released + generic drugs)



\* Share of market based on monetary value

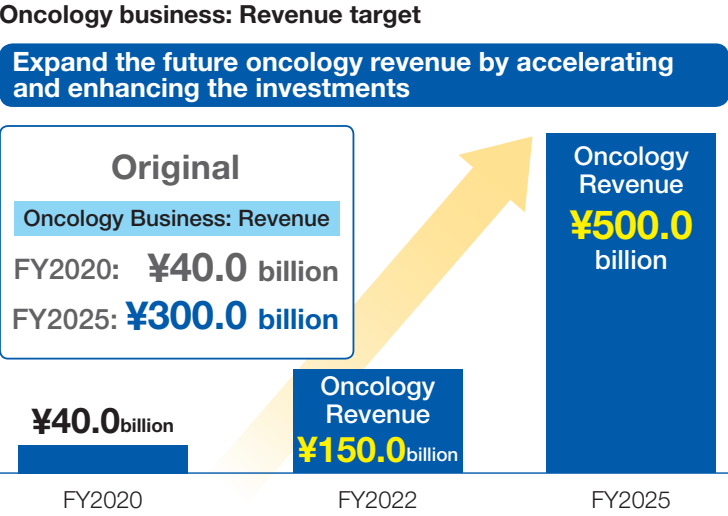


# Establish Oncology Business

In our 5-year business plan, we set up the target of growing oncology business revenue to ¥300.0 billion in fiscal 2025. Last year, we raised it to over 500 billion yen. The development of the ADC franchise centered on *DS-8201* and AML franchise have been steadily accelerating. In fiscal 2019, we obtained approval of *quizartinib* and *pexidartinib*, and plan to submit *DS-8201* for approval.

## 1 5-Year Business Plan

We will establish an oncology business by launching several drugs currently in late-stage development. Concurrently, we will accelerate early-stage pipeline development and evaluate the further enrichment of our oncology pipeline through the acquisition of external assets. Through the acceleration of oncology research and development, we aim to grow oncology business revenue to more than ¥40.0 billion in fiscal 2020, ¥150.0 billion in fiscal 2022 and ¥500.0 billion in fiscal 2025, when this business will function as a core business.



## 2 Progress to Date and Future Initiatives

Daiichi Sankyo has been promoting organizational changes and strengthening human resources in order to accelerate development in the oncology area. We have completed organizational changes and have completed recruiting excellent global leaders with long years of experience in the oncology area.

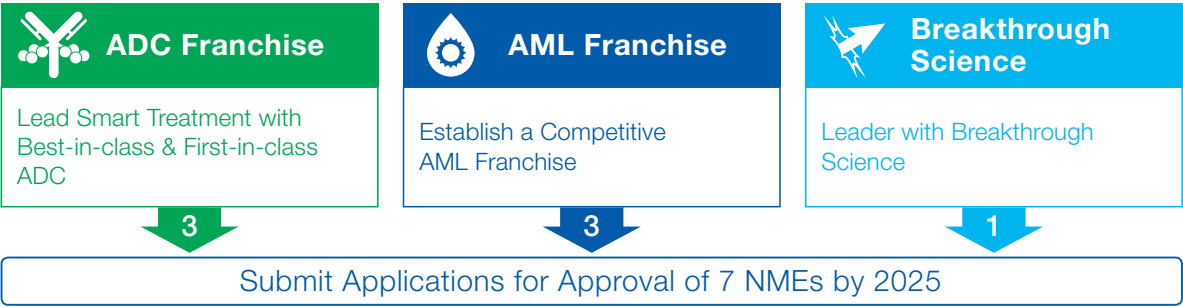
Our organizations such as research and development, pharmaceutical technology, supply chain, global marketing, and global medical affairs cooperate organically under these leaders, and all employees are working together to promote a transformation to become a “Global Pharma

Innovator with competitive advantage in oncology.”

The Oncology R&D sub unit has established three pillars, antibody drug conjugate (ADC) franchise, acute myeloid leukemia (AML) franchise, and breakthrough science\* that we will focus on.

We are aiming to become a world-leading science organization built on these three pillars and to deliver seven valuable new molecular entities (NMEs) over eight years by 2025.

\* New treatment that changes cancer treatment by applying innovative science and technology



## 3 About Cancer

Cancer is one of the diseases with high prevalence and mortality both in Japan and worldwide. Every year, approximately 14 million people are newly diagnosed with cancer across the world. In Japan, cancer has been the leading cause of death since 1981, while in 2018, annual cancer deaths reached approximately 410,000 people. Given these statistics, cancer has a devastating impact on human life and health.

**Cancer death (all types of cancer) 2018**  
(Thousands/year)

	Worldwide	Japan	U.S.	Europe
	9,555	409	617	1,943

Source: GLOBOCAN 2018, FACT SHEET

Number of new patients, number of patients with recurrent disease, 5-year survival (2018)

		Japan	U.S.	5 European countries
Breast cancer	Newly diagnosed cancer (n)	92,000	327,000	262,000
	Recurrent cancer (n)	11,000	35,000	37,000
	5-year survival (%)	90%	85%	—
Gastric cancer	Newly diagnosed cancer (n)	130,000	26,000	56,000
	Recurrent cancer (n)	23,000	11,000	25,000
	5-year survival (%)	61%	24%	—
Non-small-cell lung cancer	Newly diagnosed cancer (n)	114,000	189,000	196,000
	Recurrent cancer (n)	40,000	65,000	72,000
	5-year survival (%)	38%	18%	—
Colorectal cancer	Newly diagnosed cancer (n)	144,000	157,000	239,000
	Recurrent cancer (n)	18,000	34,000	54,000
	5-year survival (%)	64%	56%	—

Source: CancerMPact®, Kantar Health/Synix Inc.(Strict diversion of confidential information)

## 4 Cancer Treatment

### (1) Cancer treatment

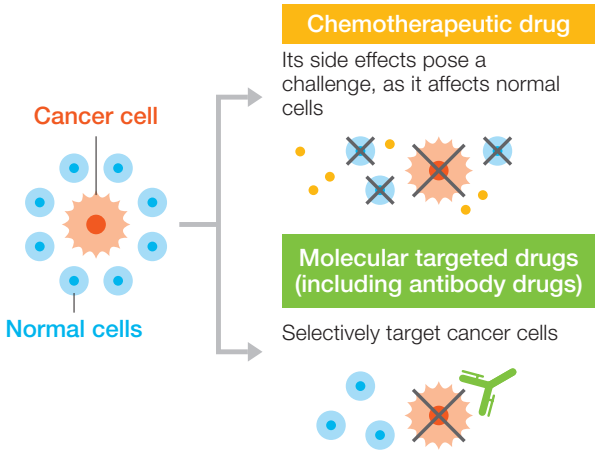
Cancer treatments are divided into two categories: systemic therapy and local therapy. Local therapy consists of surgery and radiotherapy.

	Type	Methodology	Characteristics
Systemic therapy	Drug therapy	Attacks cancer cells with drugs	• A mainstay of treatment if local therapy is inappropriate such as hematological cancer or metastatic disease
Local therapy	Surgery	Removes cancer surgically	• Cancer can be cured if it remains in the primary lesion
	Radiotherapy	Eliminates cancer cells with radiation	• Exerts therapeutic effects without surgically removing organs • Sometimes combined with drug therapy and surgery

### (2) Drug therapy (chemotherapeutic drugs and molecular targeted drugs)

Previously, chemotherapeutic drugs played a principal role in drug therapy. Chemotherapeutic drugs are small molecule drugs that produce therapeutic effects on highly proliferative cells. They also affect to maintain function, such as gastrointestinal and bone marrow cells. This impact on normal cells are the cause of most of the chemotherapy-induced side effects.

On the other hand, molecular targeted drugs target genes and proteins that are highly expressed in cancer cells. They are less likely to affect rapidly dividing normal cells. Although molecular targeted drugs have their own unique side effects, they have relatively fewer side effects than conventional chemotherapeutic drugs.



Daiichi Sankyo's ADC (Antibody Drug Conjugate)

1 What is ADC?

An ADC, which is short for Antibody Drug Conjugate, is an agent that covalently combines an antibody with a chemotherapeutic drug, payload, through a linker. Antibody drugs and chemotherapeutic drugs each have their own advantages and disadvantages, but ADC has the potential to exploit the strengths of both while mutually compensating for the disadvantages of both drugs.

Antibody drug

- High target selectivity
- Fewer side effects, relative to chemo
- Sometimes insufficient efficacy

Chemotherapeutic drug

- Low target selectivity
- Many potential side effects
- Potent anti-tumor effects (cytotoxic activity)

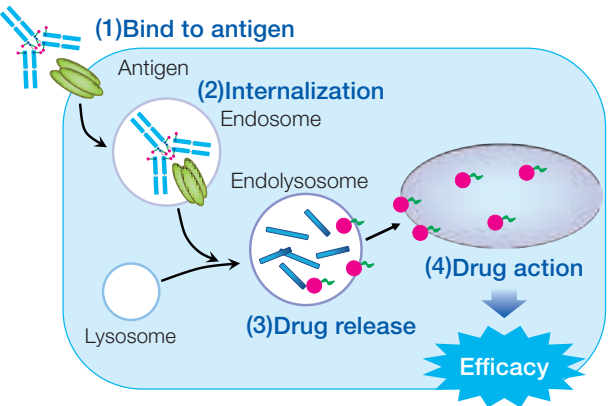
ADC

- High target selectivity
- Potent anti-tumor effects (cytotoxic activity)
- Fewer side effects, relative to chemo

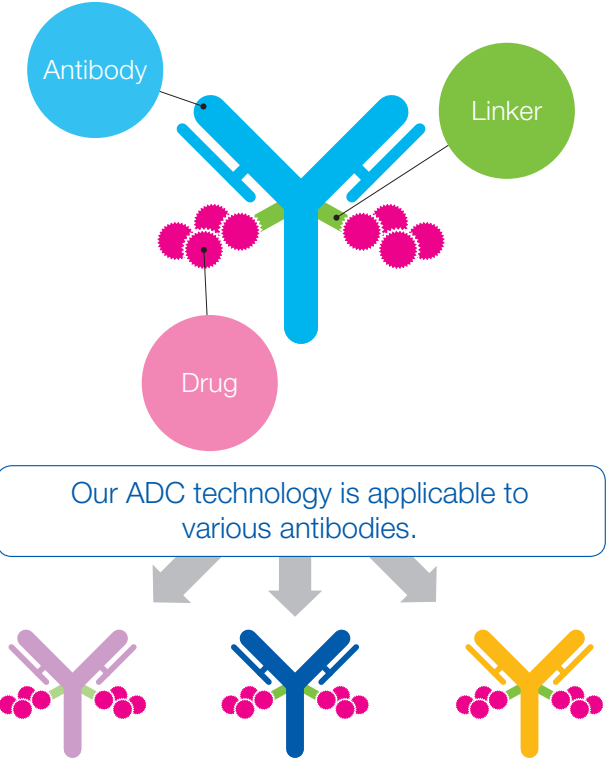
2 Mechanism of Action with ADC

ADC exerts its therapeutic effects through the following steps:

- (1) ADC binds to an antigen on the surface of a cancer cell
- (2) Subsequently, ADC-antigen complex is internalized into the cancer cell
- (3) Lysosomes cleaves the ADC linker in the cancer cell, resulting in the release of the cytotoxic payload
- (4) Cancer cells undergoes therapeutic effects by the released payloads



3 Structure of Daiichi Sankyo's ADC



4 Characteristics of Daiichi Sankyo's ADC

Daiichi Sankyo began development on ADC technology in 2010. There were already preceding products in the market that used ADC technology at that time, and our entry to the research and development was certainly not early. Daiichi Sankyo's researchers screened over 100 types of linkers to bind the antibody to the payload. The key aim was to overcome the shortcomings of existing ADC technology. These efforts ultimately produced the ADC construct used in DS-8201 and other ADC products. The main characteristics of this technology are summarized in the figure below.

Each characteristic is described in detail on the following page.

Characteristic 1	New payload	Characteristics of Payload
Characteristic 2	High potency of payload	
Characteristic 3	Bystander effect	
Characteristic 4	Payload with a short systemic half-life	
Characteristic 5	Stable linker	Characteristics of Linker
Characteristic 6	Tumor selective cleavable linker	
Characteristic 7	High drug-antibody ratio	

Characteristic 1

New payload

The payload of Daiichi Sankyo's ADCs currently in the research and development stage is *DXd*, a new derivative of the DNA topoisomerase I inhibitor *DX-8951* created by former Daiichi Pharmaceutical. As a cytotoxic in early development of *DX-8951* had promising potency, but with an unacceptable risk-benefit profile.

Characteristic 2

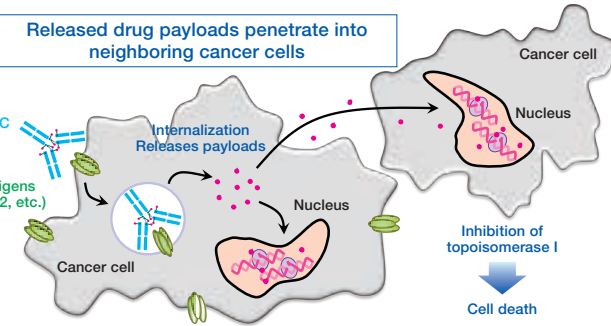
High potency of payload

*DXd* is approximately 10 times as potent as *SN-38* (the active metabolite of irinotecan featuring the same mechanism of action). Providing further rationale was the pre-clinical pharmacology finding that demonstrated that *DXd* is effective in cancer cells that are less sensitive or resistant to the payload of *T-DM1*, the standard of care for certain type of HER2 positive breast cancer.

Characteristic 3

Bystander effect

The "bystander effect" means a process where after the ADC binds to an antigen expression-positive cancer cell (HER2 positive, for example), the payload is released from the ADC in the cancer cell, penetrates the membrane, and exerts cytotoxic effects on neighboring cancer cells. The *DXd* payload is designed to have higher lipophilicity and membrane permeability. In general, antigen expression-positive cancer cells and antigen expression-negative cancer cells are present concomitantly in the tumor microenvironment. Through this bystander effect, it is hypothesized that the drug has also impacts on tumors with a high proportion of cancer cells that are antigen expression-negative.



Characteristic 4

Payload with a short half-life in the blood

After intravenous administration, an increased blood concentration of drug payloads released from an ADC has the potential to cause side effects. Daiichi Sankyo's drug payload is less likely to be released while in the blood because of its stable linker, and the drug payload is designed to be eliminated quickly from the blood (a short half-life) following release.

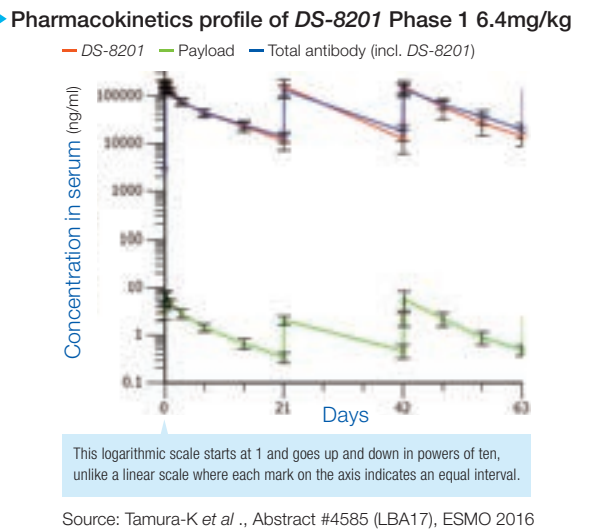
Payloads	Half-life in rats (hours)
<i>DXd</i> *1 (payload of Daiichi Sankyo's ADC)	0.9
<i>DM1</i> *2 (payload of <i>T-DM1</i> )	3.3-10

Source: \*1 In-house report \*2 KADCYLA BLA

Characteristic 5

Stable linker

For ADC technology to exhibit cancer cell-specific efficacy, the payloads must be reliably delivered to cancer cells, and here the linker plays an important role. If the linker is unstable, the ADC may degrade after administration and the payloads will be released in the blood. This can reduce efficacy before the payloads are carried to the cancer cells, and can potentially cause side effects if the payloads affect normal cells. Pharmacokinetic analysis of the phase 1 study has confirmed the in vivo stability of Daiichi Sankyo's ADC construct. The graph below demonstrates that the linker is stable by showing that the blue line representing the blood concentration of antibodies (antibodies present as ADC and the antibody following ADC degradation) high overlap with the red line representing the blood concentration of *DS-8201*.



Characteristic 6

Selectively cleaved linker in cancer cells

The linker must be stable in the blood and yet readily release its payload once internalized into the cancer cell following binding to the cancer-cell antigen. The linker of Daiichi Sankyo's ADC is cleaved by enzymes including cathepsins, which are highly expressed in cancer cells, causing payload release. Therefore, the possibility of the linker being cleaved in parts other than cancer cells is minimized. In addition, the cleavage site is situated at an appropriate location for efficiently releasing the payload inside cancer cells.

Characteristic 7

High drug-antibody ratio

The drug-antibody ratios (the number of payloads held on a single antibody) for currently approved ADCs range unevenly between two and seven, whereas Daiichi Sankyo's ADC can load a maximum of eight payloads with high uniformity. Historically, ADCs bearing more payloads per antibody cause aggregation after being formulated. But Daiichi Sankyo's ADC construct and its formulation minimizes aggregation, even with the high DAR. For example, *DS-8201* and *U3-1402* have a DAR of eight, but they are highly uniformed. Furthermore, we possess technology to control the drug-antibody ratios according to antigen expression and internalization rates. For example, *DS-1062* is optimized as a DAR of four.



Daiichi Sankyo's ADC Franchise

At present, Daiichi Sankyo has seven ADC projects for different antibody targets with the same linker and payload.

Clinical trials began for *DS-8201*, *U3-1402*, and *DS-1062* are in progress, with data presented at numerous medical conferences. Phase 1 studies are slated to start in fiscal 2019 for *DS-7300* and *DS-6157*.

ADC franchise pipeline

Project (target)	Preceded indications	Discovery	Pre-clinical	Phase 1	Pivotal
<i>DS-8201</i> (HER2)	Breast cancer Gastric cancer Colorectal cancer Non-small-cell lung cancer				
<i>U3-1402</i> (HER3)	Breast cancer Non-small-cell lung cancer				
<i>DS-1062</i> (TROP2)	Non-small-cell lung cancer				
<i>DS-7300</i> (B7-H3)	Solid tumors			Start clinical study in FY2019	
<i>DS-6157</i> (GPR20)	Gastrointestinal stromal tumor (GIST)			Start clinical study in FY2019	
<i>DS-6000</i> (undisclosed)	Kidney cancer Ovarian cancer				
Project code pending (TA-MUC1)	Solid tumors				

DS-8201 development plan (as of April 2019)

	FY2018	FY2019	FY2020	FY2021	FY2022
Multiple Tumors	P1	Graphs and charts in this section are from this study			
Breast cancer (Global)	HER2 positive breast post <i>T-DM1</i> pivotal P2				
	HER2 positive breast post <i>T-DM1</i> vs. phys choice P3				
	HER2 positive breast vs <i>T-DM1</i> P3				
	HER2 low breast P3				
Gastric cancer (Global)	HER2 expressing gastric 3rd line vs phys choice pivotal P2 (JP/Asia)				
	HER2 expressing gastric 2nd line vs SOC P3(JP/Asia)				
	HER2 expressing gastric P2 (US/EU)				
Colorectal cancer	Colorectal cancer P2				
Lung cancer (Global)	Non-small cell lung cancer P2				
Combination with IO/TKI	Breast/bladder with <i>nivolumab</i> P1b				
	Breast/NSCLC with <i>pembrolizumab</i> P1b				
	Solid tumor with <i>avelumab</i> P1b				
	Solid tumor with <i>TKI</i> P1b				

1 DS-8201 (anti-HER2-ADC)

*DS-8201* is an anti-HER2 antibody-drug conjugate which our proprietary linker and payload are conjugated to anti-HER2 antibody. This project is most advanced of our ADC franchise, with clinical studies underway in breast cancer, gastric cancer, lung cancer, colorectal cancer, and bladder cancer.

( 1 ) What is HER2?

HER2 is an antigen found on the cell surface. It has a structure similar to the epidermal growth factor receptor (HER1/EGFR). It is a receptor tyrosine kinase associated with cell proliferation. HER2, which is overexpressed on the surface of cancer cells, such as those of breast cancer, gastric cancer, colorectal cancer, lung cancer, and bladder cancer, induces cancer cell proliferation by activating signal transmission.

*DS-8201* exerts its efficacy by binding to this HER2.

( 2 ) DS-8201 overall development plan

The figure below shows the overall development plan for *DS-8201* as of April 2019. We are currently discussing the future development plan with AstraZeneca.

( 3 ) Phase 1 study for multiple tumor targets

In the phase 1 study, which was started in September 2015, *DS-8201* was administered to approximately 300 patients with HER2-expressing breast cancer, gastric cancer, colorectal cancer, lung cancer, and other solid tumors. Although they were heavily pre-treated, many of them showed a significant response irrespective of cancer types.

Interim data from this study was presented at American Society of Clinical Oncology (ASCO), European Society for Medical Oncology (ESMO), World Conference on Lung Cancer, and San Antonio Breast Cancer Symposium (SABCS) in 2018.

In addition, papers on the breast cancer and gastric cancer from phase 1 study were accepted in April 2019 by the journal *The Lancet Oncology*. The major data compared to similar drugs are shown below.

Regarding breast cancer, overall response rate (ORR) was 59.5%, duration of response (DOR) was 20.7 month and overall survival (OS) was not reached in patients who were treated by *DS-8201* after progression with *T-DM1*, standard therapy for second line treatment.

Regarding gastric cancer, ORR was 43.2%, DOR was 7.0 months and OS was 12.8 months in patients who were treated by *DS-8201* after progression with *trastuzumab*, standard therapy for first line treatment.

This trial is fully enrolled, and final results will be presented at a future international medical conference.

Phase 1 study breast cancer, comparison to similar drugs

Breast	<i>Pertuzumab</i> + <i>trastuzumab</i> + <i>docetaxel</i> ( 1L ) <sup>*1</sup>	<i>T-DM1</i> ( 1L, failed study ) <sup>*2</sup>	<i>T-DM1</i> ( 2L ) <sup>*3</sup>	<i>T-DM1</i> ( 3L+ ) <sup>*4</sup>	<i>DS-8201</i> <sup>*5</sup>
mPFS	18.5m	14.1m	9.6m	6.2m	22.1m
DoR	20.2m	20.7m	12.6m	9.7m	20.7m
OS	56.5m	53.7m	30.9m	22.7m	NR
ORR	80%	60%	43.6%	31%	59.5%
Median prior Rx for adv. disease	0	0	1	4	7 100% prior <i>T-DM1</i> 88% prior <i>pertuzumab</i>

<sup>\*1</sup> CLEOPATRA (NEJM 2012), <sup>\*2</sup> MARIANNE (J Clin Oncol 2017), <sup>\*3</sup> EMILIA (NEJM 2012), <sup>\*4</sup> TH3RESA (*The Lancet Oncol* 2017) <sup>\*5</sup> *The Lancet Oncology*, 29 April 2019, m: Months, NR:Not Reached

Phase 1 study gastric cancer, comparison to similar drugs

Gastric	<i>Trastuzumab</i> + Chemo ( 1L ) <sup>*1</sup>	<i>Ramucirumab</i> + Chemo ( 2L ) <sup>*2</sup>	<i>T-DM1</i> ( failed study; 2+L ) <sup>*3</sup>	<i>DS-8201</i> <sup>*4</sup>
mPFS	6.7m	4.4m	2.7m	5.6m
DoR	6.9m	4.4m	4.3m	7.0m
OS	13.8m	9.6m	7.9m	12.8m
ORR	47%	28%	21%	43.2%
Median prior LoT	0	1	1	3

<sup>\*1</sup> ToGA (*The Lancet* 2010), <sup>\*2</sup> RAINBOW (*The Lancet Oncol.* 2014), <sup>\*3</sup> GATSBY (*The Lancet Oncol.* 2017), <sup>\*4</sup> *The Lancet Oncology*, published April 29, 2019, LoT: Line of Therapy, m: Month

COLUMN

Listing of abbreviations

Abbreviations	English	Implications
CR	Complete response	Complete response (complete resolution of cancer)
DCR	Disease control rate	Disease control rate (percentage of patients with controlled disease status)
DOR	Duration of response	Duration of response (duration of response)
DLT	Dose limiting toxicity	Dose-limiting toxicities (toxicities that may explain the inability to escalate doses)
MTD	Maximum tolerated dose	Maximum tolerated dose (Maximum dose of a drug that can be administered without causing unacceptable side effects)
ORR	Overall response rate	Overall response rate (expressed as the proportion of patients who responded to treatment and the sum of CR and PR)
OS	Overall survival	Overall survival (time from start of treatment to death)
PD	Progress disease	Disease progression (worsening disease despite treatment)
PFS	Progression-free survival	Progression-free survival (without cancer progression)
PR	Partial response	Partial response (a reduction in the size of the cancer by 30% or more that lasts for 4 weeks)
SD	Stable disease	The size of the cancer is almost unchanged before and after treatment

Overview and progress of 5-Year Business Plan: Establish Oncology Business

( 4 ) Interstitial lung disease

Interstitial lung disease is a group of disorders that damage the walls of the alveoli in the lungs and the spaces around the blood vessels and small airways. It is usually diagnosed by chest X-ray or chest CT. Over 380 drugs are known to induce ILD and other respiratory diseases, with significant issues being that the majority of ILD emerges from unpredictable, or idiosyncratic circumstances. Drug-related ILD is diagnosed by distinguishing signs and symptoms (such as fever, cough, and shortness of breath) from other disorders.

ILD has been recognized as a critical adverse event for *DS-8201* from the earliest stage of the program. And a decision was taken to evaluate all suspected ILD cases via an external and independent adjudication committee. At the December 2018 San Antonio Breast Cancer Symposium (SABCS), interim data on suspected ILDs was presented for the 665 cases treated with *DS-8201*.

Of the 665 cases, 66 cases (9.9%) were reported by the investigator to be potential ILD cases. Of these, a lower occurrence of 15 out of 269 cases (5.6%) was found in

breast cancer patients treated with the low dose of 5.4 mg/kg. As a result, the dosage to be used in 3 breast cancer phase 3 trials was set to 5.4 mg/kg.

As early detection and early treatment is considered important in stopping ILDs from worsening, all study protocols were revised spring 2019. Prior to participating in the study, patients receive an explanation on the risks of ILDs when obtaining informed consent. They are then asked to immediately contact the physician in charge of their treatment should any symptoms or signs indicating the possibility of ILD appear. We also provide information to healthcare professionals about monitoring, evaluating, interruption of *DS-8201* as needed and the treatment information of potential ILD symptoms.

These changes of protocol are made to all our ADC projects.

We continue to recognize ILD as critical adverse events and continue monitoring safety. At the same time, we are actively organizing a broad campaign to further drive awareness of safety use.

► Number of ILDs by severity in all patients

Population	Adjudication status	Grade					Total
		1	2	3	4	5	
All subjects All doses, N = 665	Investigator reported, n (%)	30 (4.5)	23 (3.5)	6 (0.9)	2 (0.3)	5 (0.8)	66 (9.9)
	Cases adjudicated, n	16	13	4	0	5	38
	Adjudicated as drug-related ILD, n	11	12	3	0	4	30

► Number of ILDs by severity in breast cancer patients treated with 5.4 mg/kg

Population	Adjudication status	ILD Severity Grade					Total
		1	2	3	4	5	
Breast Cancer 5.4 mg/kg N = 269	Investigator reported, n (%)	8 (3.0)	4 (1.5)	2 (0.7)	0	1 (0.4)	15 (5.6)
	Cases adjudicated, n	3	3	0	0	1	7
	Adjudicated as drug-related ILD, n	2	2	0	0	1	7

Source: Powell et al., Abstract #P6-17-06, SABCS 2018

COLUMN

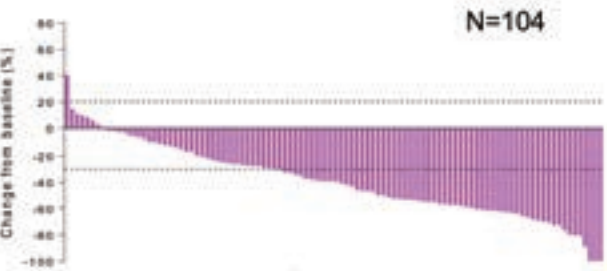
Grades of adverse events	
Grade 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
Grade 2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL
Grade 3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death related to adverse event

( 5 ) Progress of HER2 positive breast cancer clinical studies

HER2 positive breast cancer treatment has significantly improved compared to previous treatments with the emergence of *trastuzumab*, *pertuzumab*, *T-DM1*, which are HER2 targeted drugs. Even so, we believe that there still remains many challenges to be dealt with, such as patients refractory to treatment with existing drugs and attenuation of drug efficacy due to acquired drug resistance.

The graph below is a waterfall chart representing efficacy in HER 2 positive metastatic breast cancer patients. Favorable effects are suggested, despite the condition of some patients worsening post-treatment with *trastuzumab* and *T-DM1* (some with *pertuzumab*).

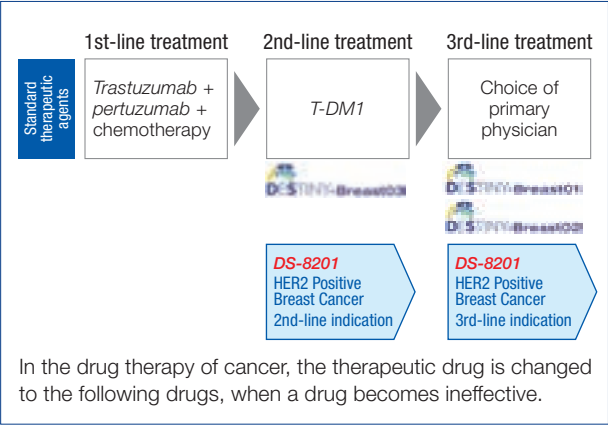
► HER2 positive breast cancer (SABCS 2018)



Source: Iwata-H et al., Abstract #2501, ASCO 2018

Currently, 1) pivotal phase 2 study for third line treatment (post *T-DM1*) of HER2 positive metastatic breast cancer (DESTINY-Breast01 study), 2) phase 3 study for the same treatment (DESTINY-Breast02 study), and 3) phase 3 study for second line treatment (vs. *T-DM1*) of HER2 positive metastatic breast cancer (DESTINY-Breast03 study) are being conducted in Japan, the United States, Europe, and Asia.

► HER2 positive breast cancer drug therapy



In the drug therapy of cancer, the therapeutic drug is changed to the following drugs, when a drug becomes ineffective.

Topline results for the DESTINY-Breast01 study were obtained in April 2019, achieving the initial goals set out for the study. In response, we will submit applications in the United States during the first half of fiscal 2019, in Japan during the second half of fiscal 2019, and in Europe during the first half of fiscal 2020.

The US FDA has granted a Breakthrough Therapy Designation for the treatment of metastatic breast cancer beyond third line treatment. As a result, a faster review period compared to regular reviews is expected.

► HER2 positive metastatic breast cancer 3rd line submission plan

US	Japan	EU
Submit application in the first half of fiscal 2019	Submit application in the second half of fiscal 2019	Submit application in the first half of fiscal 2020
Estimated evaluation time: 6 months after application is received by FDA	Estimated evaluation time: Up to 12 months after application	Estimated evaluation time: 12 months after application
Fast Track Designation <sup>*1</sup> Breakthrough Therapy Designation (Breakthrough Therapy) <sup>*2</sup>		

<sup>\*1</sup> A system in the U.S. aimed at expediting the development and review of drugs that can be expected to have a high therapeutic effect on severe unmet medical needs

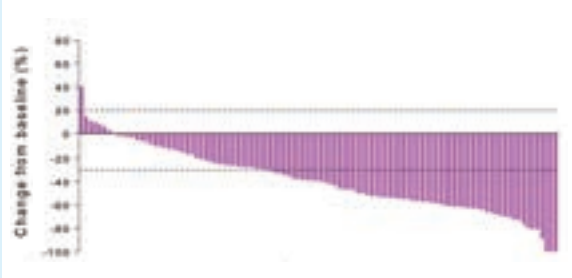
<sup>\*2</sup> A system that facilitates the development and review in the U.S. of drugs that may be more effective than existing drugs for serious diseases

COLUMN

How to Read Graphs

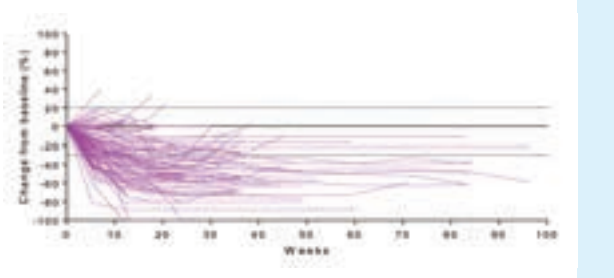
Waterfall Chart

Maximum tumor shrinkage from baseline tumor status prior to drug administration. Each bar represents the outcome of each patient, from right to left, with a high rate of cancer shrinkage.



Spider Plot

Relationship between percent change in tumor size and duration of treatment. Each line represents the outcome of each patient.





Overview and progress of 5-Year Business Plan: Establish Oncology Business

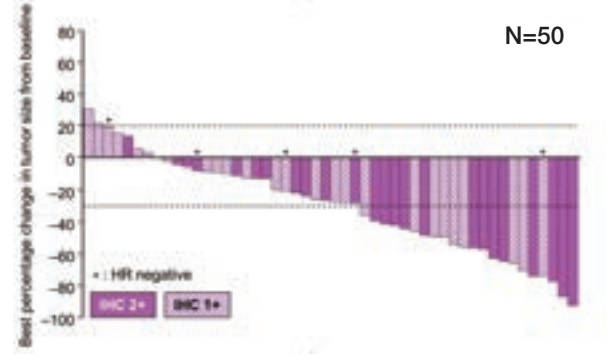
( 6 ) Progress of HER2 low expression breast cancer clinical study

To date, breast cancers HER2 status has been classified into two types by immunostaining that detects expression: HER2-positive and HER2-negative. However, it has been revealed that HER2 is expressed (IHC2+/ISH-, IHC1+) in some types of breast cancers classified as HER2-negative. For the purposes of our clinical development program, we are now calling these patients “HER2 low”. It is said that HER2 low accounts for approximately 44% of breast cancer patients. To date, there are no approved HER2 targeted agents that have shown clinical benefit for patients with HER2-low tumors.

The graph below is a waterfall chart representing efficacy in HER 2 low metastatic breast cancer patients. Even though some patients were heavily pre-treated, favorable effects, ORR 44%, are suggested.

Based on this result, a phase 3 study (DESTINY-Breast04 study) is currently underway for patients with HER2 low expressing metastatic breast cancer.

►HER2 low expressing breast cancer (SABCS 2018)



	Confirmed ORR, n/N (%)	Confirmed DCR, n/N (%)	Duration of Response, median (range), mo	PFS, median (95% CI), mo
All (N = 51)	19/43 (44.2)	34/43 (79.1)	9.4 (1.5+, 23.6+)	7.6 (4.9, 13.7)
Subgroups				
IHC 1+ (n=27)	7/21 (33.3)	14/21 (66.7)	7.9 (2.1+, 11.3)	5.7 (1.4, 7.9)
IHC 2+ (n=24)	12/22 (54.5)	20/22 (90.9)	11.0 (1.5+, 23.6+)	13.6 (NA)
HR+ (n=45)	18/38 (47.4)	31/38 (81.6)	11.0 (1.5+, 23.6+)	7.9 (4.4, 13.7)
Prior CDK4/6 inhibitor (n=15)	4/12 (33.3)	9/12 (75.0)	NR	7.1 (NA)

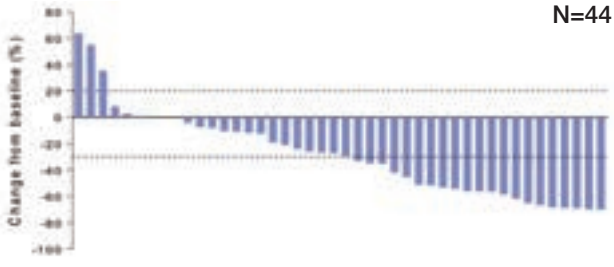
Source: Modi-S et al., Abstract #P6-17-02, SABCS 2018

( 7 ) Progress of gastric cancer clinical study

About 10% to 20% of gastric cancer patients overexpress HER2. However, while *trastuzumab* has been approved for first line treatment, no other HER2-targeting drug has been approved following progression after *trastuzumab*.

The graph below is a waterfall chart representing efficacy in HER 2 positive metastatic gastric cancer patients. As this interim data shows, *DS-8201* exhibits high antitumor activity even for HER2 positive metastatic gastric cancer.

►HER2 positive gastric cancer (ASCO 2018)



Source: Iwata-H et al., Abstract #2501, ASCO 2018

Based on this result, a phase 2 study (DESTINY-Gastric01 study) is currently underway in Japan and in Asia for patients with HER2 positive metastatic gastric cancer post *trastuzumab*. The study is proceeding with the goal to submit an application for approval by the first half of fiscal 2020.

The Ministry of Health, Labour and Welfare of Japan has granted a SAKIGAKE Designation for this indication, resulting in a potentially faster review period.

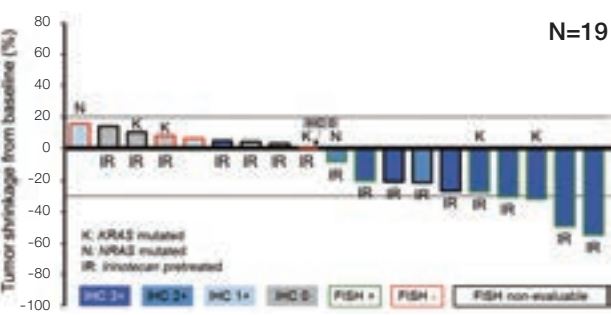
In addition to the study in Japan and the Asia, a phase 2 study for patients in the US and Europe is planned to start in fiscal 2019.

( 8 ) Progress of colorectal cancer clinical study

About 1% to 2% of colorectal cancer patients express HER2. However, no HER2-targeting drug has been approved so far.

Although, the number of cases are low at this point, a certain level of antitumor effect (see graph below) has been achieved in the treatment of HER2-expressing colorectal cancer in a phase 1 study. A global phase 2 study is currently underway for HER2-expressing colorectal cancer patients.

►HER2-expressing Colorectal Cancer (ESMO 2018)



	Confirmed ORR, % (n/N)	Confirmed DCR, % (n/N)	DOR, median (range), months	PFS, median (range), months	OS, median (range), months
CRC N=19	15.8% (3/19)	84.2% (16/19)	NR (0.0+, 5.5+)	3.9 (2.1,8.3)	NR (1.0+, 17.9+)

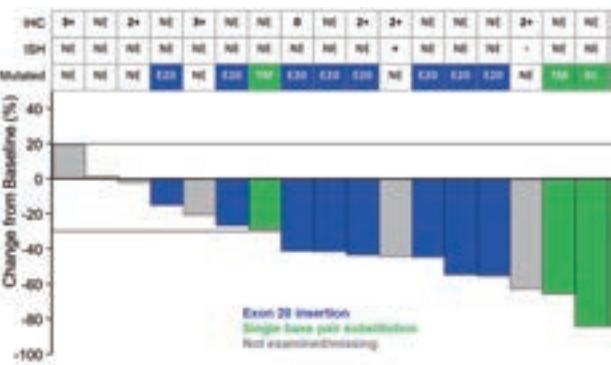
Source: Yoshino-T et al., Abstract #563P, ESMO 2018

( 9 ) Progress of lung cancer clinical study

According to the 2018 WHO worldwide cancer statistics (estimate), lung cancer was the most common cancer in terms of number of patients affected and number of deaths. Of the various lung cancers, it has been reported that 4% to 35% of non-small-cell lung cancer (NSCLC) patients are HER2-expressing, but similar to colorectal cancer, no HER2-targeting drug has been approved.

Although the number of cases are low at this point, a remarkable antitumor effect (see graph below) has been achieved in the treatment of HER2-mutated lung cancer in a phase 1 study. A global phase 2 study is currently underway for HER2-expressing and HER2-mutated lung cancer patients.

►HER2-expressing non-small-cell lung cancer (WCLC 2018)



E20: exon 20 insertion, EC: single base pair substitution at extracellular domain, TM: single base pair substitution in transmembrane domain, NE: not examined.

	Confirmed ORR, % (n/N)	Confirmed DCR, % (n/N)	DOR, median (range), months	PFS, median (range), months
HER2-expressing or HER2-mutated NSCLC N=18	58.8% (10/17)	88.2% (15/17)	9.9 (0.0+, 11.5)	14.1 (0.9, 14.1)
HER2-mutated NSCLC N=11	72.7% (8/11)	100% (11/11)	11.5 (0.03+, 11.5)	14.1 (4.0+, 14.1)

Source: Tsurutani-J et al., Abstract #13325, WCLC 2018

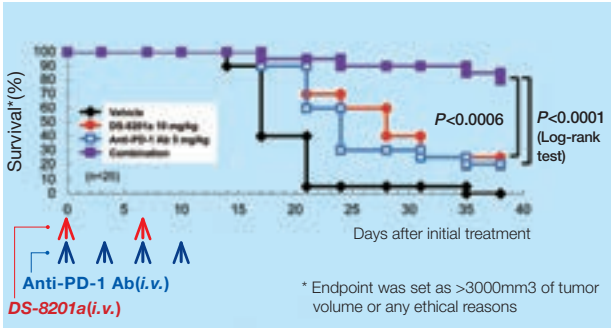
( 10 ) Progress of studies on combinations with immune checkpoint inhibitors

The results of pre-clinical studies show that the efficacy of *DS-8201* can be increased by combining with immune checkpoint inhibitors such as *nivolumab* without compromising safety.

To identify the most effective combination, we are considering a combination study with three different immune checkpoint inhibitors. Currently, a phase 1 study in combination with *nivolumab* is underway for patients with breast cancer and bladder cancer.

Furthermore, preparations are being made for phase 1 studies in combination with *pembrolizumab* or *avelumab*.

►Combination benefit of DS-8201a and an anti-PD-1 antibody in vivo



Source: Iwata-T et al., Abstract #1031, ASCO 2017

COLUMN

How to measure HER2

Since the expression level of HER2 varies depending on the cancer type and patient, patient selection in *DS-8201* studies measure HER2 using the immunostaining method IHC/ISH.

Staining methods used in pathology

- Measure proteins and nucleic acids that you want to detect in tissues and cells
- A technique that enables microscopic observation through staining using pigments and enzymes

IHC: abbreviation of immunohistochemistry

- Observes protein expression levels including HER2 (surface of cancer cell)

ISH: abbreviation of in situ Hybridization

- Observes amplification levels of HER2 gene (DNA), etc.(nuclear of cancer cell)
- Ex.) FISH (Fluorescence in situ hybridization)

Commonly Used	HER2 Status	DS terminology for Future Use	Percentage in Total Breast Cancer
HER2 positive or HER2 over-expressing	IHC 3+	HER2 positive (HER2 overexpressing)	20.3%
	IHC 2+/ISH+		
HER2 negative	IHC 2+/ISH-	HER2 low	43.9%
	IHC 1+/ISH-		
	IHC 0	HER2 negative	35.8%

Overview and progress of 5-Year Business Plan: Establish Oncology Business

2 U3-1402 (anti-HER3-ADC)

U3-1402 is an anti-HER3 ADC which our proprietary linker and payload are conjugated to *patritumab* (an anti-HER3 antibody). Several studies involving *patritumab* reached phase 2. However, limited efficacy was observed, while side effects were limited. Thus its development as an antibody drug was abandoned. It now finds new life as an ADC and is developing for potential first-in-class drug approval.

( 1 ) What is HER3?

HER3 is found on the cell surface. It is receptor tyrosine kinase and has a structure similar to the epidermal growth factor receptor (HER1/EGFR). HER3 is over-expressed on the surface of cancer cells, such as those of breast cancer, lung cancer, colorectal cancer, and prostate cancer, and the expression of HER3 is induced by some antitumor drugs.

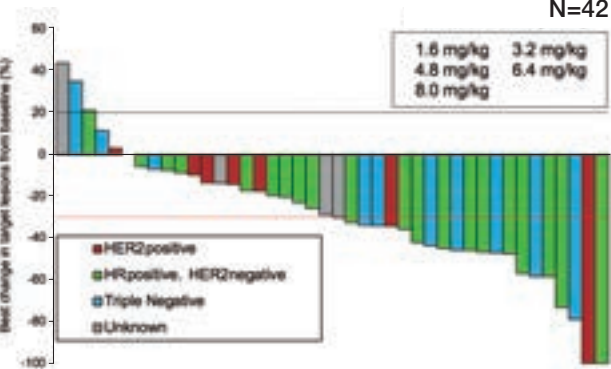
U3-1402 exerts its efficacy by binding to this HER3.

( 2 ) Progress of HER3-positive breast cancer clinical study

A phase 1 study in patients with HER3-positive refractory/metastatic breast cancer was started in December 2016, for which we presented interim efficacy and safety data from the dose escalation part of the study at the San Antonio Breast Cancer Symposium (SABCS) in 2018.

The graph below is a waterfall chart representing efficacy. Favorable antitumor effects are suggested with ORR 42.9%, despite the condition that most patients progressed after multiple available drugs.

HER3 positive breast cancer (SABCS 2018)



Source: Masuda-N *et al.*, Abstract #PD1-03, SABCS 2018

Concerning the safety, U3-1402 was tolerated over the 7.6-month median exposure period. The dose was also increased to 8 mg/kg, but the maximum tolerated dose was not reached.

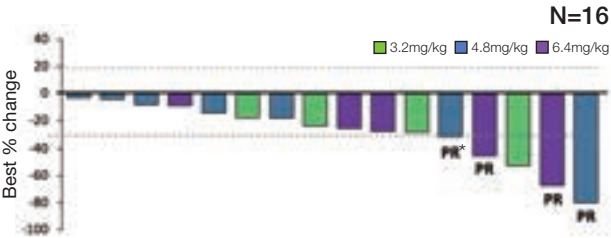
Currently, recommended dose for expansion was selected and the drug is undergoing the dose expansion part of the phase 1 study.

( 3 ) Progress of EGFR-mutated non-small-cell lung cancer clinical study

A phase 1 study in patients with advanced EGFR-mutated non-small-cell lung cancer was started in January 2018, for which we presented interim efficacy and safety data from dose escalation part at the American Society of Clinical Oncology (ASCO) in 2019.

The graph below is a waterfall chart representing efficacy. Regarding the efficacy of the 16 evaluable cases, a shrinkage in tumor size were seen in all patients even though patients were enrolled without prior HER3 selection. Although there are a limited number of cases, some exhibited antitumor activity against mutated cancer cells that appear after treatment with tyrosine kinase inhibitors such as *osimertinib*. We will evaluate further.

EGFRm NSCLC (ASCO 2019)



\* PR: Confirmed partial response  
Source: Janne-P *et al.*, Abstract #9010, ASCO 2019

Concerning safety, most of the adverse events were of grade 1 or 2, and while there is dose-limiting toxicity, the maximum tolerated dose had not yet been reached. The drug will undergo the dose expansion part of the phase 1 study in the second half of fiscal 2019. In addition, HER3 is highly expressed in cancers such as colorectal cancer and prostate cancer, so expansion into other types of cancer is being considered.

3 DS-1062 (anti-TROP2-ADC)

DS-1062 is an anti-TROP2 ADC which our proprietary linker and payload are conjugated to an anti-TROP2 antibody.

( 1 ) What is TROP2?

TROP2 is an antigen highly expressed on the membrane of cancer cells, and is known to be associated with cancer cell proliferation, metastasis, and drug resistance.

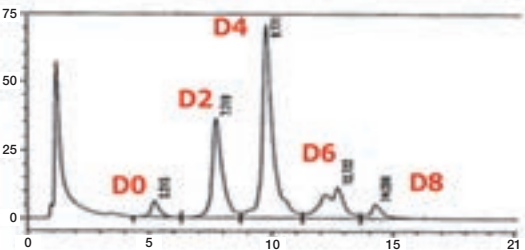
DS-1062 exerts its efficacy by binding to this TROP2.

( 2 ) Why is the drug-antibody ratio (DAR) four?

The drug linker and payload of DS-1062 is the same as DS-8201 and U3-1402, but DS-1062 has an average of 4 payloads per antibody compared to 8 of DS-8201 and U3-1402.

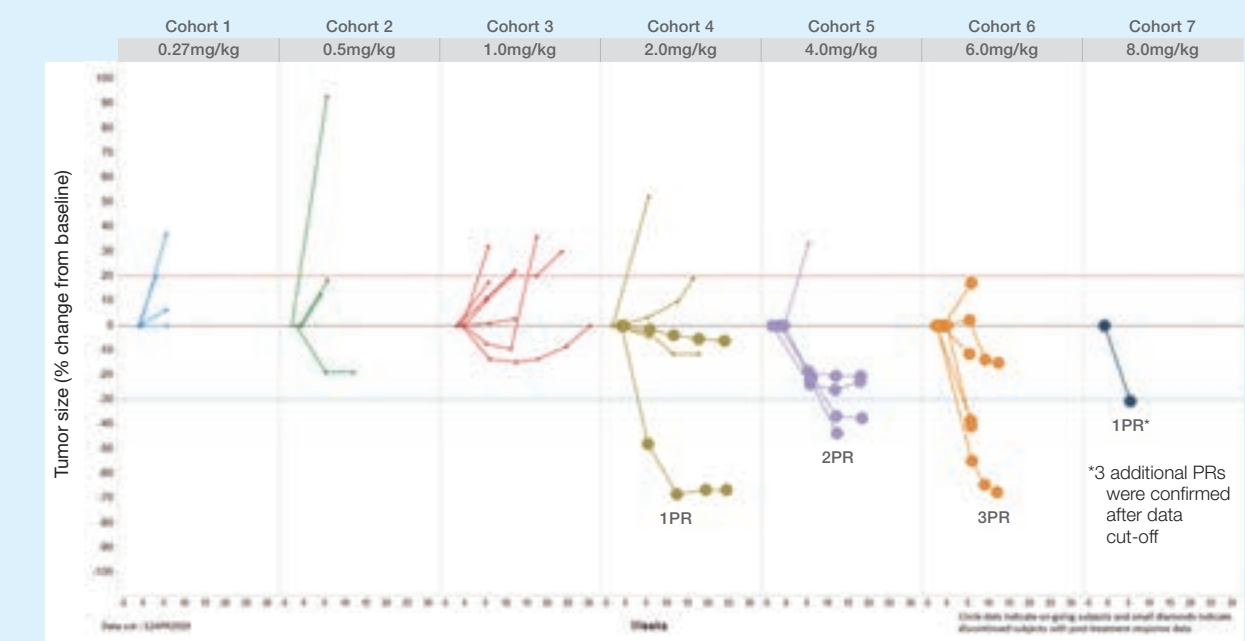
Since it is known that TROP2 is expressed in normal cells, such as skin cells, the number of payloads is controlled at four in order to maintain a better safety margin.

Distribution of the number of payloads by reverse phase chromatography



Source: In-house Data

NSCLC (ASCO2019)



Source: Sands-J *et al.*, Abstract #9051, ASCO 2019

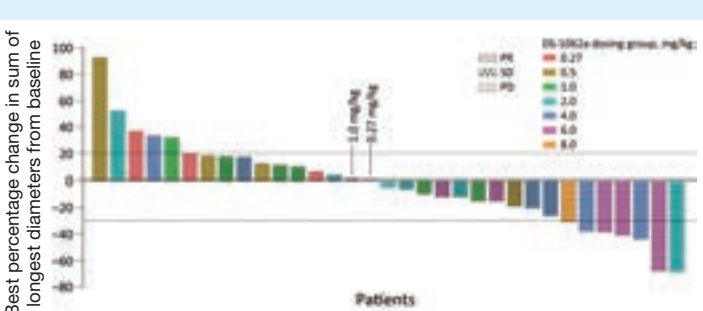
( 3 ) Progress of non-small-cell lung cancer clinical study

A phase 1 study in patients with non-small-cell lung cancer (NSCLC) was initiated in February 2018, for which we presented interim efficacy and safety data from dose escalation part at the American Society of Clinical Oncology (ASCO) in 2019 for the first time.

With respect to efficacy, 10 of the 19 evaluable patients showed partial responses (responses in 7 of these patients require further confirmation). As shown in below waterfall chart, partial responses are seen in cohort above the 2.0 mg/kg. Also shown in spider plot, partial responses are dose dependent.

This study was conducted in NSCLC patients who were unresponsive to standard treatments, experienced recurrence with standard treatments, or where a standard treatment does not exist. In addition, as TROP2 is highly expressed in non-small-cell lung cancer, and as such, presence or absence of TROP2 expression was not measured prospectively. Regardless of this condition, this study is notable that it displays dose-dependent antitumor effect.

NSCLC (ASCO2019)



Source: Sands-J *et al.*, Abstract #9051, ASCO 2019



Overview and progress of 5-Year Business Plan: Establish Oncology Business

Concerning safety, of the 39 non-small-cell lung cancer (NSCLC) patients, 16 (41.0%) experienced adverse events grade 3 or higher at least once. Although dose-limiting toxicity was observed as a grade 3 rash (in one patient), the maximum tolerated dose had not yet been reached (at the data cut-off date).

DS-1062 initiated the dose expansion part of phase 1 study from July 2019. Based on the interim data from this study, we are considering to expand development of DS-1062 into other cancer indications.

4 DS-7300 (anti-B7-H3-ADC)

DS-7300 is an anti-B7-H3 ADC which our proprietary linker and payload are conjugated to an anti-B7-H3 antibody. The drug linker is the same as that of DS-8201 and U3-1402, but DS-7300 has a DAR of 4 like DS-1062.

( 1 ) What is B7-H3?

B7-H3 is a type I transmembrane protein belonging to the B7 family. B7-H3 is overexpressed in many types of solid tumors, and is suggested to be related to a poor prognosis in some solid-tumors such as NSCLC and prostate cancer.

DS-7300 exerts its efficacy by binding to this B7-H3.

( 2 ) Phase 1 study in patients with selected solid tumor

In fiscal 2019, initiaion of phase 1 study of DS-7300 in patients with selected solid tumors is planned.

5 DS-6157 (anti-GPR20-ADC)

DS-6157 is an anti-GPR20 ADC which our proprietary linker and payload are conjugated to an anti-GPR20 antibody. The drug linker is the same as the DS-8201 and U3-1402, with 8 payloads.

( 1 ) What is GPR20?

GPR20 is an orphan G protein-coupled receptor (GPCR) whose ligand has not been identified. GPR20 is a seven-pass transmembrane protein and specifically expressed in GIST (gastrointestinal stromal tumors).

DS-6157 exerts its efficacy by binding to this GPR20.

( 2 ) What is GIST?

GIST is the most common mesenchymal tumors of the gastrointestinal tract. Currently, three tyrosine kinase inhibitors have been approved in its treatment, but there are still unmet medical needs in regard to relapse, refractory, and resistant patients.

In fiscal 2019, initiation of phase 1 study of DS-6157 in patients with GIST is planned.

6 Other ADCs

Pre-clinical research is currently underway for DS-6000 (target undisclosed), which targets renal cancer and ovarian cancer, as well as ADC of anti-TA-MUC1 antibody from Glycotope.

The drug linker of these compounds are the same as the DS-8201, U3-1402 and DS-1062.

Since Daiichi Sankyo's ADC technologies are applicable to a wide variety of antibodies, we are always examining possibilities for collaboration with other companies to increase the range of antibodies we can apply our ADC technologies to.

We are also focusing on developing different drugs and linkers and research on antibody-modifying technologies, assuming that DS-8201 and other ADCs are ineffective or become resistant during treatment in some cases.

ADC franchise pipeline

Project (target)	Preceded indications	Discovery	Pre-clinical	Phase 1	Pivotal
DS-8201 (HER2)	Breast cancer Gastric cancer Colorectal cancer Non-small-cell lung cancer				
U3-1402 (HER3)	Breast cancer Non-small-cell lung cancer				
DS-1062 (TROP2)	Non-small-cell lung cancer				
DS-7300 (B7-H3)	Solid tumors				Start clinical study in FY2019
DS-6157 (GPR20)	Gastrointestinal stromal tumor (GIST)				Start clinical study in FY2019
DS-6000 (undisclosed)	Kidney cancer Ovarian cancer				
Project code pending (TA-MUC1)	Solid tumors				

Breast Cancer

The current status of breast cancer and the existing standard of care

Breast cancer is the most common cancer in women, and the numbers of new and recurrent breast cancer cases in Japan, U.S. and Europe in 2017 are provided in the figure to the right.

Data published by the Ministry of Health, Labour and Welfare shows that the number of patients who died of breast cancer in Japan continues to rise and reached approximately 14,000 in 2016, more than three times higher than 35 years ago, with breast cancer ranked first as the cause of death in women aged 30 to 64 years.

Breast cancer patients by stage (new, recurrence) 2017

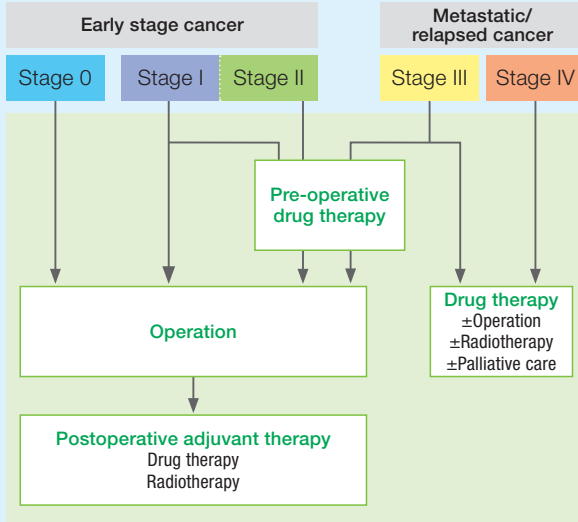
	Japan		U.S.		Europe	
	New	Recurrence	New	Recurrence	New	Recurrence
Stage 0	12	0.1	63	0.1	—	—
Stage I	40	0.1	133	2	121	1
Stage II	33	1	84	2	88	2
Stage III	7	1	26	3	35	4
Stage IV	2	9	16	27	16	30
Total	95	11	321	34	260	37

Source: CancerMPact®, Kantar Health/Synix inc. (Strict diversion of confidential information)

Breast cancer is generally classified into the stages below, and surgery is the standard of care. Pre-operative or post-operative drug therapy is given to some patients to prevent cancer recurrence. In addition, in patients in whom surgical procedures are inappropriate because of metastases and other conditions, drug therapy is principally used.

Stage 0	Non-invasive cancer (including Paget's disease)
Stage I	The lump (tumor) in the breast is 20 mm or smaller and has not spread to the lymph nodes
Stage II	The lump is between 20 mm-50 mm and has not spread to the lymph nodes or the lump is 20 mm or smaller and has spread to the lymph nodes
Stage III	The lump has spread to several lymph nodes The lump is larger than 50 mm and has spread to the lymph nodes The lump has spread to skin and chest wall, inflammatory breast cancer
Stage IV	The lump has spread to other organs (lung, bone, liver, brain, etc.)

Source: created based on the Nyugan toriatsukai kiyaku [Breast cancer handling rules] 18th edition



Source: created based on the National Cancer Center's Cancer Information Service

In drug therapy for breast cancer, tests are performed to look at receptors on cancer cells first, and select anticancer drugs which are appropriate for the receptor status.

Subtype	Treatment option (example)
HER2 positive	HER2 targeted drugs
HR* positive / HER2 negative	Hormone therapy
HR negative / HER2 negative (triple negative)	Chemotherapy

\* hormone receptor

We are conducting clinical studies in DS-8201 for HER2 positive and HER2 low metastatic breast cancer and in U3-1402 for HER3 positive refractory/metastatic breast cancer.

Breast cancer subtype classification and our pipeline

	HER3+		HER3-	
	HR+	HR-	HR+	HR-
HER2+	DS-8201		DS-8201	
HER2 Low				
HER2-	U3-1402			

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Lung Cancer

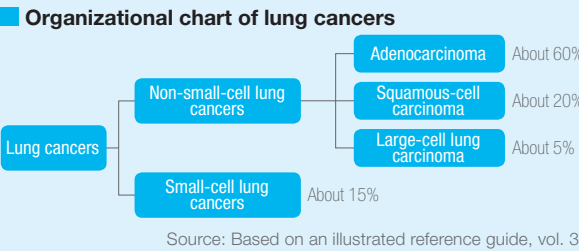
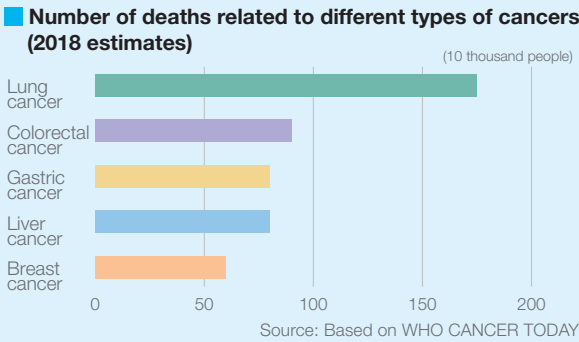
The current status of lung cancer and the existing standard treatments

Lung cancer occurs when bronchi or lung cells become cancerous through a variety of factors, with smoking known to be the largest risk factor. Other risk factors include chronic obstructive pulmonary disease, the inhalation of asbestos, arsenic, chromium, or other carcinogens due to occupational exposure or air pollution, as well as aging.

According to statistics (estimates) provided by the WHO regarding cancer around the world in 2018, lung cancer has the highest number of incident cases and deaths worldwide, with 2.09 million patients and 1.76 million people dying from the disease.

Lung cancers are classified into two groups based on their histological characteristics: small-cell lung cancers and non-small-cell lung cancers, with the latter accounting for about 85% of all cases.

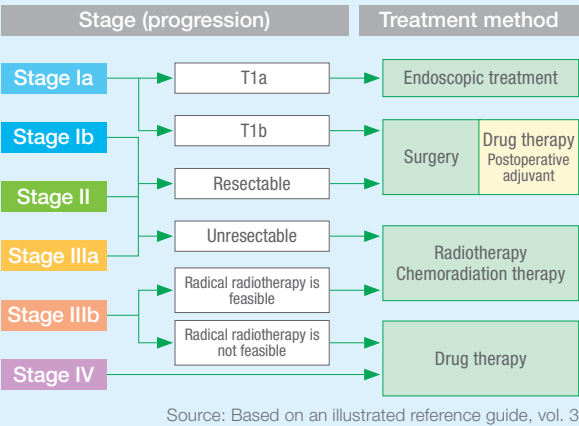
The following paragraphs describe treatments for non-small-cell lung cancers.



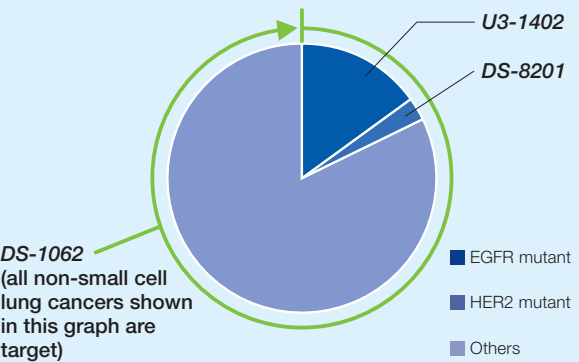
Lung cancer is categorized into stages I through IV based on a combination of the size and extension of infiltration of the tumor (T), the degree of metastases to nearby lymph nodes (N), and the presence of distant metastasis (M).

Treatments for non-small-cell lung cancers include surgery, radiotherapy, drug therapy, or combinations of these. The method of treatment is selected based on the stage of the cancer. If the tumor can be removed, treatment is carried out centered on surgery. However, if surgery is not a viable option due to the patient's general state, age, or the presence of other complicating diseases, treatment is carried out with a focus on radiotherapy. Drug therapy is used if tumors progressed further.

In drug therapy for non-small-cell lung cancers, different treatments are used depending on the stage. A platinum-based drug combination therapy was conventionally used for stages IIIb to IV, but recent methods of treatment involve selecting drugs after investigating the genetic mutations in the cancers.



Percentage of non-small cell lung cancer driver genes (US/EU) and our pipeline



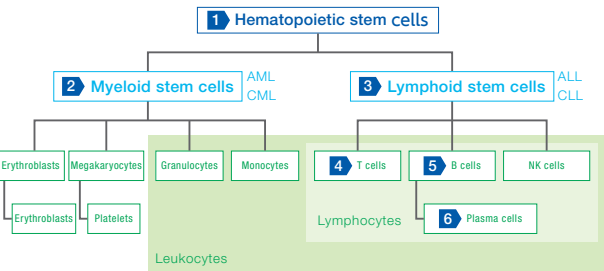
Daiichi Sankyo's AML Franchise

Leukemia is a disease in which hematopoietic stem cells in the bone marrow multiply at an abnormal rate and then become cancerous. Leukemia is classified into four types: acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphocytic leukemia (ALL) and chronic lymphocytic leukemia (CLL). Although there are cancer types such as CML for which remission can be expected with molecular targeted drugs, the five-year survival rate of AML is still about 26%, which is very low. Daiichi Sankyo is developing AML therapeutics with various targets, aiming to eliminate AML unmet medical needs.

AML franchise pipelines

Development status	Stage	Mechanism of action
Quizartinib (FLT3)	P3/LCM	FLT3 inhibitor. Displays a potent inhibitory activity against mutated gene called FLT3-ITD, which is present in around 30% of AML patients.
DS-3032 (MDM2)	P1	MDM2 inhibitor. Activates p53, a tumor suppressor gene, by inhibiting MDM2, which suppresses wild-type p53 activity.
DS-3201 (EZH1/2)	P1	EZH1/2 inhibitor. Both EZH1 and EZH2 are an enzyme to suppress gene expression. Inhibits both EZH1 and EZH2 which facilitating the inactivation of tumor suppressor genes.
PLX2853 (BET)	P1	BET inhibitor. Suppresses the expression of cancer related genes by inhibiting binding between BET and histone acetylated lysine.
Axi-Cel® (CD19 CAR-T)	P2	A cell therapy (chimeric antigen receptor T cell: CAR-T) targeting CD19 expressed on the surface of B cells.

Differentiation of hematopoietic stem cell



Disease	Overview	Applicable Daiichi Sankyo Compounds
1 Myelodysplastic syndrome	● Disease resulted from abnormality in hematopoietic stem cells	DS-3032
2 Myeloid leukemia	● Disease in which myeloid stem cells become cancerous ● Acute (AML) and chronic (CML) variations	Quizartinib DS-3201, DS-3032, PLX2853
3 Lymphocytic leukemia	● Disease in which lymphoid cells become cancerous ● Acute (ALL) and chronic (CLL) variations	DS-3201
4 T-cell lymphoma	● Generic term for hematopoietic tumors derived from mature T cells. Peripheral T-cell lymphoma (PTCL), adult T-cell lymphoma (ATL), etc.	DS-3201
5 B-cell lymphoma	● non-Hodgkin's lymphoma in which B-cell become cancerous	DS-3201 Axi-Cel®
6 Multiple myeloma	● Disease in which plasma cells in bone marrow become cancerous	

1 Quizartinib (FLT3 inhibitor)

AML is a disease with high mortality rate. In particular, AML patients with mutated FLT3, which is a receptor tyrosine kinase involved in the proliferation of cancer cells, are known to have a particularly high degree of malignancy and extremely poor prognosis with a rate of recurrence two years after bone marrow transplants that is three times higher than that of other forms of AML. Quizartinib is a tyrosine kinase inhibitor that displays specific potent inhibitory activity against FLT3-ITD.

In 2018, we applied for approval in Japan, the United States, and Europe, based on the results of the QUANTUM-R study in patients with relapsed/refractory AML.

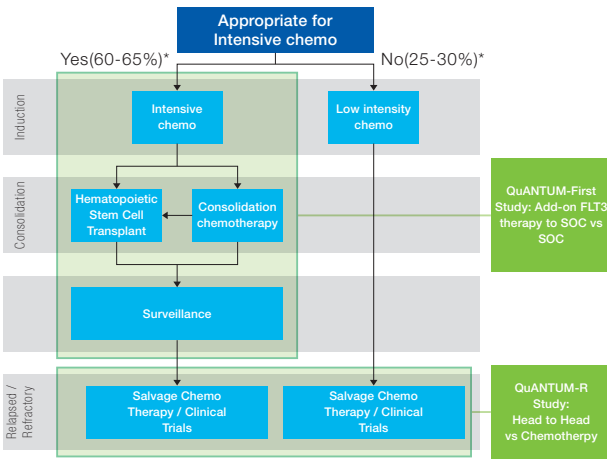
In Japan, the Ministry of Health, Labour and Welfare approved quizartinib for the treatment of relapsed/refractory FLT3-ITD AML in June 2019. We will launch it under the brand name VANFLYTA®.

In the United States, we received a Complete Response Letter\* in June 2019. We plan to decide upon our next step in the United States after detailed review of the contents of the Complete Response Letter.

In Europe, quizartinib is under review, with approval expected in the second half of fiscal 2019.

Enrollment of patient is proceeding smoothly in the QUANTUM-First study to evaluate the efficacy and safety of quizartinib in combination with the standard of care as a first line treatment for AML as well as in continuation therapy.

\* A document issued by the FDA when the approval application has been reviewed and the current content does not result in approval



\* Patients who cannot treated by intensive/low intensity chemo (5-10%)



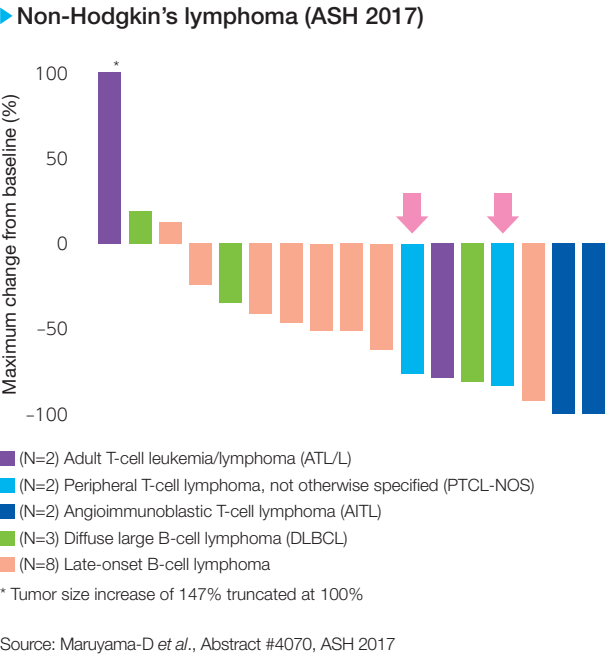
Overview and progress of 5-Year Business Plan: Establish Oncology Business

2 DS-3201 (EZH1/2 inhibitor)

EZH1 and EZH2 are histone-methylating enzymes with similar functions, and some cancer cells shows dependent growth on them.

The phase 1 study of *DS-3201* is currently underway in patients with relapsed/refractory non-Hodgkin's lymphoma in Japan and the US. Based on the favorable interim data from this study, particularly in patients with relapsed or refractory peripheral T-cell lymphoma (PTCL), the Ministry of Health, Labour and Welfare has granted *DS-3201* SAKIGAKE Designation.

PTCL is a type of non-Hodgkin's lymphoma that occurs in T-cells, and is said to have a particularly poor prognosis if it recurs. There are few treatment options and a high degree of unmet medical need.



The phase 1 study of *DS-3201* is ongoing in the U.S. in patients with relapsed/refractory acute myeloid leukemia and acute lymphatic leukemia. In addition, phase 1 study is ongoing in the U.S. in patients with small cell lung cancer.

Daiichi Sankyo's Breakthrough Science

Breakthrough Science is the third pillar, with the goal of creating first-in-class or best-in-class compounds with breakthrough mechanism of action or modality.\*

\* The foundation of drug development and therapeutic approaches such as protein drugs including low molecular compounds, peptide (medium sized molecule) drugs, and antibody drugs, nucleic acid drugs, cell therapy and regenerative medicine.

► Breakthrough science pipeline

Products (Targets)	Indication	Mechanism of action
<i>Pexidartinib</i> (CSF-1R/KIT/FLT3)	Submitted	Receptor tyrosine kinase inhibitor showing specific inhibitory activity against CSF-1R, KIT and FLT3-ITD
<i>DS-1647</i> (G47Δ) (oncolytic herpes virus)	P2	A third-generation strand of oncolytic herpes simplex virus 1 (HSV-1) created by using genetic modification technologies to modify HSV-1 so that it only multiplies in cancer cells
<i>DS-1205</i> (AXL)	P1	AXL receptor tyrosine kinase inhibitor. High expression of AXL is said to be associated with resistance to EGFR tyrosine kinase inhibitors in EGFR-mutant non-small cell lung cancer
<i>DS-1001</i> (mutant IDH1)	P1	A selective inhibitor of mutant isocitrate dehydrogenase IDH1. Inhibits mutant enzyme expressed by IDH1 gene mutation frequently seen in malignant brain tumors (glioma), acute myeloid leukemia, cholangiocarcinoma, chondrosarcoma

1 Pexidartinib (CSF-1R/KIT/FLT3 inhibitor)

*Pexidartinib* is a receptor tyrosine kinase inhibitor showing specific inhibitory activity against CSF-1R/KIT/ and FLT3. We obtained approval in the United States in August 2019 based on the results of a placebo-controlled phase 3 study (ENLIVEN) in patients with tenosynovial giant cell tumor (TGCT) and launched under the brand name *Turalio*™. We also applied for approval in Europe in March 2019.

TGCT is a type of benign tumor occurring in joints. It is known that there is no treatment method other than surgery and it can cause extreme inconvenience in daily life. The recurrence rate for diffuse disease is also high, and in some cases, limb amputation may be unavoidable.

*Pexidartinib* is the first drug to be indicated for TGCT.

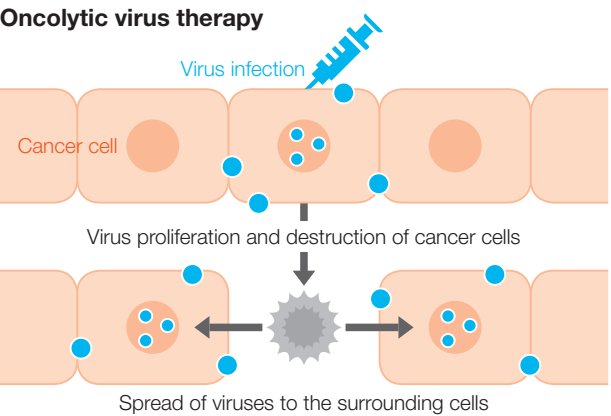


2 DS-1647 (oncolytic virus G47Δ)

*DS-1647* is a cutting-edge (third-generation) oncolytic virus created by Professor Tomoki Todo of the Institute of Medical Science of the University of Tokyo, by using genetic modification technologies to modify herpes simplex virus type 1 so that it only multiplies inside cancer cells. Clinical and pre-clinical studies are ongoing for glioblastoma and several other cancer types. Daiichi Sankyo is working with Professor Todo to develop *G47Δ*.

Glioma is classified into four grades according to the grade of malignancy and glioblastoma is the most common and most malignant (grade 4) . Even if radiation therapy is given after surgery, the 5-year survival rate is about 10%, making it extremely difficult to cure.

In investigator initiated study in glioblastomas conducted by Professor Todo, interim analysis was conducted in July 2018, and the primary endpoint, 1-year survival rate, was 92.3%, confirming that the drug has high efficacy. Using this result, we plan to apply for approval in 2H of fiscal 2019. The Ministry of Health, Labour and Welfare granted a SAKIGAKE Designation, resulting in a potentially faster review period.



COLUMN

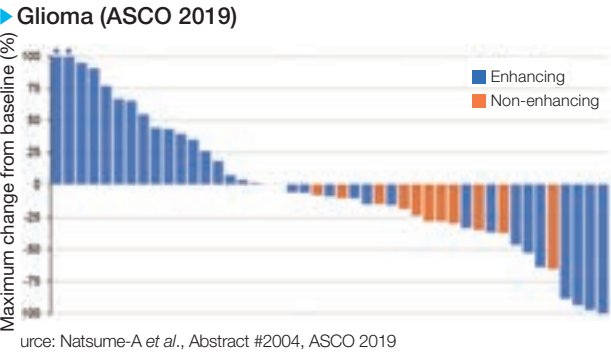
Classification of gliomas

A glioma is a type of malignant brain tumor that begins in glial cells in the brain and spinal cord. Brain tumors are not staged like other cancer but are classified as grades I to IV.

Malignancy Grade	Major Types of Glioma	
	Diffuse stellate cell tumor	Oligodendrocyte tumor
II	Diffuse astrocytoma	Oligodendroglioma
III	Anaplastic astrocytoma	Anaplastic oligodendroglioma
IV	Glioblastoma	

3 DS-1001 (mutant IDH1 inhibitor)

It is known that mutations in the gene encoding isocitrate dehydrogenase 1 (IDH1) are frequently seen in a variety of tumors including glioma, acute myeloid leukemia, cholangiocarcinoma, and chondrosarcoma. *DS-1001* is a selective inhibitor of mutant IDH1 and has characteristic of high penetration into the brain. We presented interim efficacy and safety data from the phase 1 study in patients with recurrent IDH mutated glioma that started in January 2017 at the American Society of Clinical Oncology (ASCO) in 2019. The graph below is a waterfall chart representing efficacy. Although this study had a small sample size, we observed a certain level of efficacy from *DS-1001* in both enhancing and non-enhancing patients. Regarding safety, the maximum tolerated dose was not reached up to 1,400mg/kg twice daily, and preliminary safety data suggested that *DS-1001* is well tolerated.



Enhancing	Patients who have tumor(s) with gadolinium enhancement on MR images. It is common in high-grade gliomas like glioblastoma
Non-enhancing	Patients who have no gadolinium-enhanced tumor. Most common in low-grade gliomas

In glioma, IDH1 mutations are said to be present in around 80% of lower grade gliomas. Lower-grade gliomas often arise in the generation in their 30s and 40s, who are in the prime of their working life. Although they are generally growing slowly, most of them eventually transform into more aggressive tumors and result in death. Treatment options for lower grade gliomas and its recurrent disease are very limited.

We will continue to move forward with development of *DS-1001*, to assess its efficacy and safety in glioma.

# Strategic Collaboration to Maximize the Value of DS-8201

## The DS-8201 Strategic Collaboration

In order to maximize the value of DS-8201, created using our proprietary ADC technology, we entered into joint development and commercialization agreement in March 2019 with AstraZeneca, a company with a wealth of global experience and expertise in oncology.

## Overview of the Collaboration

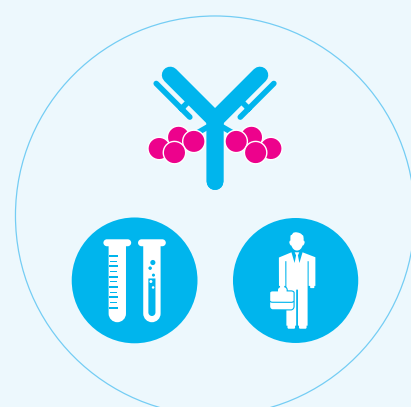
### Our collaborator:

AstraZeneca plc  
(headquarters: Cambridge, UK)



### Content of collaboration:

Joint development and commercialization for DS-8201



## Financial Terms

Up to \$6.90 billion (759.0 billion yen) in total

▶ Upfront payment	\$1.35 billion (148.5 billion yen)
▶ Regulatory and other contingencies (Maximum)	\$3.80 billion (418.0 billion yen)
▶ Sales-related milestones (Maximum)	\$1.75 billion (192.5 billion yen)

(\$1 = 110 yen)

## Development

- ▶ Joint development as monotherapy and combination therapy for HER2 expressing cancers
- ▶ Equally share development costs and efforts
- ▶ Daiichi Sankyo will continue development of combination therapy that are currently being investigated



## Commercialization

- ▶ Global (excluding Japan): Both companies will jointly commercialize and share profits
- ▶ Japan: Daiichi Sankyo will commercialize on a stand-alone basis and pay royalties to AstraZeneca



## Sales booking by region

- Daiichi Sankyo: Japan, US, certain countries in Europe, and certain other markets where Daiichi Sankyo has affiliates
- AstraZeneca: All other markets worldwide, including China, Australia, Canada and Russia

## Manufacturing and supply

- ▶ Daiichi Sankyo manufactures and supplies DS-8201



## The Significance of This Collaboration

### 1 Accelerate DS-8201 commercialization and development

This collaboration will allow earlier market penetration for cancer types and indications currently in development.

AstraZeneca's oncology business reaches over 70 countries around the world. They have extensive expertise in market access through the relationships with payers and oncology specialists, and medical affairs. The early market penetration of DS-8201 can be realized through our collaboration with AstraZeneca.

For example, in regions such as China where Daiichi Sankyo has little experience in development and commercialization, AstraZeneca's development experience and sales network can be used to realize earlier launches and increase revenue.

### Accelerate DS-8201 commercialization and development

#### Early market penetration

Cancer types and indications currently under development

- ▶ Accelerating market penetration in U.S. and Europe
- ▶ Early launch in other markets other than Japan, U.S and Europe

#### Accelerate and expand development

Cancer types and indications for future development

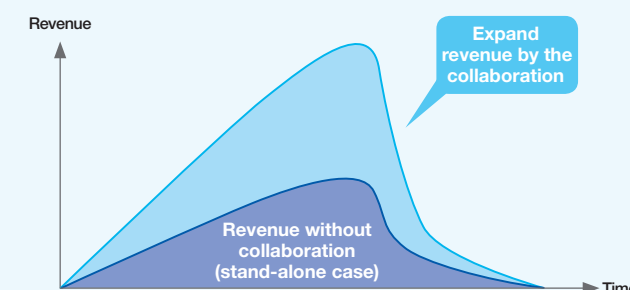
- ▶ Advancing development plans
- ▶ Further expansion of cancer types and indications

In addition, this collaboration will accelerate/expand any future development on cancer types and indications. AstraZeneca has developed many innovative oncology drugs and has extensive development and registration experience globally including emerging countries.

As shown in the graph maximizing the product value of DS-8201, by collaborating with AstraZeneca, we can greatly increase the revenue of DS-8201 compared to if Daiichi Sankyo were to develop and market the product alone.

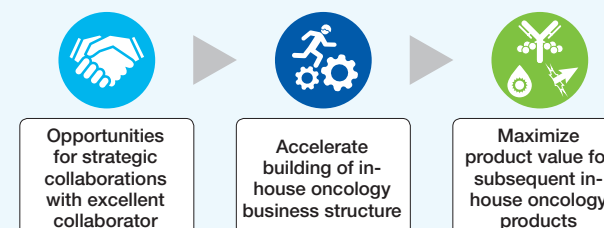
In addition, the product value of DS-8201 is maximized with considerations such as the upfront payment and various milestones.

### Maximizing the product value of DS-8201



## The Significance of This Collaboration

### 2 Accelerate the establishment of Daiichi Sankyo's global oncology infrastructure



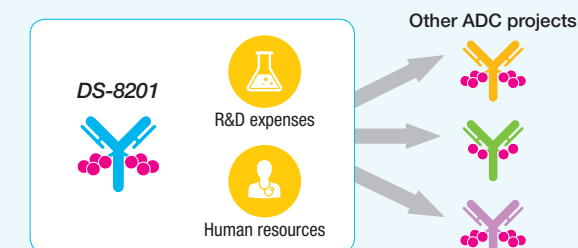
AstraZeneca has rich experience and resources in the global oncology area, and we will create various strategies in collaboration, assigning and sharing roles and executing the strategy. This will also accelerate the establishment of Daiichi Sankyo's oncology business infrastructure.

In addition to DS-8201, we have 6 other ADCs and other oncology-related projects. We will be able to maximize the product values of those projects in the future through this experience.

## The Significance of This Collaboration

### 3 Expand resource allocation for other ADC projects following DS-8201

By being able to allocate R&D expenses and human resources that was focused on DS-8201 to other ADC projects, it can accelerate development and increase the value of our pipeline.



### Governance with AstraZeneca

A joint committee framework has been established between Daiichi Sankyo and AstraZeneca, and the creation/execution of development and marketing strategies is implemented through discussion and mutual agreement between the two companies. Currently, the joint committee framework has a common vision to "Transform" treatments for patients with HER2-expressing cancer. More specifically, this involves the creation of an overall vision and strategy for DS-8201, management of profits and losses for business collaborations, approval of major investments in development and business, management of overall results and important milestones, and promotion of preparations for a global launch.



**We will further enhance our corporate governance to put Our Mission into practice.**

We will establish corporate governance structure including an operation of the Board that is even more responsive to the trust of our diverse stakeholders, and endeavor to continue to further improve our corporate governance.

George Nakayama  
Representative Director and  
Chairman of the board

The following introduces the corporate governance system of the Group, with focus on the mechanism for decision making, oversight, and delegation of the Board of Directors' authority and another mechanism for reinforcing it.

		2005	2007	2010	2014	2015	2016	2017	2018	2019
Chairman of the Board		Kiyoshi Morita		Takashi Shoda	George Nakayama				George Nakayama	
	CEO	Takashi Shoda		George Nakayama					Sunao Manabe	
Members of the Board	Outside	4 persons							4 persons (including one female member)	
	Inside	6 persons							5 persons	
Members of the Audit and Supervisory Board	Outside	2 persons			2 persons (including one female member)		3 persons (including two female members)			
	Inside	2 persons								
Nomination Committee	Members of the Board	2 outside persons and 1 internal person			4 outside persons					
	Members of the Audit and Supervisory Board						1 observer (outside)			
Compensation Committee	Members of the Board	2 outside persons and 1 internal person			4 outside persons					
	Members of the Audit and Supervisory Board						1 observer (outside)			
Remuneration system (Incentive)	Short term	Performance-based bonus								
	Long term	Share remuneration-type stock option plan							Restricted share-based remuneration plan	
Corporate Governance Code		Explained about 3 items immediately after applying the Code					Complied with all the items		Explained about 1 item after revision Complied with all the items	

I Securing and enhancing the effectiveness of the important business decision and oversight functions of the Board of Directors

In principle, the Board of Directors Meetings of Daiichi Sankyo are held once a month. We are committed to establish and enhance the effectiveness of the Board's appropriate decision-making and oversight functions as follows:

1. Participation of Members of the Board (Outside) and the Audit and Supervisory Board (Outside)

- (1) The Company has nine Members of the Board, of which four are outside members. Each Member of the Board (Outside) actively makes suggestions and appropriate remarks in the Board of Directors Meeting, based on insight as corporate managers in various industries and sectors, including the telecommunication, general heavy industries, IT, business strategy and marketing strategy, and/or expert knowledge and insight as medical doctor, playing important roles in enhancing the decision-making and oversight functions of the Board.
- (2) The Audit and Supervisory Board has five members, of which three are outside members and conducts audits of legal compliance and appropriateness of management.
- (3) Both of the Nomination and the Compensation Committees are established to ensure management transparency. The four Members of the Board (Outside) serve as members and one Member of the Audit and Supervisory Board (Outside) participates in each committee as the observer.
- (4) In addition to the qualification and performance requirements, etc. defined in the Member of the Board Regulations and The Code of Audit and Supervisory Board Member Auditing Standards, both Members of the Board (Outside) and Member of the Audit and Supervisory Board (Outside) meet the independence criteria of the Tokyo Stock Exchange (TSE) and the independence judgment criteria for outside directors set forth by the Company. All the members are reported as independent directors to the TSE.

Outside directors for FY2019

	Name	Age*	Years of Office	Independent Director	Significant Past Positions	Nomination Committee	Compensation Committee	Significant Specialty/Background			
								Corporate Management	Medicine/Pharmacy	Legal/Administration	Finance/Accounting
Members of the Board (Outside)	Noritaka Uji	70	5 years	✓	Former Representative Director, Senior Executive Vice President, Nippon Telegraph and Telephone Corporation (NTT)	✓ (Chairman)	✓	Communication			
	Tsuguya Fukui	67	4 years	✓	President of St. Luke's International University (to present) President of St. Luke's International Hospital (to present)	✓	✓		Medicine		
	Kazuaki Kama	70	—	✓	Former President, Chairman & Representative Director of IHI Corporation	✓	✓ (Chairman)	Heavy Industry			Finance
	Sawako Nohara	61	—	✓	President, IPSe Marketing, Inc. (to present)	✓	✓	IT Business			
Members of the Audit and Supervisory Board (Outside)	Sayoko Izumoto	65	2 years	✓	Former Partner at Deloitte Touche Tohmatsu LLC (C.P.A.)		✓ (Observer)				Accountant
	Tateshi Higuchi	66	1 year	✓	Former Superintendent General Former Ambassador Extraordinary and Plenipotentiary of Japan to the Republic of the Union of Myanmar	✓ (Observer)				Administration Diplomat	
	Yukiko Imazu	50	1 year	✓	Partner Lawyer, Anderson Mori & Tomotsune (to present)					Lawyer	

\* The ages listed above are as of June 2019

2. Enhancement of discussion for strengthening the decision-making and oversight functions of the Board

In order to improve and strengthen the effectiveness of the Board's important business decision and oversight functions, the Company properly submits matters for resolution and to be reported to the Board of Directors in accordance with laws and the article of association in a timely manner. In fiscal 2018, productive discussions were held on subjects, such as the 5-year business plan, business strategy, business investment, corporate governance (evaluation of the Board of Directors, status of cross-shareholdings, policy and procedure for appointment and dismissal of the CEO, CEO successor plan, payment of bonus to Members of the Board, revised Japan's Corporate Governance Code), and revisions of internal rules on important management matters.

When holding the Board of Directors Meeting, we promote enrichment and deepening of discussions by providing a preliminary briefing on the agenda of the meeting to Members of the Board (Outside) and Members of the Audit and Supervisory Board (Outside) each time in an attempt to provide information that will lead to promoting their understanding.

Major agenda of the Board of Directors Meeting for fiscal 2018

Matters Resolved	Matters Reported
Global development and commercialization collaboration for DS-8201	Monthly financial conditions
Revision of the 5-year business plan	Internal audit
Vaccine business, reorganizations of the Supply Chain Function	Auditors' audit
Sale of real estate held	Compliance management activities
Succession of long-listed products and contrast agents	Status of operation of the internal control system

3. the Board of Directors' address at ESG issues

The Company has established the Corporate Ethics Committee chaired by the compliance officer and the EHS Management Committee chaired by the chief executive officer of EHS. The Board of Directors receives reports from the both committees regarding important matters and conducts oversight on ESG issues.

For the overview of the corporate governance structure refer to page 65.

(1) Corporate Ethics Committee

We have established the Corporate Ethics Committee for the Daiichi Sankyo Group to promote management that complies with domestic and international laws and regulations as well as corporate ethics and fulfills corporate social responsibility, and to ensure compliance of its executives and employees. The Committee also has one appointed external attorney to ensure objectivity.

In fiscal 2018, the Corporate Ethics Committee Meeting was held in July and February to deliberate on the revision of the Global Marketing Code of Conduct and the Anti-Bribery and Anti-Corruption policy due to a revision to the IFPMA Code of Practice\*, activity plan for fiscal 2019 (enlightenment, education, monitoring, investigation, revision of rules, etc. related to corporate ethics), and so on.

\* IFPMA Code of Practice: An international voluntary standard for the pharmaceutical industry defined by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) on ethical promotion of pharmaceuticals to healthcare professionals and negotiations between the member companies and healthcare professionals.

(2) EHS Management Committee (EHS: Environment, Health and Safety)

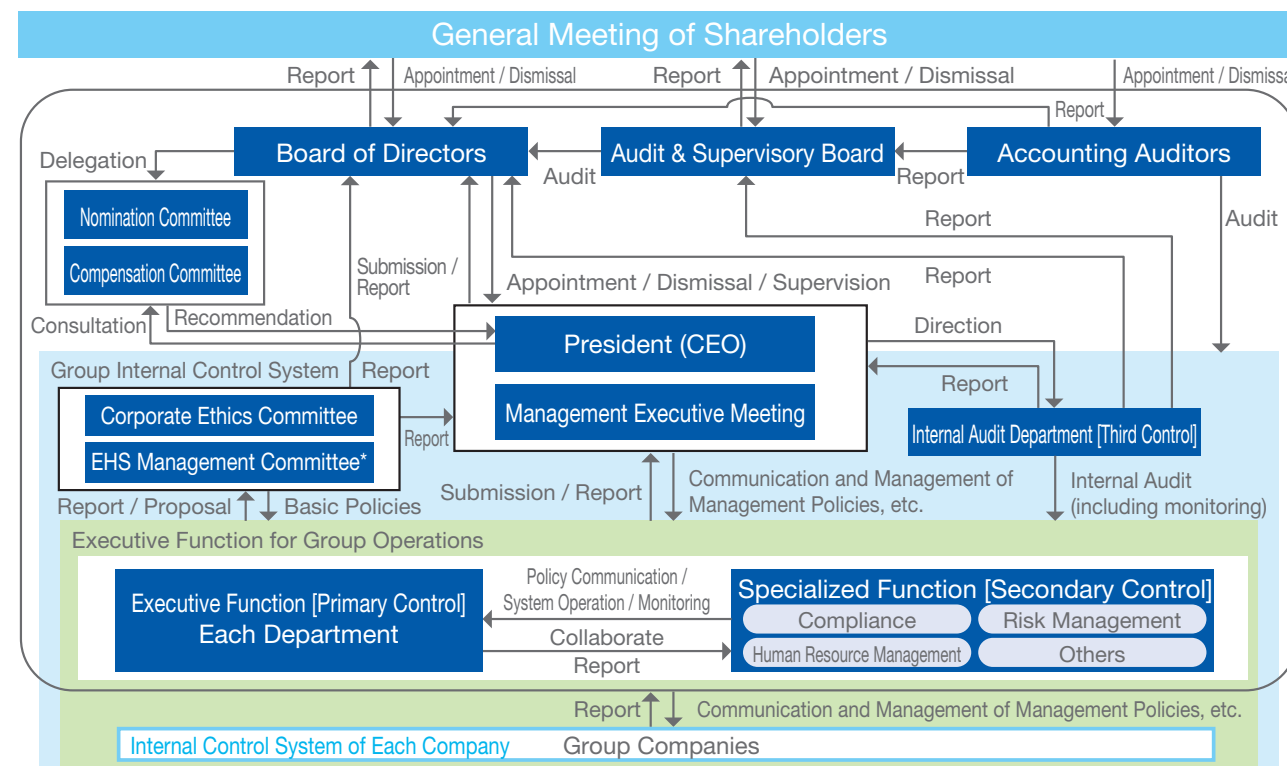
In order to ensure environmental conservation, health and safety in overall business activities at the Daiichi Sankyo Group and thereby to contribute to a sustainable society as well as to operate and promote management of the environment, health, and safety with a high likelihood of risk in an integrated manner, we have formulated the Global EHS Policy and the EHS Management Policy and established a new EHS Management Committee consisting of committee members including from Group companies in April 2019. As a result, we have developmentally dissolved the Environmental Management Committee into the new organization and deliberate on policies, target setting, and activities on the global EHS management in the meeting held twice a year in July and February.

In fiscal 2018, we held the Environmental Management Committee Meeting, the former committee structure, in July and February to deliberate on climate change measures, optimization of the environmental management system, and endorsement of the TCFD\* recommendations.

\* TCFD (Task Force on Climate-related Financial Disclosures): This task force was established in December 2015 by the FSB (Financial Stability Board). The FSB is an international organization joined by central banks and financial regulators from the major powers.



(As of June 18, 2019)



\* EHS Management Committee: Environment, Health, Safety

To establish an executive system that can flexibly and dynamically respond to changes in business environment, proper delegation of Board of Directors' authority to corporate officers including CEO and the establishment of an essential internal control system that enables such delegation are essential.

The Company clearly defines the scope of conduct of operations to be delegated by the Board of Directors in the Management Executive Meeting Regulations and the Approval policy and employs a Corporate Officer System as the mechanism and system that contribute to proper and speedy management decision-making and the conduct of operations.

The Company has established an internal control system in accordance with the Basic Policy on Establishing Internal Control Structure that was resolved in Board of Directors Meetings for the following purposes:

- Secure the effectiveness and efficiency of operations
- Ensure the reliability of financial reporting
- Adhere laws and regulations regarding business activities
- Safeguard assets

The system is operated based on a solid control system comprised of self-monitoring by each organization responsible for the Business/Functional Unit (Key Control), deployment and monitoring of the policy to each organization by the

In establishing the internal control system, we have developed a system for ensuring that Members of the Audit and Supervisory Board effectively conduct audits and confirm the status of operation of the internal control system mainly with respect to risk management, compliance, subsidiary management, and audits by Internal Audit Department and the Audit and Supervisory Board during the Board of Directors Meeting in March every year.

To secure and improve the effectiveness of the important business decision-making and oversight functions of the Board of Directors, we work to operate the system and implement measures as follows:

To clarify the management responsibility of Members of the Board and reinforce their oversight of management and the conduct of operations, their terms of office are set at one year, and four out of nine are Members of the Board (Outside).

The Company utilizes the evaluation of the Board of Directors, for the Board itself and Members to conduct a self-evaluation and recognize the current issues. The Members of the Board work on improvement measures for issues extracted from the evaluation and confirm the current evaluation and the status of improvement from the previous year. We conduct an evaluation of the Board of Directors every fiscal year and continue to work to improve the functions and effectiveness of the Board of Directors.

**COLUMN**

The evaluation of the Board of Directors conducted in fiscal 2018 confirmed that the overall effectiveness of the Board of Directors has been ensured.

In addition, for the following issues concluded as requiring further improvement in the previous evaluation, improvements have been made.

- (1) Setting agenda giving more consideration to strengthening the functions of the Board of Directors
- (2) Enriching and deepening the content of materials, briefing, and reports of the Board of Directors
- (3) Continuing to provide information that will lead to promoting the understanding of the Members of the Board (Outside)

These issues have been confirmed as ones that should continue to be worked on in fiscal 2019.

To ensure management transparency, nomination of candidates for Members of the Board, Members of the Audit and Supervisory Board, and Corporate Officers and compensation thereof are deliberated on by the Nomination Committee and the Compensation Committee, respectively, which are established as voluntary committees.

These committees consist of at least three Members of the Board, of whom Members of the Board (Outside) form a majority, and are chaired by an Member of the Board (Outside). Both committees are comprised entirely of Members of the Board (Outside) at present and one Member of the Audit and Supervisory Board (Outside) participates in each committee as an observer.

In fiscal 2018, meetings were held eight times to discuss matters required for nominating candidate Members of the Board, Members of the Audit and Supervisory Board, and Corporate Officers, plans for training successors for the President and CEO, Advisors and the Advisory System, etc.

COLUMN

Policies and procedures for appointment of Members of the Board, Members of the Audit and Supervisory Board, and CEO and Dismissal of Members of the Board and CEO.

The Company has defined policies and procedures for the appointment of candidate Members of the Board, Members of the Audit & Supervisory Board, and CEO as well as for the dismissal of Member of the Board and CEO.

For candidates for Members of the Board, the Board of Directors appoints the candidates after they have been sufficiently verified by Nomination Committee. For candidates for Members of the Audit and Supervisory Board, the Board of Directors appoints the candidates after they have been verified by Nomination Committee and then verified and agreed to by the Audit and Supervisory Board. An appointment of Members of the Board and Members of the Audit and Supervisory Board is referred to the General Meeting of Shareholders. As for candidates for the CEO, they are appointed in accordance with the successor plan, qualification requirement definitions, etc. that are repeatedly discussed by the Nomination Committee, and an appointment (including re-appointment) of the CEO is determined by the resolution of the Board of Directors after the sufficient deliberation by the Nomination Committee and the subsequent recommendations by the Committee.

V O I C E

Message from Chairperson of the Nomination Committee

The Nomination Committee is an advisory committee delegated by the Board of Directors. The primary roles of this committee are to maintain transparency while examining and making proposals for the appointment and dismissal of Members of the Board and Corporate Officers. As the Chairman of the Nomination Committee, I lead discussions from the perspective of the ongoing growth of Daiichi Sankyo and the qualities required of its management.

The new structure with Chairman Nakayama and President and CEO Manabe following the General Meeting in June 2019 is also a result of discussion by the Nomination Committee for the last several years. In a severe business environment, I will continue to examine measures for further strengthening the management structure, including the evaluation of the management, realization of a more diverse and younger team of Corporate Officers, and cultivation of candidates for future management positions in order to support the ongoing growth of Daiichi Sankyo.



Noritaka Uji  
Member of the Board  
(Outside)  
(Independent Director)

(2) Compensation Committee

The Compensation Committee has been established to deliberate on compensation of Members of the Board and Corporate Officers at the request of the Board of Directors and contribute to the enhancement of management transparency.

In fiscal 2018, meetings were held six times to deliberate on the verification of the remuneration levels, standard for calculating the bonus and bonus payment amounts and allocation of restricted stocks, etc. for Members of the Board and Corporate Officers.

Basic design of remuneration to Members of the Board and Members of the Audit and Supervisory Board

- The remuneration to Members of the Board (excluding Members of the Board (Outside)) is designed to provide remuneration that contributes to maximize corporate value. Specifically, in addition to a basic remuneration as fixed remuneration, performance-based bonuses serving as short-term incentive and restricted share-based remuneration serving as long-term incentive are adopted as variable remuneration. The percentage of each remuneration component is designed to be 60% for basic remuneration, 20% for performance-based bonus, and 20% for restricted share-based remuneration if 100% of the performance goal is achieved.
- The performance-based bonuses serving as short-term incentives are calculated by adopting revenue, indicating the size of the business, as an index with a high correlation to the maximization of corporate value, ratio of operating income to revenue, indicating the efficiency of business activities, and profit attributable to owners of the Company, indicating the final outcome of corporate activities, as the relevant indices.

The Remuneration system for Members of the Board and Member of the Audit and Supervisory Board for Fiscal 2018

Member of the Board (Outside) Members of the Audit and Supervisory Board	Basic Remuneration (fixed) 100%		
Members of the Board (excluding Members of the Board (Outside))	Basic Remuneration (fixed) 60%	Performance-Based Bonus 20%	Restricted Share-Based Remuneration 20%

Breakdown of Performance-Based Bonus (Fiscal 2018)	Evaluation Index	Evaluation Criteria	Weight	Goal	Achievement	Evaluation Factor	Bonus Payment Rate
	Revenue	Degree of achievement of the budget for the fiscal year	10%	¥910.0 billion	¥929.7 billion	100.8%*	156.2%
	Ratio of operating profit to revenue (operating profit)	Degree of achievement of the budget for the fiscal year	10%	8.6% (¥78.0 billion)	9.0% (¥83.7 billion)	102.6%*	
	Profit attributable to owners of the Company	Degree of achievement of the target value in the 5-year business plan	80%	¥55.0 billion	¥93.4 billion	169.8%	

\* The evaluation factors of revenue and operating profit margin are calculated by fixed formulas using the comparison of the actual results and the targets.

- For the remuneration of Members of the Board (Outside) and Members of the Audit and Supervisory Board (Outside), short-term and long-term incentives are not provided and only basic remuneration is granted.
- The level of remunerations is set aiming to provide medium to high level remunerations in the industrial sector, referring to the levels of other companies learned from the surveys of external specialist institutions. The level of remunerations is confirmed and deliberated by the Compensation Committee every year. Going forward, the Compensation Committee plans to examine increasing the amount and ratio of variable remuneration to increase the incentive for further improving our corporate value.

Remuneration for Members of the Board and Member of the Audit and Supervisory Board for Fiscal 2018

Classification of Members of the Board and Member of the Audit and Supervisory Board	Total payment amount including remuneration (millions of yen)	Total amount of remuneration for Members of the Board and Member of the Audit and Supervisory Board by type (millions of yen)			Number of eligible Members of the Board and Member of the Audit and Supervisory Board
		Basic Remuneration	Performance-Based Bonus	Restricted Share-Based Remuneration	
Members of the Board (excluding Members of the Board (Outside))	591	322	158	112	6*
Members of the Audit and Supervisory Board (excluding Members of the Audit and Supervisory Board (Outside))	75	75	—	—	2
Members of the Board (Outside)	60	60	—	—	4
Members of the Audit and Supervisory Board (Outside)	45	45	—	—	5*

\* The amount of remuneration, etc. and the number of Members of the Board (excluding Members of the Board (Outside)) and Members of the Audit and Supervisory Board (Outside) include one Member of the Board and two Members of the Audit and Supervisory Board (Outside) who retired at the end of his or her term of office as of the end of the 13th General Meeting of Shareholders held on June 18, 2018.

V O I C E

Message from Chairperson of the Compensation Committee

I have been appointed to serve as the new Chairperson of the Compensation Committee from this fiscal year. As visualization and expansion of disclosure of remuneration of Members of the Board are demanded in recent years, I feel the weight of responsibility as the Chairperson.

The major role of the Compensation Committee is to create a remuneration system that functions as an appropriate incentive for motivating Members of the Board to achieve our management vision and the 5-year business plan. At the same time, it is also important to design and operate a system that enables us to secure the transparency of management fulfill our accountability to shareholders.

In light of Daiichi Sankyo's system created through experience, I will examine the system for more appropriate remuneration from a new point of view.



Kazuaki Kama  
Member of the Board  
(Outside)  
(Independent Director)



Corporate Governance:  
Messages from Members of the Board (Outside) and  
Members of the Audit and Supervisory Board  
(Outside) (Independent Directors)



**Noritaka Uji**  
Member of the Board (Outside)  
(Independent Director)

There is a clear need for management systems capable of furnishing a speedily and flexible response to changes in the business environment and a Board of Directors' structure that sufficiently incorporates external viewpoints. I therefore feel immense responsibility to live up to expectations with this regard as a Member of the Board (Outside).

Over the medium term, Daiichi Sankyo will need to overcome the challenges presented by the loss of exclusivity for some of its products. This period will be an incredibly important time for transformation to build foundations for future growth to ensure that the Company can continue growing. This topic was discussed when formulating the 5-year business plan. Advancing this plan to achieve our vision that is responsive to changes, amid the situation where the business environment significantly changes within and outside the Company due to a large-scale alliance and the like, will be of utmost importance. Based on this belief, I will take action while incorporating the perspective of "aggressive governance."

I am committed to offering viable advice and suggestions based on my experience as a manager in the information and communication industry and the insight gained through this experience, thereby contributing to more lively discussions among the Board of Directors. At the same time, from my external standpoint, I will strive to facilitate effective corporate governance with regard to such areas as formulating strategies and conducting appropriate investments for future growth and selecting members of the management team.

Furthermore, I believe leveraging digital transformation due to advances in information and communications technology (ICT) in the management of the Company so as to contribute to the healthy and rich lives of people around the world is also important.

Development of a pharmaceutical innovation changes the lives (life expectancy, quality of life, performance) of people who are suffering from a target disease and consequently affects the development and state (population composition, work style, social security) of the entire society significantly. The Company is currently caught in the gap between gloom due to the patent cliff and optimism brought immediately before the launch of a new drug, which requires all kinds of efforts and decision-making for the administration and operation of the Company.

Meanwhile, the importance of the roles required for Members of the Board (Outside) is increasingly recognized without mentioning the case of inappropriate accounting involving Toshiba in 2015 or the Nissan/Ghoshn case since last year. As the Corporate Governance Code introduced in 2015 was actually revised in 2018, the trends of society are increasingly being reflected swiftly in the code of conduct for corporate governance.

I recognize that my role in the Company is to contribute to far-sighted decision making that takes into account the interest of our shareholders, employees, and all other stakeholders with thorough understanding of such a circumstance while adhering to laws and the Corporate Governance Code.



**Kazuaki Kama**  
Member of the Board (Outside)  
(Independent Director)

I understand the role of the Board of Directors as "conducting monitoring for sustainable growth and increased corporate value of the Company," specifically, the decision-making on the management policy (management board) and the monitoring and supervising the conduct of operations by Members of the Board and Corporate Officers (monitoring board).

Members of the Board (Outside) are required to assess the effectiveness of the management strategy and risks associated with the implementation of the strategy and to constantly verify the effectiveness of governance and internal control to prevent damage to corporate value, from the standpoint of a third party who are not involved in the conduct of operations.

Providing advice, etc. based on my experience and knowledge as a corporate manager of a heavy machinery manufacturer in a directly opposite position of the Company as well as the expertise and practical experience in the area of finance and accounting, I will contribute to the best of my ability to improved effectiveness of the Board of Directors of the Company.

Taking risks is necessary for the growth of a company. Daiichi Sankyo is also looking to take risks in pursuit of growth.

Members of the Board (Outside) tend to be negative when it comes to implementing a strategy for taking risks. I will fulfill my role from the standpoint of supporting the Corporate Officers by taking a positive stance in implementing strategies and monitoring the PDCA cycle for implementing the strategies.

I was appointed a Member of the Board (Outside) in June 2019.

I think our 2025 Vision of becoming a "Global Pharma Innovator with competitive advantage in oncology" is an excellent vision that is socially beneficial as well as gives people great hope in terms of coping with disease people around the world are wishing to overcome.

I am delighted to engage in the management of the Company as a Member of the Board (Outside).

I would like to offer advice and suggestions to the management of the Company from the viewpoint of an outsider based on my accumulated knowledge on business strategies and innovation eco-systems in the digital field and skills to derive desired products and services from the standpoint of a consumer. I will also comment my opinions on corporate governance at the board meetings, by leveraging my experience as an external director in other industries companies and as an expert member in many Policy Councils.

On the other hand, since I do not have much knowledge about the pharmaceutical industry, I will try to understand the actual conditions of the Company by taking opportunities to inspect the field and exchange opinions with each division as much as possible. So that I will strive to fulfill my role as a Member of the Board and improve our corporate value. Thank you.



**Tsuguya Fukui**  
Member of the Board (Outside)  
(Independent Director)



**Sawako Nohara**  
Member of the Board (Outside)  
(Independent Director)



**Sayoko Izumoto**  
Member of the Audit and  
Supervisory Board (Outside)  
(Independent Auditor)

The mission of certified public accountants, as professionals on auditing and accounting, "shall be to ensure matters such as the fair business activities of companies, etc. and the protection of investors and creditors by ensuring the reliability of financial documents and any other information concerning finance from an independent standpoint, thereby contributing to the sound development of the national economy." (refer to Article 1 of the Certified Public Accountants Law) "Members of the Audit & Supervisory Board are responsible for ensuring the sound and sustainable growth of the Company, and establishing good corporate governance in response to the public trust by supervising the performance of duties of the Directors." (refer to Article 2 paragraph 1 of the Code of Audit and Supervisory Board Member Auditing Standards) Although both Certified Public Accountants and Members of the Audit & Supervisory Board conduct audit, the former deals with financial documents and information and the latter, performance of duties of the Directors. While the final goal of the former is a sound development of the entire national economy, that of the latter is to establish good corporate governance. For the last two years I have been working to conduct audits with different objectives and approaches as a Member of the Audit and Supervisory Board, but I still continue to wonder if there is anything else I can do.

Daiichi Sankyo has entered an agreement on global development and commercialization regarding *DS-8201*, accelerating its large-scale R&D. Accordingly, our perspective, battlefield, and funds for the development will increase more than twofold. I consider being able to participate in this historical opportunity of a large project worked on by the entire Group as a Member of the Audit and Supervisory Board is the ultimate fortune. I will further strive to establish good corporate governance of the Company that can respond to the public trust and thereby creating corporate value.

It has been one year since I assumed my position as a Member of the Audit and Supervisory Board (Outside) being appointed at Ordinary General Meeting of Shareholders held last year.

I believe it is not easy for a company to realize sustainable growth under the ever-changing circumstances in and outside of Japan and amid the increasingly severe management environment. With the aim of becoming a "Global Pharma Innovator with competitive advantage in oncology," the Company has been advancing steadily under the 5-year business plan.

From a different viewpoint, on the other hand, it seems that the Company is about to enter a drastic transitional period. I think we are required to commit to building a flexible and resilient organization that resists changes.

As a government police official, I had long been working to create a society that is resistant to or that are not prone to crimes or accidents, in an attempt to realize a society where people in Japan can live more safely and securely. Both creating a society and building an organization are essentially the same. I will strive to respond to the expectations and trust of many stakeholders in collaboration with Internal Audit Department, accounting auditors, and Members of the Audit and Supervisory Board of our Group companies, especially from the viewpoint of corporate governance.



**Tateshi Higuchi**  
Member of the Audit and  
Supervisory Board (Outside)  
(Independent Auditor)



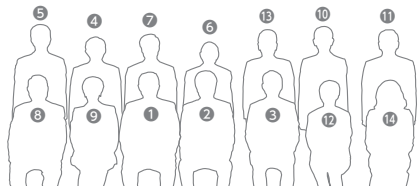
**Yukiko Imazu**  
Member of the Audit and  
Supervisory Board (Outside)  
(Independent Auditor)

Today, a higher priority is placed on transparency and compliance in corporate management than ever before. As the Work Style Reform Act entered into force last April, reviewing the work style of each employee is now a pressing issue. Leveraging my experience in corporate legal affairs and corporate governance with a focus on labor and employment cases as a lawyer, I, as a Member of the Audit and Supervisory Board of the Company, will continuously strive to contribute to establishing good corporate governance in response to the public trust.

Toward the implementation of the 2025 Vision, the Company has been promoting transformation, and the forming of an alliance with AstraZeneca for *DS-8201* is a critical step forward. However, when a company tries to make a change, not only opportunities but also risks will arise. In order to select and execute the best strategy from various choices within time constraint, an organization needs to make quick decisions. A Member of the Audit and Supervisory Board in the capacity of a lawyer is expected to contribute to providing a sense of security to shareholders and increasing corporate value of the Company. In order to achieve these, I will always offer objective opinions from an auditor's view in accordance from the legal mind and a neutral stance, so that unnecessary legal disputes and damages to corporate value will be avoided. I will continue to endeavor to secure compliance and sound management of the Company in pursuit of its sustainable growth.



Corporate Governance:  
Introduction of Members of the Board  
and Members of the Audit and  
Supervisory Board



Members of the Board

Representative Director  
and Chairman **George Nakayama ①**

**Career Summary, Positions, and Assignments**  
1979 Entered Suntory Limited ("Suntory")  
2000 Director of Suntory  
2002 President of Daiichi Suntory Pharma Co., Ltd.  
2003 Resigned as Director of Suntory  
2003 Member of the Board of Daiichi Pharmaceutical Co., Ltd. ("Daiichi")  
2006 Member of the Board, Vice President of Corporate Strategy Department of Daiichi  
2007 Corporate Officer, Vice President of Europe/US Business Management Department of the Company  
2009 Executive Officer, Vice President of Overseas Business Management Department of the Company  
2010 Executive Vice President, President of Japan Company of the Company  
2010 Representative Director, President and CEO of the Company  
2017 Representative Director, Chairman and CEO of the Company  
2019 Representative Director and Chairman of the Company (to present)

Representative Director,  
Member of the Board,  
President and CEO **Sunao Manabe ②**

**Career Summary, Positions, and Assignments**  
1978 Entered Sankyo Company, Limited ("Sankyo")  
2005 Vice President, Medicinal Safety Research Laboratories of Sankyo  
2007 Vice President, Medicinal Safety Research Laboratories of the Company  
2009 Corporate Officer, Vice President of Global Project Management Department, R&D Division of the Company  
2011 Corporate Officer, Head of Group HR & CSR of the Company  
2012 Corporate Officer, Vice President of Corporate Strategy Department, Corporate Strategy Division of the Company  
2014 Executive Officer, President of Japan Company and Head of Business Intelligence Division of the Company  
2014 Member of the Board, Executive Officer, President of Japan Company and Head of Business Intelligence Division of the Company  
2015 Member of the Board, Senior Executive Officer, In Charge of Global Sales & Marketing of the Company  
2016 Member of the Board, Executive Vice President, Head of General Affairs & Human Resources Division, and Medical Affairs Division of the Company  
2016 Representative Director, Member of the Board, Executive Vice President, Head of General Affairs & Human Resources Division, and Medical Affairs Division of the Company  
2017 Representative Director, Member of the Board, President and COO of the Company  
2019 Representative Director, Member of the Board, President and CEO of the Company (to present)

Representative Director, Member of the Board,  
Executive Vice President and CFO, Head of  
Corporate Strategy & Management Division **Toshiaki Sai ③**

**Career Summary, Positions, and Assignments**  
1979 Entered Daiichi Pharmaceutical Co., Ltd.  
2007 Vice President, Management System Department of the Company  
2008 Vice President, Corporate Communications Department of the Company  
2010 Corporate Officer, Vice President of Corporate Communications Department of the Company  
2012 Corporate Officer, Vice President of Global Brand Strategy Department, Corporate Strategy Division of the Company  
2014 Executive Officer, Vice President of Corporate Strategy Department, Corporate Strategy Division of the Company  
2015 Senior Executive Officer, Head of Corporate Strategy Division of the Company  
2015 Member of the Board, Senior Executive Officer, Head of Corporate Strategy Division of the Company  
2017 Member of the Board, Senior Executive Officer, Head of Global Brand Strategy Division of the Company  
2018 Member of the Board, Executive Vice President and CFO, Head of Corporate Strategy & Management Division of the Company  
2018 Representative Director, Member of the Board, Executive Vice President and CFO, Head of Corporate Strategy & Management Division of the Company (to present)

Member of the Board, Senior Executive  
Officer, In charge of Vaccine Business  
and Quality & Safety Management **Toshiaki Tojo ④**

**Career Summary, Positions, and Assignments**  
1980 Entered Daiichi Pharmaceutical Co., Ltd.  
2010 Vice President, Supply Chain Technology Department, Supply Chain Division of the Company  
2011 Corporate Officer, Vice President, Supply Chain Technology Department, Supply Chain Division of the Company  
2011 Corporate Officer, Vice President, Supply Chain Planning Department, Supply Chain Division of the Company  
2013 Corporate Officer, Head of Quality and Safety Management Division of the Company  
2014 Executive Officer, Head of Quality and Safety Management Division of the Company  
2016 Senior Executive Officer, In charge of Vaccine Business of the Company  
2016 Member of the Board, Senior Executive Officer, In charge of Vaccine Business of the Company  
2019 Member of the Board, Senior Executive Officer, In charge of Vaccine Business and Quality & Safety Management (to present)

(Material Concurrent Positions)  
· Director and Chairman of Daiichi Sankyo Biotech Co., Ltd. (consolidated subsidiary company of the Company)

Members of the Board, Senior  
Executive Officer, Head of  
Sales & Marketing Division **Satoru Kimura ⑤**

**Career Summary, Positions, and Assignments**  
1981 Entered Daiichi Pharmaceutical Co., Ltd.  
2009 Vice President of Kyoto Branch, Sales & Marketing Division, Japan Company of the Company  
2014 Corporate Officer, Head of Sales & Marketing Division and Vice President of Marketing Department, Japan Company of the Company  
2015 Executive Officer, Head of Sales & Marketing Division of the Company  
2016 Senior Executive Officer, Head of Sales & Marketing Division of the Company  
2019 Member of the Board, Senior Executive Officer, Head of Sales & Marketing Division of the Company (to present)

Member of the Board  
(Outside)  
(Independent Director) **Noritaka Uji ⑥**

**Career Summary, Positions, and Assignments**  
1973 Entered Nippon Telegraph and Telephone Public Corporation  
1999 Director, Senior Vice President, Advanced Information Network Services Sector of NTT DATA Corporation ("NTT DATA")  
2000 Director, Senior Vice President, Corporate Strategy Planning Department of NTT DATA  
2001 Director, Senior Vice President, Industrial System Sector of NTT DATA  
2002 Director, Senior Vice President, Enterprise Business Sector of NTT DATA  
2003 Managing Director, Executive Vice President, Enterprise Systems Sector and Enterprise Business Sector of NTT DATA  
2005 Representative Director, Executive Officer of NTT DATA  
2007 Representative Director, Senior Executive Vice President, Nippon Telegraph and Telephone Corporation ("NTT")  
2012 Adviser of NTT  
2014 Member of the Board of the Company (Outside) (to present)

(Material Concurrent Positions)  
· External Director of Yokogawa Electric Corporation  
· Honorary Chairman of Japan Institute of Information Technology  
· Honorary President of Japan Telework Association  
· Visiting Professor of Center for Global Communications, International University of Japan

Member of the Board (Outside)  
(Independent Director) **Tsuguya Fukui ⑦**

**Career Summary, Positions, and Assignments**  
1992 Professor, Department of General Medicine of Saga Medical School Hospital  
1994 Professor, Department of General Medicine of Kyoto University Hospital  
1999 Professor, Department of Clinical Epidemiology, Kyoto University Graduate School of Medicine  
2000 Professor, Department of Clinical Epidemiology, Professor, Department of Health Informatics, Dean, School of Public Health, Kyoto University Graduate School of Medicine  
2001 Professor, Department of Clinical Epidemiology, Professor, Department of Health Informatics, Director, EBM Collaborative Research Center, School of Public Health, Kyoto University Graduate School of Medicine  
2004 Chief of Staff, Department of Internal Medicine, Vice President, St. Luke's International Hospital  
2005 President of St. Luke's International Hospital (to present)  
2012 Chairperson of the Board of Trustees of St. Luke's College of Nursing (currently St. Luke's International University)  
2015 Member of the Board (Outside) of the Company (to present)  
2016 President of St. Luke's International University (to present)

(Material Concurrent Positions)  
· President of St. Luke's International University  
· President of St. Luke's International Hospital  
· Executive Director of Japan Hospital Association  
· President of The Japan Medical Library Association

Member of the Board (Outside)  
(Independent Director) **Kazuaki Kama ⑧**

**Career Summary, Positions, and Assignments**  
1971 Entered Ishikawajima-Harima Heavy Industries Co., Ltd. (currently, IHI Corporation)  
1987 Executive Vice President of IHI INC. (New York)  
2002 Associate Director and Deputy General Manager of Finance and Accounting Division of Ishikawajima-Harima Heavy Industries Co., Ltd.  
2004 Executive Officer and General Manager of Finance and Accounting Division of Ishikawajima-Harima Heavy Industries Co., Ltd.  
2005 Managing Executive Officer, General Manager of Finance and Accounting Division of Ishikawajima-Harima Heavy Industries Co., Ltd.  
2005 Board Director, Managing Executive Officer, General Manager of Finance and Accounting Division of Ishikawajima-Harima Heavy Industries Co., Ltd.  
2007 President and Chief Executive Officer of Ishikawajima-Harima Heavy Industries Co., Ltd.  
2012 Chairman of the Board of IHI Corporation  
2016 Board Director of IHI Corporation  
2016 Executive Corporate Advisor of IHI Corporation (to present)  
2019 Member of the Board (Outside) of the Company (to present)

(Material concurrent positions)  
· Executive Corporate Advisor of IHI Corporation  
· Outside Director of SUMITOMO LIFE INSURANCE COMPANY  
· Statutory Auditor (Outside) of Tokyo Stock Exchange, Inc.

Member of the Board (Outside)  
(Independent Director) **Sawako Nohara ⑨**

**Career Summary, Positions, and Assignments**  
1980 Entered Mitsubishi Petrochemical Co., Ltd. (currently, Mitsubishi Chemical Corporation)  
1988 Entered Life Science Institute Co., Ltd.  
1995 Entered InfoCom Research, Inc.  
1998 Head of the E-Commerce Business Development Group of InfoCom Research, Inc.  
2001 President of IPSe Marketing, Inc. (to present)  
2006 Outside Director of the Board of NEC Corporation  
2009 Project Professor of the Graduate School of Media and Governance, Keio University (to present)  
2012 Audit & Supervisory Board Member (Outside) of Sampo Japan Insurance Inc.  
2013 Outside Director of the Board of NKSJ Holdings, Inc. (currently, Sampo Holdings, Inc.) (to present)  
2014 Outside Director of the Board of Nissha Printing Co., Ltd. (currently, Nissha Co., Ltd.)  
2014 Outside Director of the Board of JAPAN POST BANK Co., Ltd. (to present)  
2018 Outside Audit & Supervisory Board Member of Tokyo Gas Co., Ltd. (to present)  
2019 Member of the Board (Outside) of the Company (to present)

(Material concurrent positions)  
· President of IPSe Marketing, Inc.  
· Project Professor of the Graduate School of Media and Governance, Keio University  
· Outside Director of the Board of Sampo Holdings, Inc.  
· Outside Director of the Board of JAPAN POST BANK Co., Ltd.  
· Outside Audit & Supervisory Board Member of Tokyo Gas Co., Ltd.

Members of the Audit and Supervisory Board

Member of the Audit and  
Supervisory Board **Ryoichi Watanabe ⑩**

**Career Summary and Positions**  
1981 Entered Sankyo Company, Limited ("Sankyo")  
2003 Vice President, Accounting Department of Sankyo  
2004 Vice President, Business Performance Management Department of Sankyo  
2007 Vice President, Corporate Accounting Department of the Company  
2009 Vice President, Corporate Finance & Accounting Department of the Company  
2012 Vice President, General Affairs & Procurement Department, General Affairs & Human Resources Division of the Company  
2014 Vice President, Finance & Accounting Department, Corporate Management Division of the Company  
2015 Vice President, Internal Audit Department of the Company  
2016 Corporate Officer, Vice President, Internal Audit Department of the Company  
2019 Corporate Officer, in charge of Internal Audit Department of the Company  
2019 Member of the Audit and Supervisory Board of the Company (to present)

Member of the Audit and  
Supervisory Board **Kenji Sato ⑪**

**Career Summary and Positions**  
1988 Entered Daiichi Pharmaceutical Co., Ltd.  
2016 Vice President, R&D General Affairs & Human Resources Department, R&D Division of the Company  
2019 Principal, R&D General Affairs & Human Resources Department, R&D Division of the Company  
2019 Member of the Audit and Supervisory Board of the Company (to present)

Member of the Audit and  
Supervisory Board (Outside)  
(Independent Auditor) **Sayoko Izumoto ⑫**

**Career Summary and Positions**  
1976 Joined Tohmatsu Awoki & Co. (currently "Deloitte Touche Tohmatsu LLC")  
1979 Registered as Certified Public Accountant  
1995 Partner of Tohmatsu & Co. (currently "Deloitte Touche Tohmatsu LLC")  
2007 Member of Business Accounting Council, Financial Services Agency January  
2015 Member of Information and Communications Council, Ministry of Internal Affairs and Communications (to present)  
2016 Representative, Izumoto Certified Public Accountant Office (to present)  
2017 Member of Information Disclosure and Personal Information Protection Review Board, Ministry of Internal Affairs and Communications (to present)  
2017 Member of the Audit & Supervisory Board (Outside) of the Company (to present)

(Material Concurrent Positions)  
· Member of Information and Communication Council, Ministry of Internal Affairs and Communications  
· Member of Information Disclosure and Personal Information Protection Review Board, Ministry of Internal Affairs and Communications  
· Representative of Izumoto Certified Public Accountant Office  
· External Audit and Supervisory Board Member of Freund Corporation  
· External Director of Hitachi Transport System, Ltd.

Member of the Audit and  
Supervisory Board (Outside)  
(Independent Auditor) **Tateshi Higuchi ⑬**

**Career Summary and Positions**  
1978 Entered National Police Agency  
2007 Deputy Director General for Policy Evaluation and Deputy Director General of National Police Agency  
2008 Chief of Personnel and Training Bureau of Tokyo Metropolitan Police Department  
2009 Deputy Superintendent General and Acting Chief of Personnel and Training Bureau of Tokyo Metropolitan Police Department  
2010 Chief of Community Safety Bureau of National Police Agency  
2011 Superintendent General  
2014 Ambassador Extraordinary and Plenipotentiary of Japan to the Republic of the Union of Myanmar  
2018 Member of the Audit and Supervisory Board (Outside) of the Company (to present)

(Material Concurrent Positions)  
· Adviser of Sampo Japan Nipponkoa Insurance Inc.  
· External Director of Miura Co., Ltd.  
· Adviser of Nishimura & Asahi

Member of the Audit and  
Supervisory Board (Outside)  
(Independent Auditor) **Yukiko Imazu ⑭**

**Career Summary and Positions**  
1996 Entered Anderson Mōri (currently, Anderson Mōri & Tomotsune)  
2005 Partner of Anderson Mōri & Tomotsune (to present)  
2007 Associate Professor of Keio University Law School  
2014 Director of Ishibashi Foundation (to present)

(Material concurrent positions)  
· Partner of Anderson Mōri & Tomotsune  
· Director of Ishibashi Foundation



# Risk Management

The Daiichi Sankyo Group identifies factors that may prevent the Group from attaining its organizational goals and targets and that can be predicted in advance as risks. The Group is promoting risk management by taking steps to address risks inherent in corporate activities by retaining, reducing, avoiding, or eliminating these risks. In addition, we seek to minimize the adverse impacts of risks on people, society, and the Group should they occur.

Specifically, in addition to the risk management system that defines steps to address risks inherent in corporate activities, the Group has a business continuity plan (BCP\*) that enables it to continue to operate even in the event of disasters, etc., that may affect its business, as well as a crisis management system to minimize loss should a risk greater than expected occur.

\*Business Continuity Plan

## Risk Management

### Risk Management System

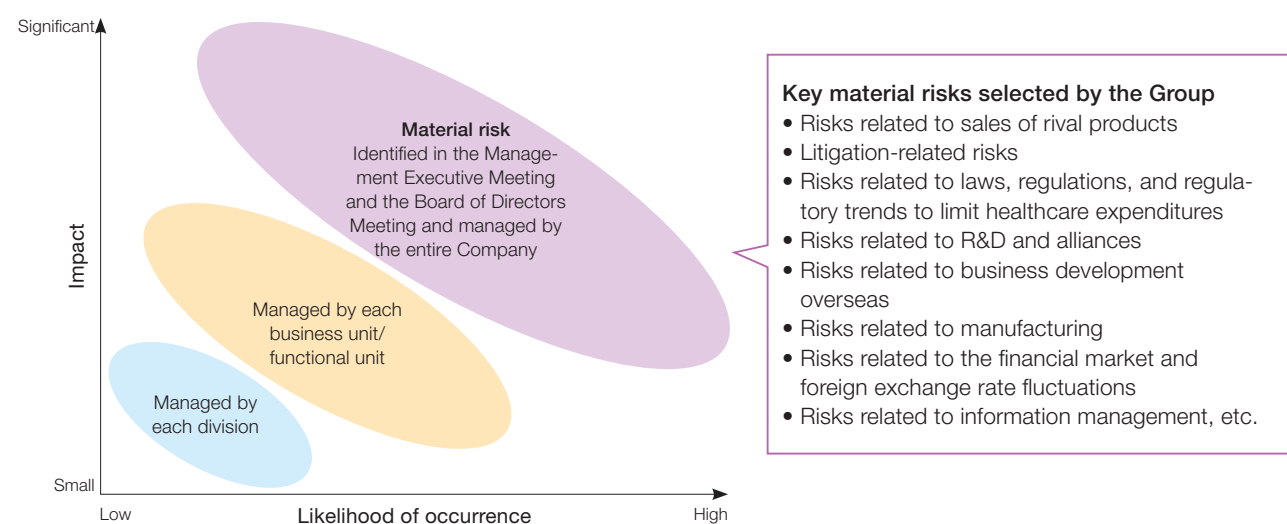
The chief financial officer (CFO) oversees Group-wide risk management as the risk management officer (RMO) and operates the risk management system in conjunction with an annual cycle of formulating and implementing business plans. In addition, the heads of each division autonomously manage risks to aid the accomplishment of their divisions' goals and targets. To this end, they analyze and evaluate individual risks, formulate and implement yearly risk management plans, and provide employees with information on underlying risks in the organization, education, and insight concerning risk management.

### Annual Cycle for the Management of Material Risks

Based on the assessment of the impact and the likelihood of occurrence, risks with the potential to significantly affect the management of the Company are identified by the Management Executive Meeting and the Board of Directors Meeting (see the conceptual diagram below on the Group's risk level classification). Individuals who have been assigned responsibility for each risk formulate risk response measures (Plan), which are then enacted by coordinating with relevant organizations (Do). The progress of risk response measures is monitored twice a year (Check). The risk response measures are corrected or improved upon as necessary (Action).

Should precursors of the potential occurrence of a material risk be detected, related information will quickly be assembled for the RMO, and appropriate measures will be taken.

### Conceptual diagram of the Group's risk level classification



## Business Continuity Plan

The Group has a business continuity plan (BCP) to prepare for four major threats to business continuity: natural disasters, facility accidents, H5N1 influenza and other infectious diseases, and system failures. Based on this plan, systems are in place to quickly restore operations in the event of an emergency and to ensure a steady supply of pharmaceutical products with assured quality to help support the continued provision of medical services.

Based on its experiences following the Great East Japan Earthquake, the Group revised its BCP in 2012. Since then, we have continued to improve upon the BCP through such means as incorporating revisions to national disaster response plans and adjusting for changes in workflow procedures and organizations related to drugs for which supply should be prioritized based

on social needs. In this manner, we strive to ensure effective response measures are taken in the event that a risk occurs. In addition, we regularly revise the list of priority supply drugs to guarantee we can quickly supply drugs used by a large number of patients, drugs needed in emergencies, and drugs with no substitutes.

To ensure the steady supply of its pharmaceutical products, in particular, the Company is taking steps to create backup supply systems by dispersing manufacturing and distribution sites and maintaining relationships with multiple suppliers for important raw materials. In addition, we have introduced private electricity generators to help minimize the impact of any interruption in the supply of electricity. Furthermore, we are reinforcing our IT foundations by installing redundancy into major systems.

## Crisis Management

In response to the declaration to "ensure crisis management" in Article 9 of the DAIICHI SANKYO Group Corporate Conduct Charter that was revised in April 2019, the Group has established a new Global Crisis Management Policy. This policy collectively defines crises as events that have occurred and require immediate response and other events with extremely high likelihood of occurrence, among potential risks in business activities. For the purpose of minimizing loss due to the occurrence of a crisis, the policy stipulates basic items related to crisis management. The Global Crisis Management Policy stipulates that "In the event of a crisis, crisis management shall be conducted promptly and certainly to minimize the loss of people, society, and the company with the principle of 'Securing the lives of Daiichi Sankyo Group employees and related parties and the safety of the local community' and 'Fulfilling the responsibilities of a company that is engaged in a business that affects human lives' and making efforts to ensure business continuity and early recovery from the crisis."

While independently promoting crisis management in each region, function, and group company, we also have a structure to flexibly and globally respond to crisis depending on the type (disaster/accident, incident including terrorism, scandal, breach of laws, information management-related problem, product-related problem) or the degree of impact of the crisis.

We have clearly defined the reporting criteria and channels and established the crisis management officer (CMO), either the CEO or an officer appointed by the CEO, and the person responsible for the initial crisis management (the vice president of the General Affairs and Procurement). For a crisis with a global impact requiring company-wide response, we strive to prevent the situation from escalating and to resolve it by sharing the relevant information with the RMO (CFO) and through quick and appropriate initial response. After the crisis has been resolved, we conduct ex-post analysis to prevent a recurrence of the crisis and improve our response.

### Initial response to crisis

