

Passion for Innovation.  
Compassion for Patients.™



Daiichi-Sankyo



**Daiichi Sankyo Group  
Value Report 2019**

# Our Mission

The **Core Values** and **Commitments** serve as the criteria for business activities and decision-making used by executive officers and employees in working to fulfill **Our Mission**. Our **Corporate Slogan** succinctly explains the spirit of Our Mission, Core Values and Commitments.

Our Mission

To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs.

Core Values

Innovation

the introduction of new ideas, methods, or invention

Integrity

the quality of being honest and of always having high moral principles

Accountability

being responsible for the effects of your actions, and being willing to explain or be criticized for them

Commitments

1. To create innovative medicines changing SOC\*

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

2. To take a global perspective, and respect regional values

3. To foster intellectual curiosity and strategic insight

4. To provide the highest quality medical information

5. To provide a stable supply of top-quality pharmaceutical products

6. To be an ethical, trusted, and respectful partner

7. To be accountable for achieving our goals

8. To demonstrate professionalism, respect for others, and teamwork

Corporate Slogan

Passion for Innovation. Compassion for Patients.™

In addition, we have established the **DAIICHI SANKYO Group Corporate Conduct Charter**. This charter calls on us to fulfill our social responsibilities by acting with the highest ethical standards and a good social conscience appropriate for a company engaged in business that affects human lives, and we model our business activities accordingly.

DAIICHI SANKYO Group Corporate Conduct Charter

The DAIICHI SANKYO Group fulfills its mission "To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs." We comply with laws, regulations and rules regarding global corporate activities, and act with the highest ethical standards and a good social conscience based on the following 10 principles of this Charter.

In order to actively respond to an ever-changing society, we address social issues and business in an integrated manner. It will enhance our corporate value, fulfill our social responsibilities and contribute to the realization of a sustainable society.

Article 1

**Contribution to healthcare**  
We diligently address medical needs by providing beneficial, safe, and reliable pharmaceuticals and services.

Article 2

**Fair business practices**  
We respect international norms, diverse cultures and customs, conduct business in a fair manner through free and fair competition, and conduct responsible procurement by complying with laws and regulations in each country and region in which we do business. We maintain productive, positive and professional relationships with our stake-holders, which include medical professionals and governments.

Article 3

**Fair disclosure of information and constructive dialogue with stakeholders**  
We actively, effectively and fairly disclose corporate information to the public and engage in an open and constructive dialogue with a wide range of stakeholders.

Article 4

**Respect for human rights**  
We conduct business that respects the human rights of all persons.

Article 5

**Enhancement of workplace environment and human resource development**  
We respect the diversity of our employees, and seek to include a diversity of thought in our daily work. We are committed to ensuring a healthy and safe working environment and do not tolerate harassment and discrimination. We provide employees the opportunity to develop their skills and abilities for the mutual growth of the individual employee and the corporation.

Article 6

**Information management**  
We take necessary measures to manage and protect personal information, business partner information as well as other confidential information of Daiichi Sankyo and others.

Article 7

**Engagement in environmental issues**  
Environmental challenges are universally critical to all of mankind. We responsibly manage the environmental impact of our operations and include our efforts for a better environment in our corporate activities and our very survival.

Article 8

**Involvement in community and contribution to its development**  
We are actively involved in community activities and contribute to its development as a good corporate citizen.

Article 9

**Thorough crisis and emergency management**  
We adhere to crisis and emergency management in the face of actions by antisocial forces, terrorism, cyber-attacks, natural disasters, pandemics and other significant issues that may threaten the order or safety of civil society and the corporate activity.

Article 10

**Role of executives and implementation of this Charter**  
Executives of the DAIICHI SANKYO Group actively build and maintain effective governance systems to implement this Charter, ensure it is understood by all Group companies, and encourage behavior based on the principles of this Charter to the business partners of Daiichi Sankyo Group. If the Charter is violated, executives of DAIICHI SANKYO Group Companies take responsibility to respond by determining the cause of infringement, taking corrective action as necessary and making efforts to prevent similar violations in the future.



**Sustainable Development Goals (SDGs)**

In light of the Sustainable Development Goals (SDGs) and other international initiatives, the Group has made revisions to the DAIICHI SANKYO Group Corporate Conduct Charter in April 2019 and has declared that the Group will contribute to the realization of a sustainable society.

# Daiichi Sankyo's Value Creation Process

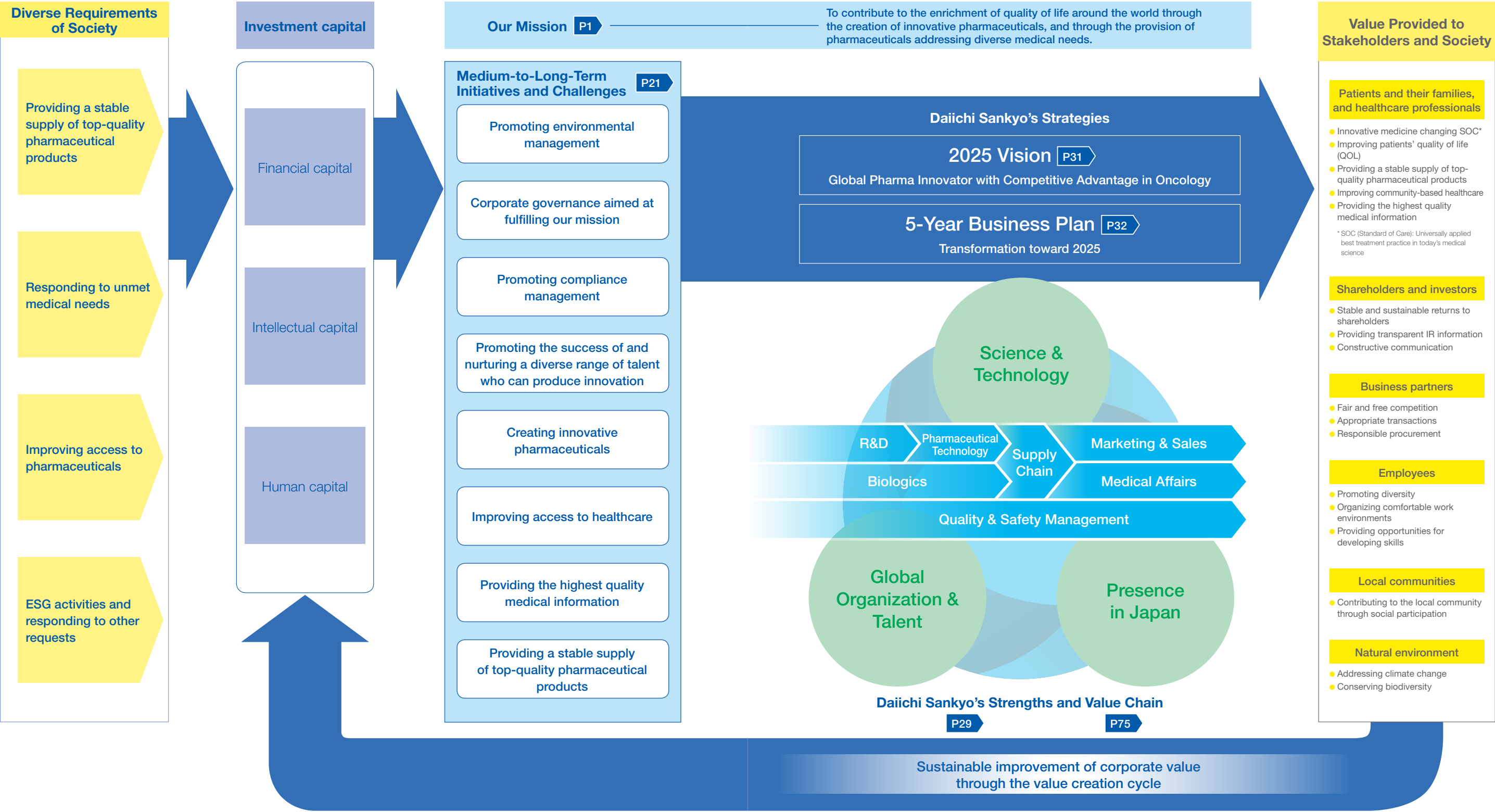
Daiichi Sankyo is requested from society for various needs including providing a stable supply of quality pharmaceuticals, responding to unmet medical needs<sup>\*1</sup>, improving access to pharmaceuticals<sup>\*2</sup>, and ESG activities. We engage in medium-to-long-term initiatives using our financial capital, intellectual capital, human capital and other capitals to enhance our long-term corporate value, as well as to realize a sustainable society.

At Daiichi Sankyo, we define our 2025 Vision as striving to become a “Global Pharma Innovator with competitive advantage in oncology,” and we are currently aiming to achieve the goals in our 5-Year Business Plan in order to realize this vision. The basis of Daiichi Sankyo's value creation is in addressing diverse medical needs through continually creating innovative pharmaceuticals while taking advantage of our strengths in science and technology,

global organization and talent, as well as our presence in Japan. At the same time, we address sustainability issues including social and the environmental issues, integrally with our business activities, and these activities also deliver value to society.

By continuing this cycle of our value creation process, we will sustainably improve our corporate value, and we will provide the values in a well-balanced manner generated by Daiichi Sankyo to our stakeholders and society, including patients, their families, healthcare professionals, our shareholders and investors, business partners, employees and local communities.

<sup>\*1</sup> Medical needs for effective treatment and drugs yet to be developed  
<sup>\*2</sup> Pharmaceuticals needed by patients being delivered sufficiently and consistently





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Value Report 2019



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Editorial Policy

Daiichi Sankyo began publishing Value Reports, its brand of integrated reports, in fiscal 2013. These reports have been positioned as communication tools for facilitating understanding with regard to the Group's corporate value, growth potential, and capacity for business continuity. Through these reports, we aim to provide easy-to-understand information on the Company's management policies, business strategies, and financial performance as well as on the various activities we conduct to contribute to the realization of a sustainable society to patients, their families, healthcare professionals, shareholders, investors, business partners, local communities, employees, and various other stakeholders.

For the latest information on the Company's activities, please refer to the Company's website, which includes a variety of contents, including financial results summaries and videos of briefing sessions for investors.

 Company's website  
<https://www.daiichisankyo.com/>



Major Keywords of Value Report 2019

- Medium-to-Long-Term Initiatives and Challenges ▶ P8, P21
- Review of 5-Year Business Plan ▶ P33
- R&D Pipeline ▶ P15
- DS-8201* ▶ P9, P45, P59
- Strategic Collaboration with AstraZeneca ▶ P9, P34, P59

Period Covered

April 1, 2018 – March 31, 2019 (fiscal 2018) and also information for the period from April 2019 onward

Cautionary Note Regarding Forward-Looking Statements

Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses are all classified as "Daiichi Sankyo's future prospects." These forward-looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material.



# Message from the CEO

We will make a concerted effort to achieve our 2025 Vision of becoming a “Global Pharma Innovator with competitive advantage in oncology.”



Sunao Manabe  
Representative Director,  
President and CEO

Dear stakeholders, I would like to begin by expressing my sincere gratitude for your continued support and understanding regarding our business.

My name is Sunao Manabe, and I took up the position of CEO in June 2019. Up until now, I have engaged in corporate activities with former CEO George Nakayama, and we have focused Daiichi Sankyo Group’s entire strength toward realizing our 2025 Vision of becoming a “Global Pharma Innovator with competitive advantage in oncology.”

Going forward, I will begin discussions regarding our next 5-year business plan, and will draw up a roadmap for achieving our 2025 Vision. In addition, I believe that one of my significant responsibilities as CEO is to make the necessary moves with consideration for the year 2025 and beyond.

I would first like to introduce Daiichi Sankyo’s medium-to-long-term initiatives and challenges for improving our long-term corporate value and realizing a sustainable society.

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

In recent years, social issues such as climate change, a growing wealth gap, as well as extortion, bribery and other forms of corruption have been recognized as global risks. Initiatives are being promoted to solve these issues through international frameworks such as the SDGs and the Guiding Principles on Business and Human Rights. Apart from compliance with laws and regulations, there is demand for companies to actively engage in initiatives to solve these social issues. Daiichi Sankyo Group has worked in such initiatives for some time as a good corporate citizen.

Activities to continually create innovative pharmaceuticals and to address diverse medical needs serve as the basis for creating value at Daiichi Sankyo. These activities also serve as solutions for issues related to sustainability, including social and environmental problems. At Daiichi Sankyo Group, we aim to conduct activities as an integral part of our business to solve social issues. Our position as a company engaging in business that affects human lives enables us to undertake such activities, and we wish to continue delivering wide-ranging value to society.

This Value Report features an overview of our medium-to-long term corporate activities, and I would also like to give a brief description of these activities here.

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

- Promoting Environmental Management
- Corporate Governance Aimed at Fulfilling Our Mission
- Promoting Compliance Management
- Promoting the Success of and Nurturing a Diverse Range of Human Resources Who Can Produce Competitive Advantage
- Creating Innovative Pharmaceuticals
- Improving Access to Healthcare
- Providing the Highest Quality Medical Information
- Providing a Stable Supply of Top-Quality Pharmaceutical Products

Message from the CEO

We recognize global warming, climate change, and other environmental problems as severe issues that can affect our lifestyles as well as our business. We are actively promoting environmental management to conduct responsible corporate activities in light of a wide range of environmental issues.

In addition, we are developing a corporate governance structure that can swiftly and dynamically respond to changes in the business environment. We are carrying out compliance management, not just to comply with laws, regulations, and rules, but also to act with the highest ethical standards and a good social conscience appropriate for a company engaged in a business that affects human lives.

With regard to human resources, we will nurture global talent and actively acquire highly experienced individuals. We will create competitive advantages by encouraging our personnel to achieve success.

In addition to addressing unmet medical needs through continually creating innovative pharmaceuticals, we are also engaging in initiatives for improving access to healthcare. These initiatives include actions for resolving access barriers to healthcare caused by social factors such as public health, education, and income inequality.

We continue to fulfill our mission as a company even after creating innovative pharmaceuticals, by providing high-quality information and sending out messages that promote proper use in appropriate patients, as well as by providing a stable supply of top-quality pharmaceutical products across the globe.

For details, refer to page 21.

As described above, the medium-to-long term initiatives and challenges at Daiichi Sankyo Group include undertakings to continually create innovative pharmaceuticals, as well as to tackle issues related to sustainability, including social and environmental problems. We strive to deliver wide-ranging value to society through these activities, and we believe that these actions ultimately contribute to the continued improvement of our corporate value.

We set forth our 2025 Vision of becoming a “Global Pharma Innovator with competitive advantage in oncology,” and are working to achieve our 4th 5-year business plan. The concept “Creating Innovative Pharmaceuticals” stands at the base of our business in terms of our current activities, and we currently have very high expectations of DS-8201 in this regard. Here, I would like to describe DS-8201 in more detail.

Submitting NDA for DS-8201

The data from a clinical study of DS-8201, the first compound in our ADC (Antibody Drug Conjugate) franchise, was first presented at the European Society for Medical Oncology (ESMO) in 2016. At that point, data was preliminary with limited number of patients; therefore efficacy and safety, as well as duration of therapy were not clear. However, as the clinical studies proceeded, data became mature, and we came to acquire data indicating an improvement in response rate as well as prolonged effects. At the end of April 2019, we published the latest data on phase 1 studies in breast and gastric cancers in the academic journal Lancet Oncology. This data demonstrated prolonged efficacy, with the progression-free survival exceeding 22 months for breast cancer.

At the end of May, we obtained results from a pivotal phase 2 study in tertiary treatment for metastatic breast cancer, and these data demonstrated clinically significant efficacy. Based on these results, we plan to submit applications for the breast cancer indication in several regions on a gradual basis: the U.S. in the first half of fiscal 2019, Japan in the second half of fiscal 2019, and Europe in the first half of fiscal 2020.

We also plan to file an NDA in Japan for the metastatic gastric cancer indication in fiscal 2020. In this way, we are finally seeing possibilities for delivering DS-8201 to patients. We are filing NDAs in an extremely short period of time; just four years after starting clinical trials in 2015. We believe that this achievement was a result of company-wide collective efforts, as well as the potential of DS-8201 created through our proprietary science and technology.

Maximizing the Product Value of DS-8201: Strategic Collaboration with AstraZeneca

In light of the steady progress in development on DS-8201 as well as our increasingly high esteem among healthcare professionals and market players, we signed a contract with AstraZeneca in March 2019 regarding global development and commercialization. We will be able to deliver DS-8201 to more patients even quicker by planning and carrying out various strategies together with our partner, who has exhibited extensive experience and resources worldwide in the field of oncology. We will each work in different roles to achieve this goal.

This strategic collaboration has significance in three main areas.

First, our collaboration with AstraZeneca will accelerate the pace of our expansion into the European market, and will spur on global development regarding new indications, in addition to advancing our schedule for entering the market in China and other countries. This will allow us to

deliver DS-8201 to more patients even quicker. Second, this experience will accelerate work to build a structure for an oncology business in the global market. Finally, this collaboration will also halve our R&D costs and personnel resource requirements, meaning that Daiichi Sankyo can allocate more resources toward ADC projects that follow after DS-8201.

When deciding on a partner for DS-8201, we focused on whether candidates gave the highest possible evaluation regarding the value of DS-8201. We then placed importance on other factors, such as whether candidates saw Daiichi Sankyo as a vital partner, and whether we could gain extensive knowledge from them in order to build a global platform for our oncology business. We have already built a relationship of trust through the co-promotion of NEXIUM in Japan, among other activities. Furthermore, after signing this contract, we have made a strong start with a Joint Committee holding vital functions in R&D, MA, marketing, supply chain, and other areas. The Joint Committee holds discussions on issues encountered in each of these areas. We will utilize this collaboration to the fullest in order to maximize the value of DS-8201.








For details, refer to page 59.

The Significance of This Collaboration

- 1 Accelerate DS-8201 development & commercialization to reach more patients earlier
- 2 Accelerate the establishment of Daiichi Sankyo's global oncology infrastructure
- 3 Expand resource allocation for other ADC programs following DS-8201

ADC (Antibody Drug Conjugate) Pipeline

Combinable with a wide range of antibodies

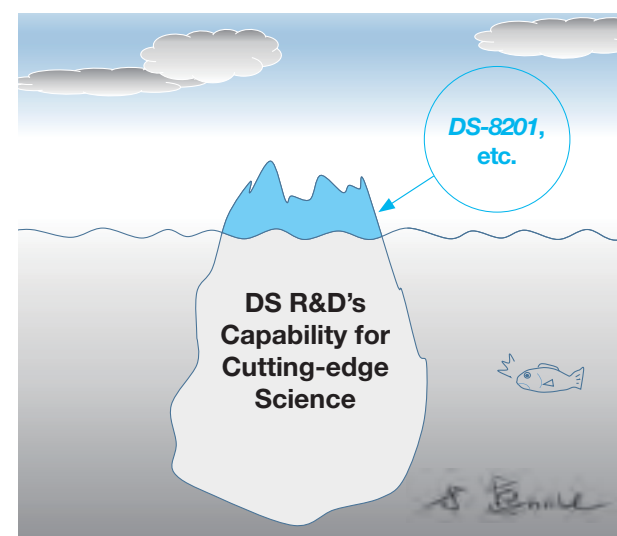
DS-8201		HER2	DS-6157		GPR20
U3-1402		HER3	DS-6000		Not disclosed
DS-1062		TROP2	Project code pending		TA-MUC1
DS-7300		B7-H3			



## Message from the CEO

### Daiichi Sankyo's R&D Capabilities and Growing Beyond ADCs

I originally specialized in safety for pre-clinical studies, and was deeply involved with *pravastatin*, *olmesartan*, *prasugrel*, *edoxaban*, and other projects. Based on my experience in these projects, as well as the history of Daiichi Sankyo group companies up to now, I feel that the level of science and technology at Daiichi Sankyo is very high and at a world-class level. I think that *DS-8201* and the other new ADC projects were born out of this history and the company DNA. This is the picture of an iceberg which I drew by myself as an image. *DS-8201* and our ADC technology are currently visible, but they are only the tip of the iceberg when it comes to Daiichi Sankyo's R&D capabilities with science and technology running throughout them.



We are working with the aim to grow beyond ADC, and have already made progress in clinical trials with compounds in new modalities, including nucleic acid drugs, oncolytic viruses, and cell therapy. We are also moving forward in research on next-generation ADC, bispecific antibodies, gene therapy, and other areas. In this way, we aim to achieve even more competitive drug discovery by utilizing a diverse range of modality technologies. As mentioned at the start of this message, I believe that one of my significant responsibilities as CEO is to make the necessary moves with consideration for the year 2025 and beyond. With a view to 2025 and onward, I wish to take a wide range of actions to grow beyond ADC going forward, grow our iceberg to many times its current size, and continue to produce results.



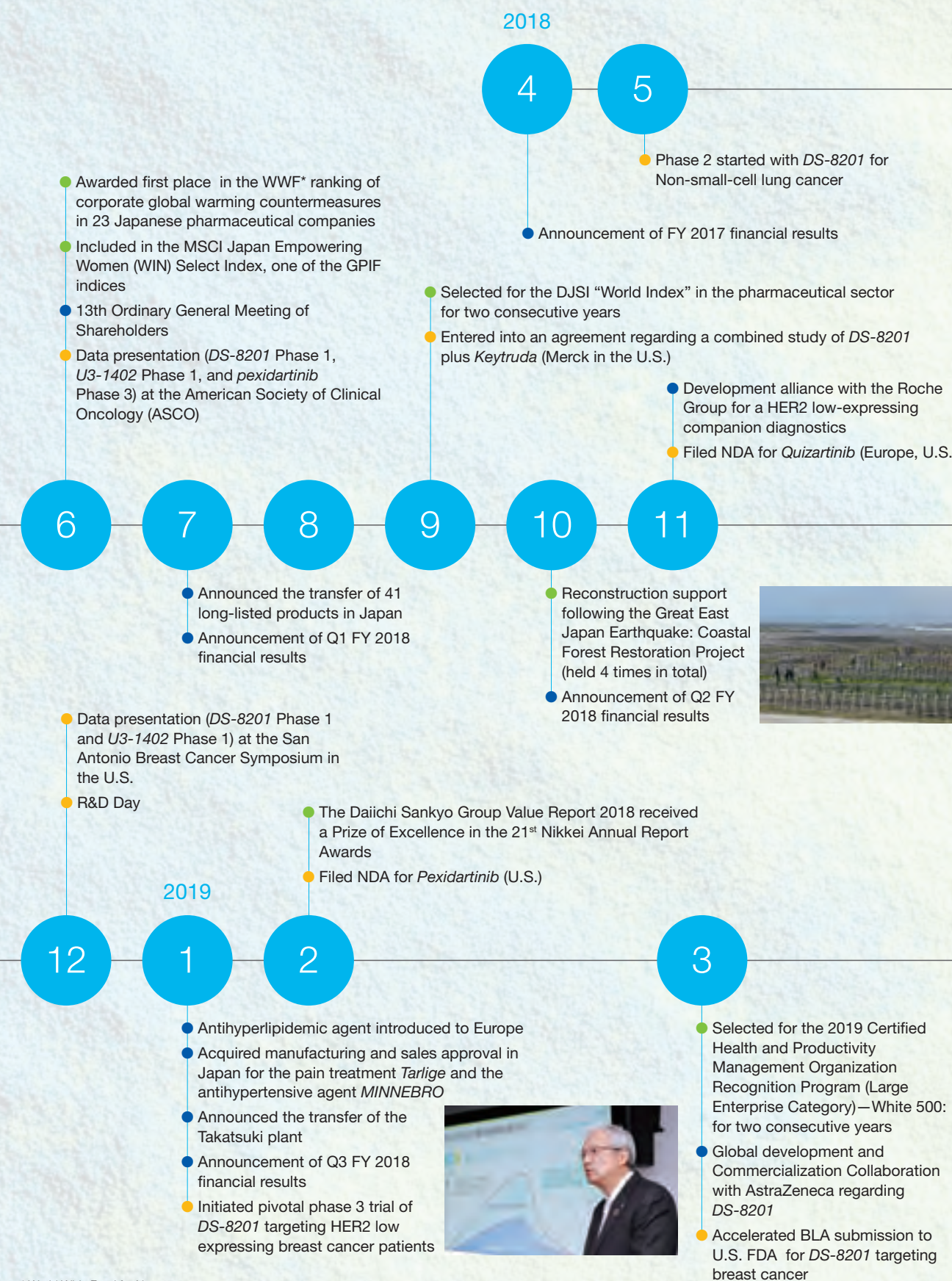
### In Closing

Fiscal 2019 marked the start of our oncology business, with plans to bring *quizartinib* and *pexidartinib* to the market as our first oncology products following our merger, as well as our work in submitting successive NDAs for *DS-8201* in the U.S. and Japan. All employees will make a concerted effort to achieve our 2025 Vision of becoming a "Global Pharma Innovator with competitive advantage in oncology" through the ADC franchise with a focus on *DS-8201*. At the same time, we will aim to achieve even more competitive drug discovery in order to grow beyond ADC in 2025 and onward. I believe that we can save even more patients with our science and technology as a result of these efforts. I would like to ask for the continued support of all of you to help us achieve this goal.

## At a glance

## Annual Topics for Fiscal 2018

● ESG  
● Business  
● R&D

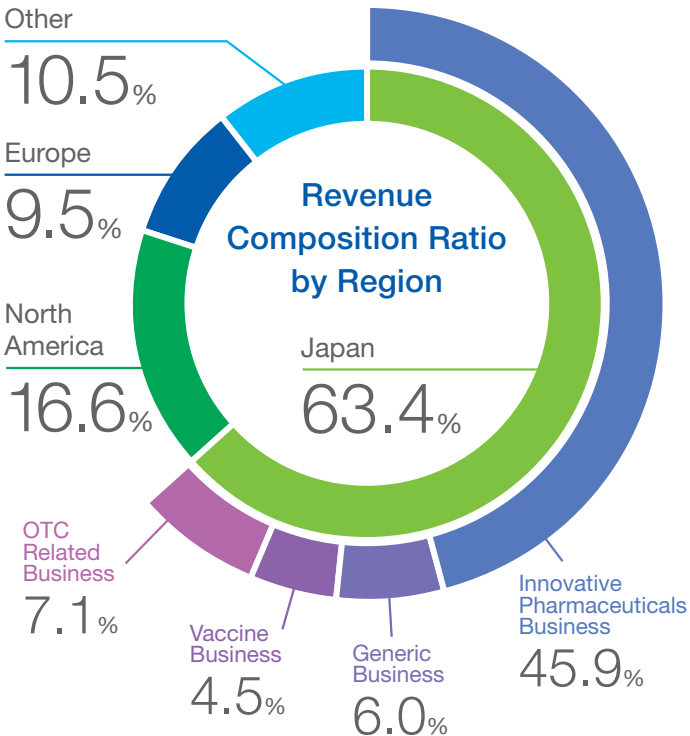


\* World Wide Fund for Nature

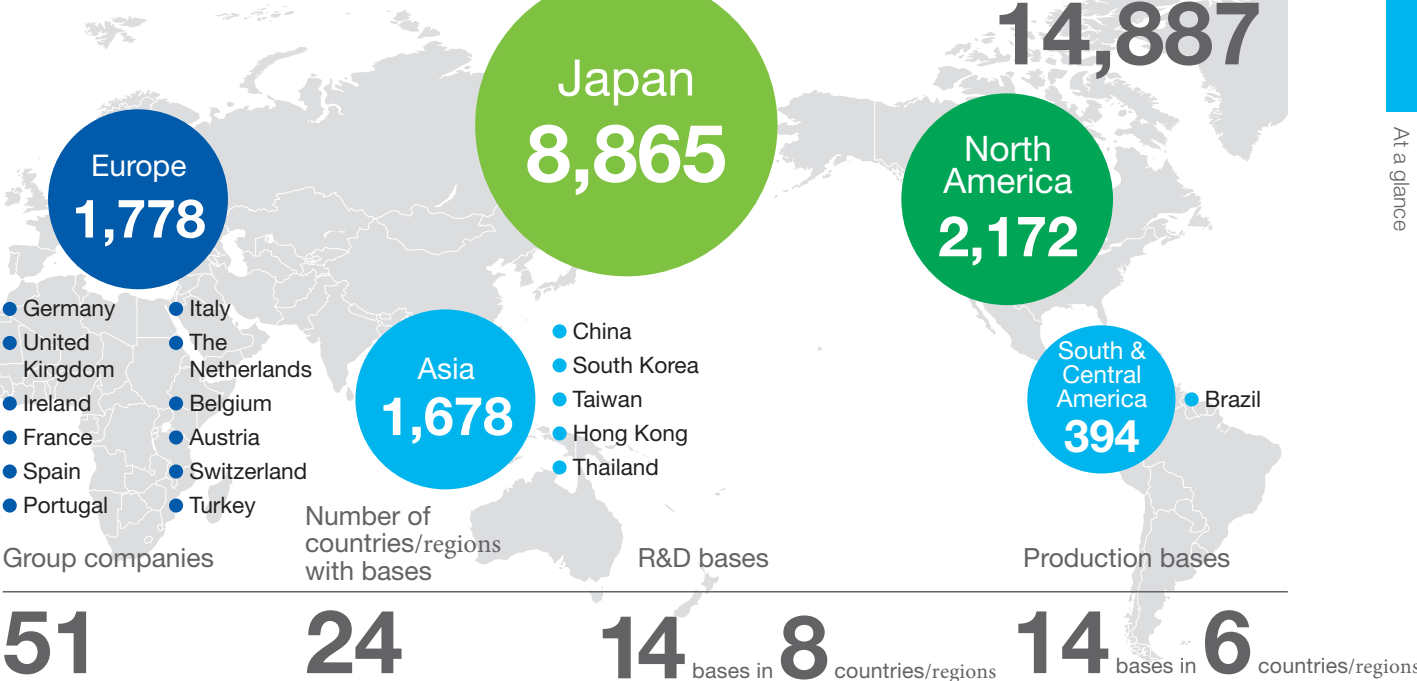


Summary of Financial Results in Fiscal 2018

		Ratio to revenue
Revenue	¥ 929.7 billion	—
Cost of sales	¥ 364.6 billion	39.2 %
SG&A expenses	¥ 277.7 billion	29.9 %
R&D expenses	¥ 203.7 billion	21.9 %
Operating profit	¥ 83.7 billion	9.0 %
Profit attributable to owners of the Company	¥ 93.4 billion	10.0 %
ROE	7.8 %	
Liabilities	¥ 838.3 billion	
Total equity	¥ 1,249.7 billion	
Total assets	¥ 2,088.1 billion	
Equity ratio	59.8 %	



Employees and Bases  
(As of March 31, 2019)



Key Products

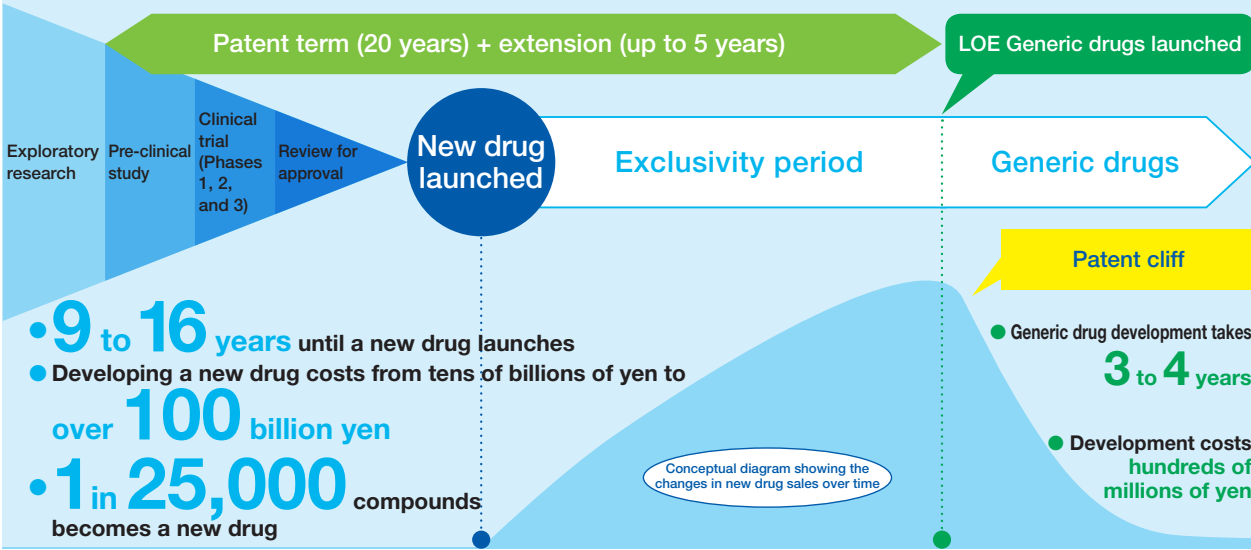
Innovative Pharmaceuticals Business

Global	Global	Japan
 <b>Anticoagulant</b> <i>LIXIANA/SAVAYSA</i> Generic name <i>Edoxaban</i> Revenue in fiscal 2018: ¥117.7 billion	 <b>Antihypertensive agent</b> <i>Olmecart/Benicar</i> Generic name <i>Olmecartan</i> Revenue in fiscal 2018: ¥105.9 billion	 <b>Ulcer treatment</b> <i>NEXIUM</i> Generic name <i>Esomeprazole</i> Revenue in fiscal 2018: ¥78.3 billion
<b>Generic Business</b>	<b>Vaccine Business</b>	<b>OTC Related Business</b>
 <b>Antihypertensive agent</b> <i>Olmecartan (AG)</i>	 <b>Seasonal influenza vaccine</b> <i>Influenza HA Vaccine</i>	 <b>Antipyretic analgesics / Topical anti-inflammatory analgesics</b> <i>Loxonin S</i>

COLUMN: Pharmaceutical Company's Business Model

Launching a new drug requires an R&D period spanning some 9 to 16 years, as well as anything from tens of billions of yen to over 100 billion yen in costs. As such, it is said that the probability of creating a new drug is one in around 25 thousand compounds.

Once approved, new drugs enjoy an exclusivity period for as long as their patents are effective. After launch, sales of the new drug grow during the exclusivity period, but then fall dramatically once the exclusivity period ends and generic drugs are launched. This fall in sales at the loss of exclusivity (LOE) is called the "patent cliff." In order to overcome the patent cliff and achieve continuous growth, it is essential to continually develop and launch new drugs through R&D.





At the Daiichi Sankyo Group, we build and expand pipelines while constantly placing focus on patients' unmet medical needs. The R&D Unit defines oncology as a priority area, and makes investments in a concentrated manner for three main pillars: the ADC (antibody drug conjugate) franchise, the AML (acute myeloid leukemia)

Major R&D Pipeline (In-House Development Projects, as of July 2019)

	Generic Name/Project Code Number/ MOA	Target Indication	Region	Stage	Partner
ADC Franchise	[fam-] Trastuzumab deruxtecan/ DS-8201/Anti-HER2-ADC	Breast cancer (HER2 positive post T-DM1)	JP/US/EU/Asia	P2 P3	AstraZeneca
		Breast cancer (HER2 positive vs. T-DM1)	JP/US/EU/Asia	P3	AstraZeneca
		Breast cancer (HER2 low expression)	JP/US/EU/Asia	P3	AstraZeneca
		Gastric cancer (HER2 positive post trastuzumab)	JP/Asia	P2	AstraZeneca
		Colorectal cancer (HER2 expressing)	JP/US/EU	P2	AstraZeneca
		Non-small cell lung cancer (HER2 expressing/mutant)	JP/US/EU	P2	AstraZeneca
		Breast cancer, bladder cancer (combination with nivolumab)	US/EU	P1	BMS
	U3-1402/Anti-HER3-ADC	Breast cancer (HER3 expressing)	JP/US	P1	
		EGFR-mutant non-small cell lung cancer	JP/US	P1	
	DS-1062/Anti-TROP2-ADC	Non-small cell lung cancer	JP/US	P1	
AML Franchise	Quizartinib/FLT3 inhibitor	Acute myeloid leukemia (relapsed/refractory)	EU/Asia	Submitted	
		Acute myeloid leukemia (first-line)	JP/US/EU/Asia	P3	
	Milademetan/DS-3032/MDM2 inhibitor	Solid tumor (lyposarcoma )	JP/US	P1	
		Acute myeloid leukemia	JP/US	P1	
	Valemetostat/DS-3201/EZH1/2 inhibitor	Peripheral T-cell lymphomas	JP/US	P1	
		Adult T-cell leukemia/lymphoma	JP	P1	
		Acute myeloid leukemia, acute lymphocytic leukemia	US	P1	
		Small cell lung cancer	US	P1	
	PLX2853/BET inhibitor	Acute myeloid leukemia	US	P1	
	Axicabtagene ciloleucel/ Axi-Cel®/Anti-CD19 CAR-T cells	B-cell lymphoma	JP	P2	Kite/Gilead
Breakthrough Science	Pexidartinib/CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	US/EU	Submitted	
	DS-1647(G47Δ)/Oncolytic HSV-1	Malignant glioma	JP	P2	
	DS-1001/ mutant IDH1 inhibitor	Glioma	JP	P1	
	DS-1205/AXL inhibitor	Non-small cell lung cancer (combination with gefitinib)	JP	P1	
		Non-small cell lung cancer (combination with osimertinib)	Asia	P1	

franchise, and Breakthrough Science (creating first-in-class or best-in-class compounds with breakthrough mechanism of action or modality). In addition to this, we aim to create innovative medicines that change the SOC for rare diseases outside of the oncology field.

	Generic Name/Project Code Number/ MOA	Target Indication	Region	Stage	Partner
Specialty medicine	Edoxaban/Factor Xa inhibitor	Atrial fibrillation in very elderly patients	JP	P3/LCM*	
	Prasugrel/Anti-platelet agent	Ischemic stroke	JP	P3/LCM*	Ube Industries
	Esaxerenone/MR antagonist	Diabetic nephropathy	JP	P3/LCM*	Exelixis
	DS-1040/TAFIa inhibitor	Acute ischemic stroke, acute pulmonary thromboembolism	JP/US/EU	P1	
	Mirogabalin/α2δ ligand	Central neuropathic pain	JP/Asia	P3/LCM*	
	DS-5141/ENA oligonucleotide	Duchenne type muscular dystrophy	JP	P2	
	DS-1211/TNAP inhibitor	Prevention of ectopic calcification diseases	US	P1	Stanford Burnham Prebys Medical Discovery Insisute
Vaccines	VN-0107/MEDI3250/Nasal cavity spray live attenuated influenza vaccine	Prevention of seasonal influenza	JP	Submitted	AstraZeneca/MedImmune
	VN-0105/DPT-IPV/Hib	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib infection	JP	P3	Sanofi
	VN-0102/JVC-001/Measles-Mumps-Rubella vaccine	Prevention of Measles, Mumps and Rubella	JP	P2	

\* Life Cycle Management

- : Projects in the field of oncology which are planned for application based on the results of Phase 2 trials
- : Projects that have been granted SAKIGAKE Designation (Japan), Breakthrough Therapy Designation (FDA), or Orphan Drug Designation

Clinical trial stages

- P1: Phase 1    Conduct trials on a small group of healthy volunteers to assess safety and pharmacokinetics of drugs (patient volunteers may be included depending on the tests)
- P2: Phase 2    Conduct trials on a small group of patient volunteers to assess safety, efficacy, dosage and administration regimen
- P3: Phase 3    Conduct trials on a large number of patient volunteers to assess safety and efficacy in comparison with existing drugs

# 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

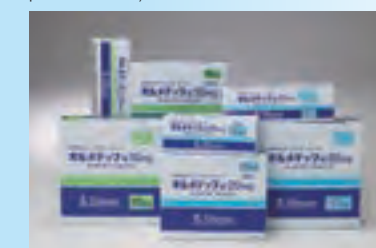
### 1989

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)

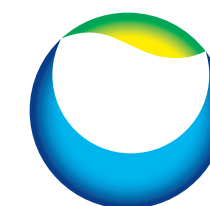


### 2005

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: *Panalidine*), an antiplatelet product



### 1985

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



### 1993

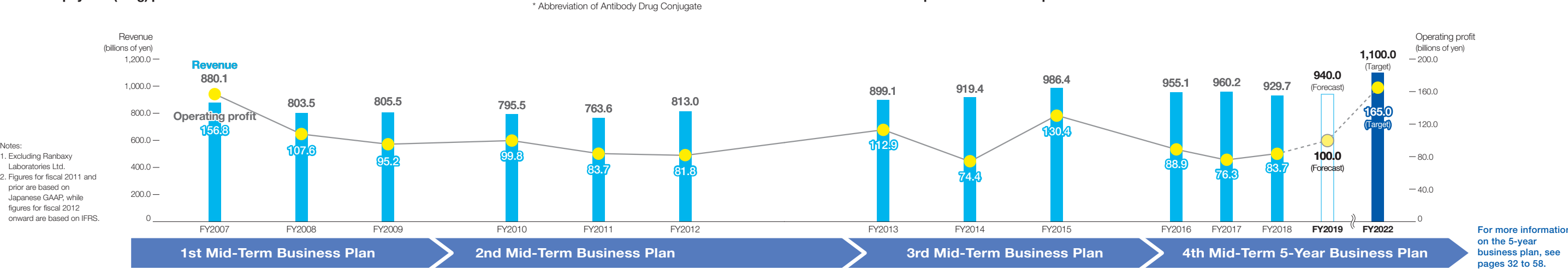
Launched *levofloxacin* (Product name: *Cravit*), a broad-spectrum oral antibacterial agent



# 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 DS-8201
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

# 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.

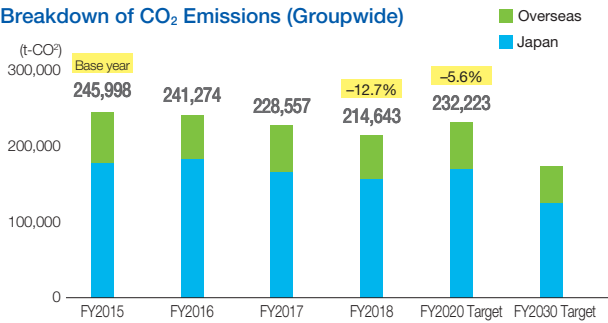
**Setting a Target to Reduce CO<sub>2</sub> (by 27% Compared to 2015) with Consideration for Long-Term Goals**

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

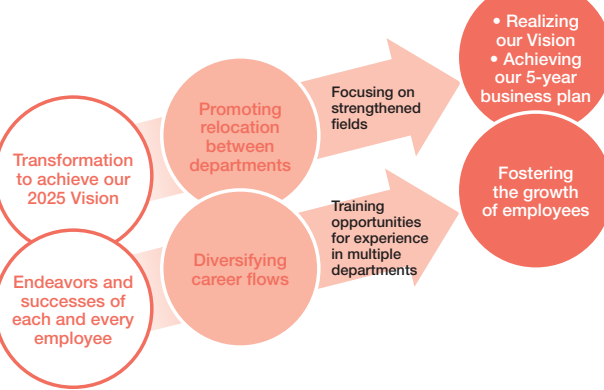
Within Daiichi Sankyo Group, we aim for optimal human resources to achieve success as leaders, regardless of their nationality, gender, or age. To this end, we actively promote and acquire human resources with a broad range of experience from both inside and outside the Group, and we promote Group talent 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

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.

Introduction of Initiatives

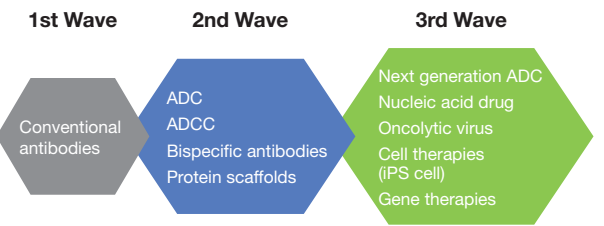
Mid-to-long-term Initiatives in R&D

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

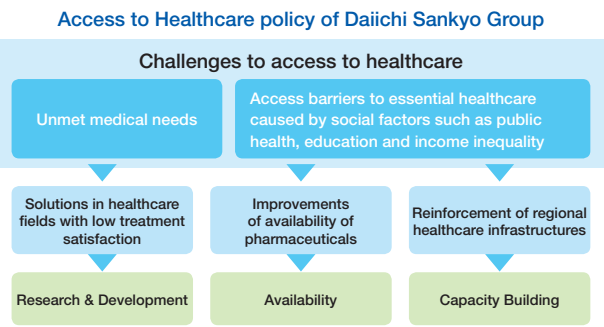
Basic Policy

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

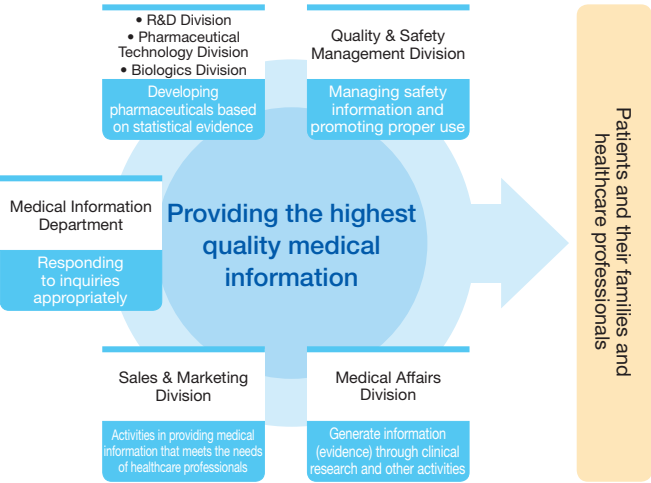
Activities in Providing Medical Information that Meets the Needs of Healthcare Professionals

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.



## 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.

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.

## 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.

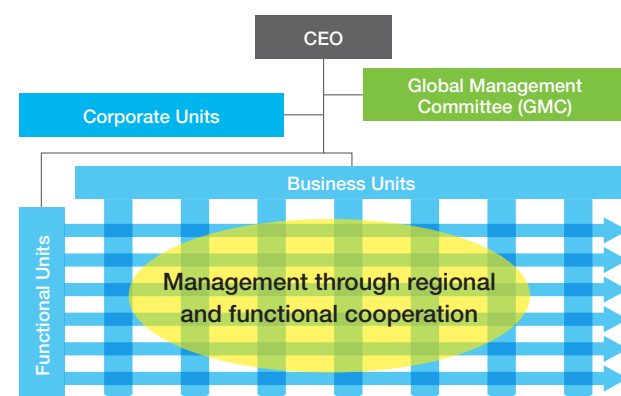


## Global Management System Uniting Intellects from Around the World

### 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.



## 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\*1 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.\*2

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

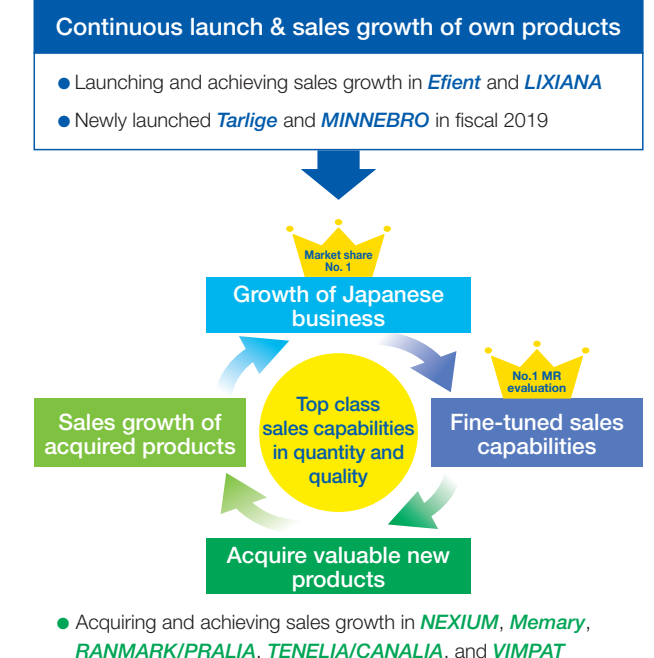
\*2 Conducted by ANTERIO Inc.

## 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?

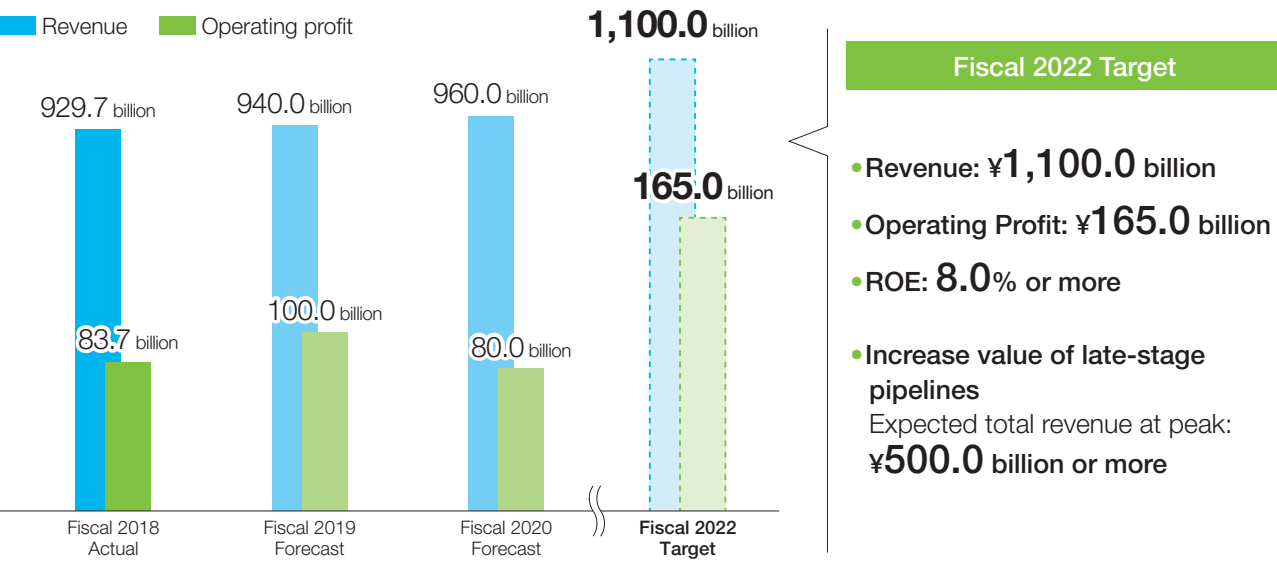
In recent years, new therapeutic drugs and therapies such as cancer immunotherapy and cell therapy have been developed. However, to overcome cancer, there is still a need for more effective and safer drugs and therapies in areas where unmet medical needs are still high. In fiscal 2019, we anticipate 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

Grow Edoxaban	Grow as the No. 1 Company in Japan	Expand U.S. Businesses
Achievements and Progress	Achievements and Progress	Achievements and Progress
<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>
Establish Oncology Business	Continuously Generate Innovative New Medicine changing Standard of Care (SOC)	Enhance Profit Generation Capabilities
Achievements and Progress	Achievements and Progress	Achievements and Progress
<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

Prioritize growth investments while also enhancing shareholder returns	Achievements and Progress
<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

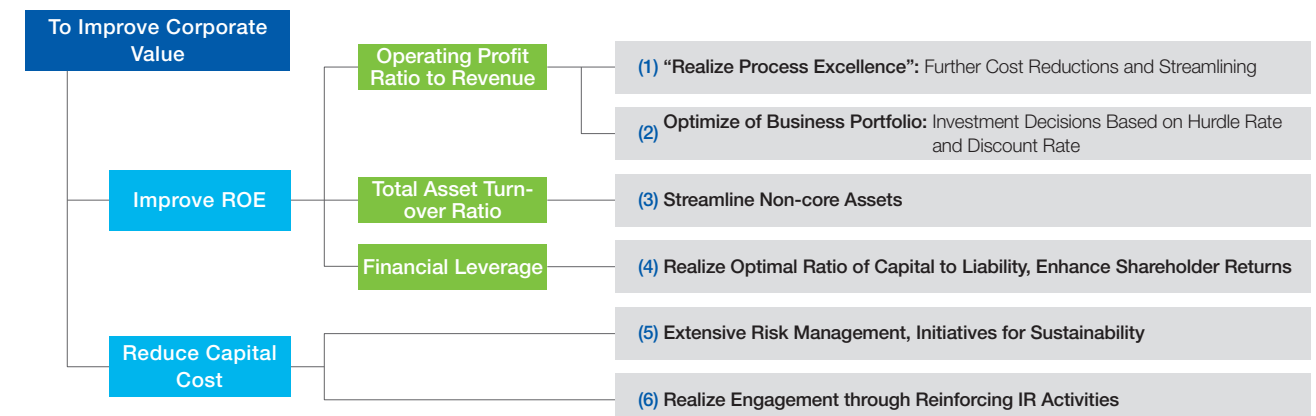
After the revision of numerical targets for the current 5-year business plan in October 2018, Daiichi Sankyo decided to form strategic alliance with AstraZeneca for *DS-8201* in March 2019. Currently, we are having discussion with AstraZeneca on the details of the

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

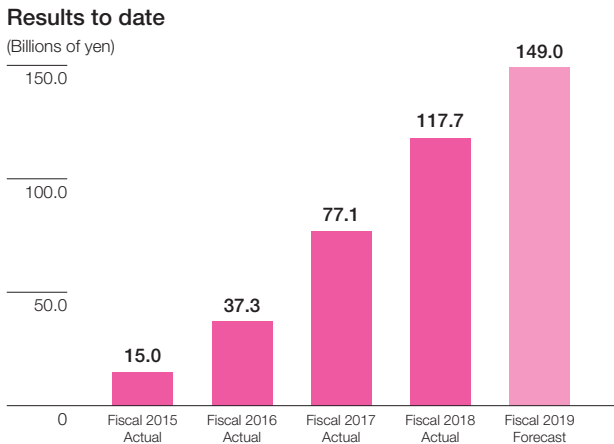
Grow *Edoxaban* Brand name: *LIXIANA* (Japan, Europe, Asia), *SAVAYSA* (U.S.)

*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.

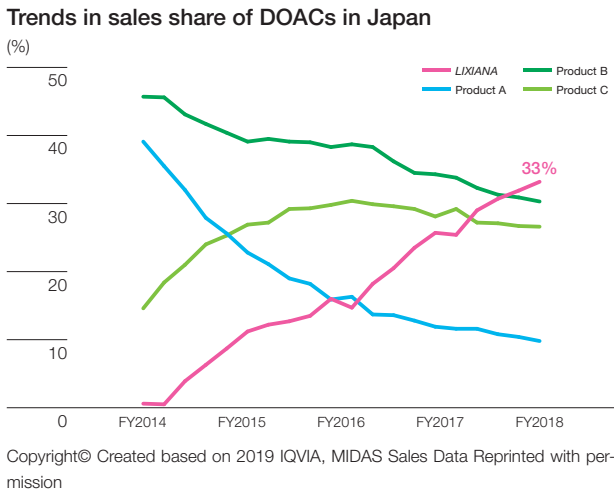


2 Progress to date

(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

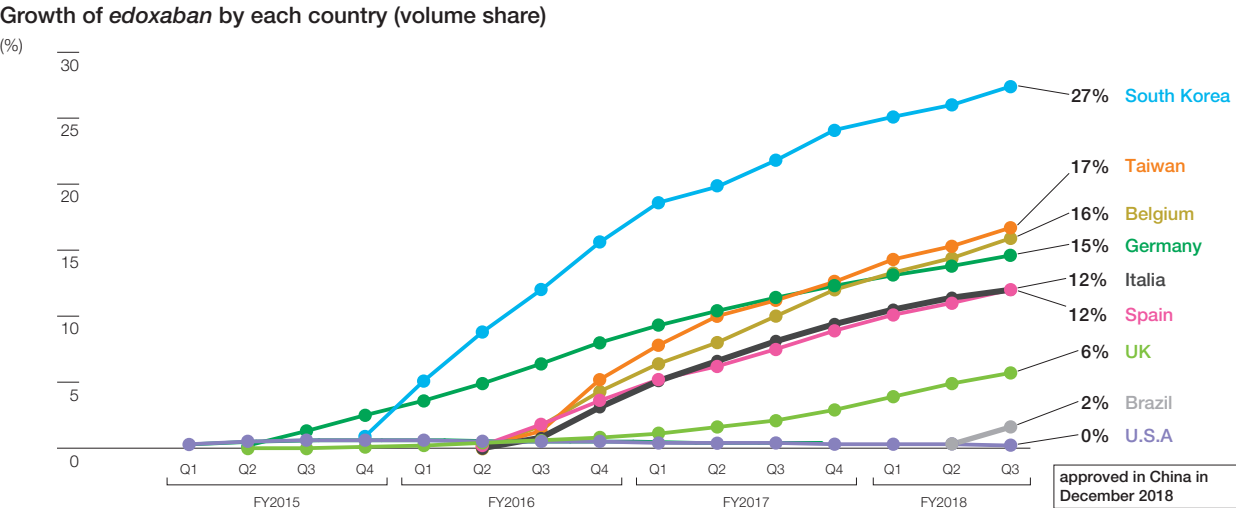
**Process of dissolving**

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 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 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.

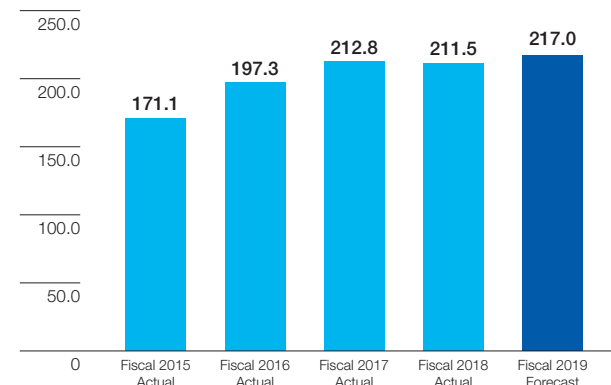
\* No. 1 in the bone resorption inhibitor market

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.)

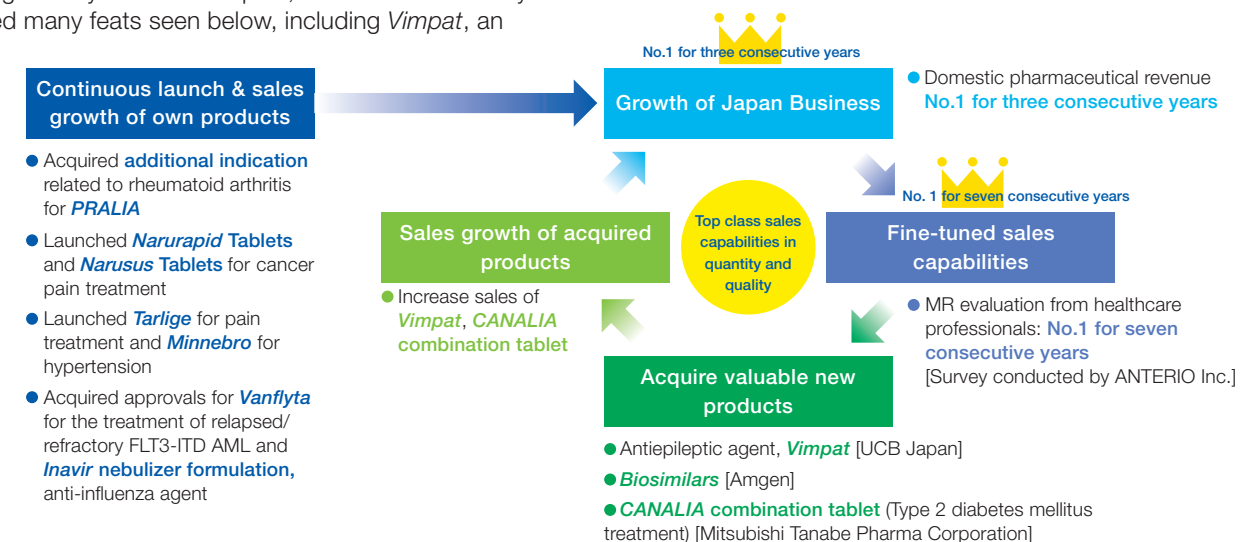
## 2 Progress to date

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



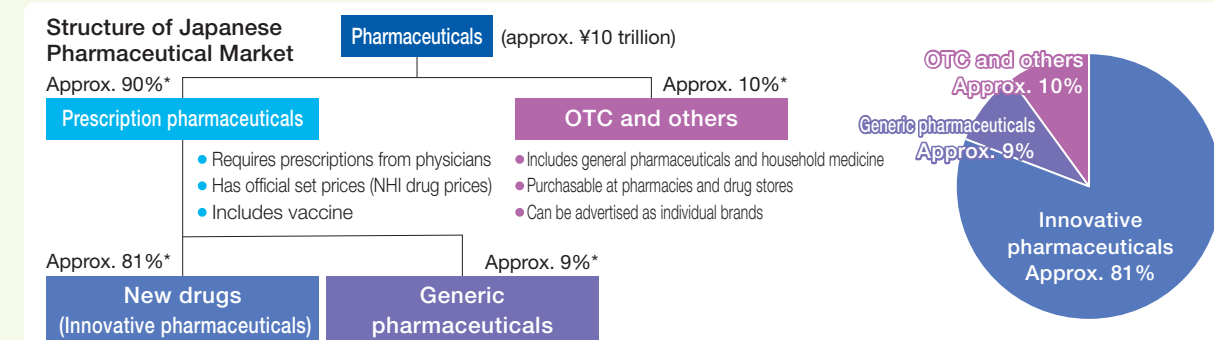
## COLUMN

## 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)



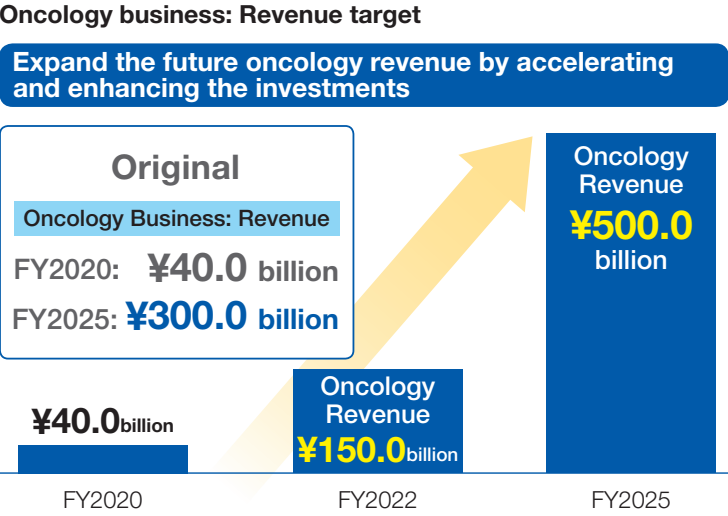
\* Share of market based on monetary value

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

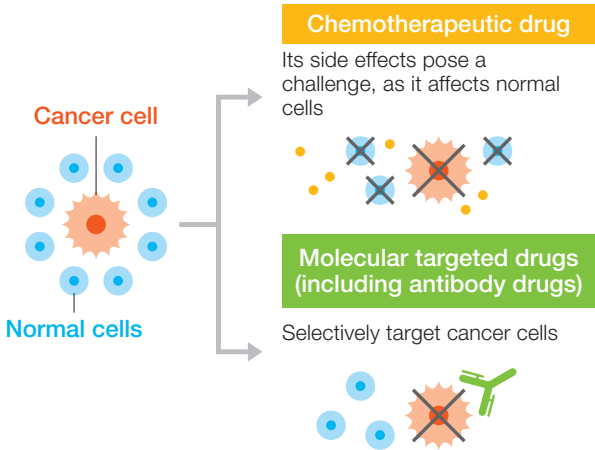
Cancer treatments are divided into two categories: systemic therapy and local therapy. Local therapy consists of surgery and radiotherapy.

	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)

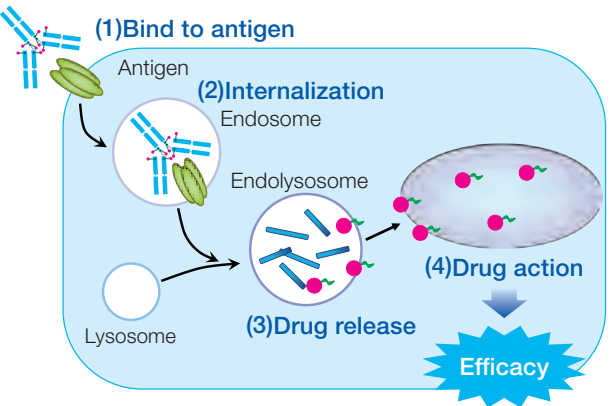
ADC

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

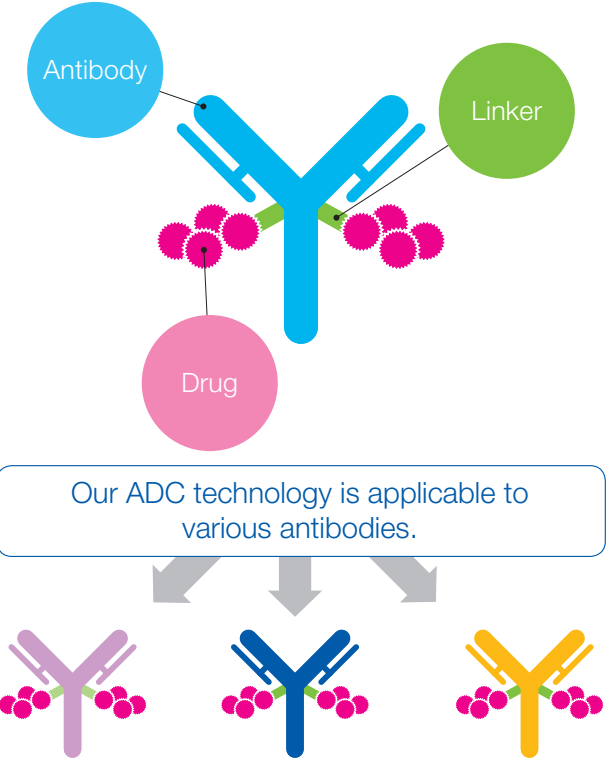
2 Mechanism of Action with ADC

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

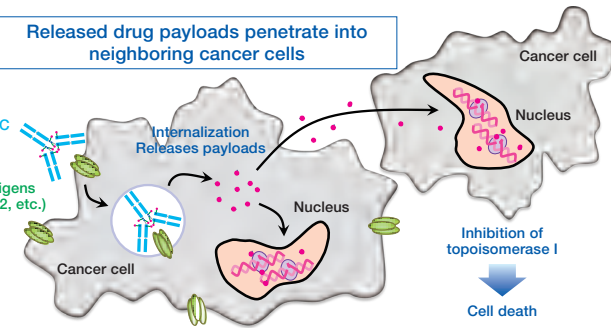
The payload of Daiichi Sankyo's ADCs currently in the research and development stage is *DXd*, a new derivative of the DNA topoisomerase I inhibitor *DX-8951* created by former Daiichi Pharmaceutical. As a cytotoxic in early development of *DX-8951* had promising potency, but with an unacceptable risk-benefit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

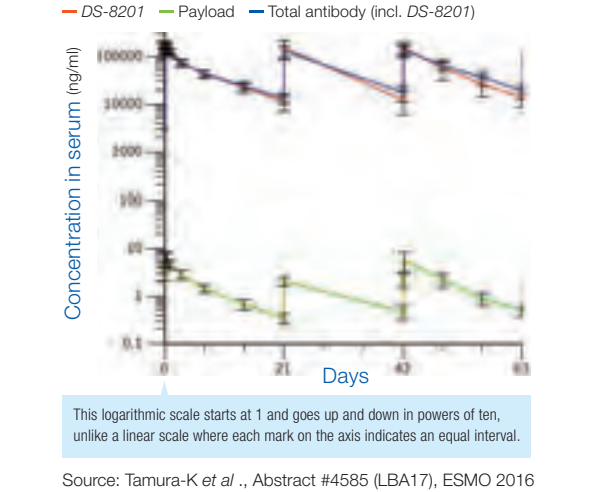
Payloads	Half-life in rats (hours)
<i>DXd</i> *1 (payload of Daiichi Sankyo's ADC)	0.9
<i>DM1</i> *2 (payload of <i>T-DM1</i> )	3.3-10

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*.

Pharmacokinetics profile of DS-8201 Phase 1 6.4mg/kg



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

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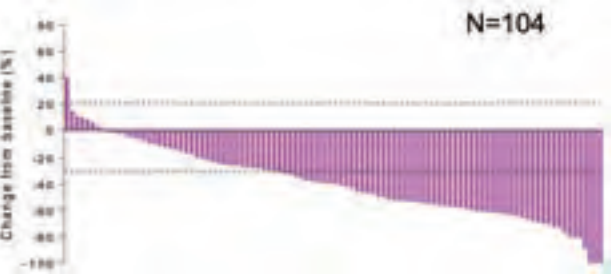
Grades of adverse events	
Grade 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
Grade 2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL
Grade 3	Severe or medically significant but not 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*).

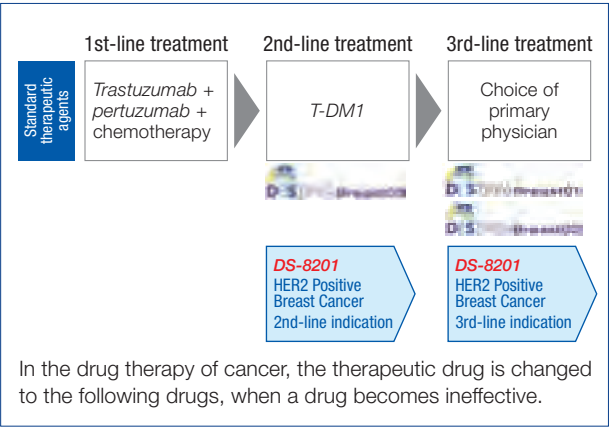
► HER2 positive breast cancer (SABCS 2018)



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



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

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### 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

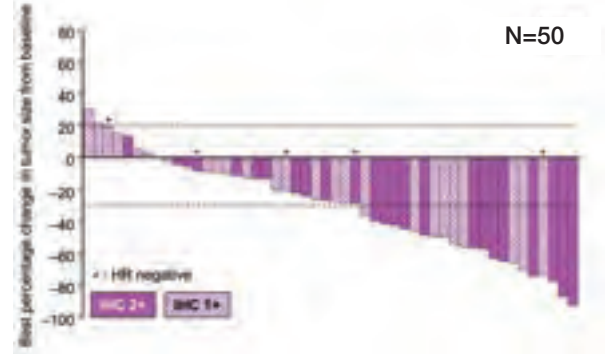
( 6 ) Progress of HER2 low expression breast cancer clinical study

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)

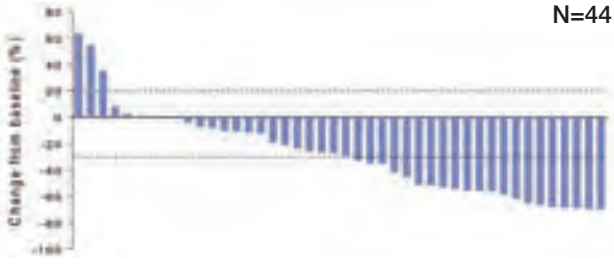
Source: Modi-S *et al.*, Abstract #P6-17-02, SABCS 2018

( 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+)

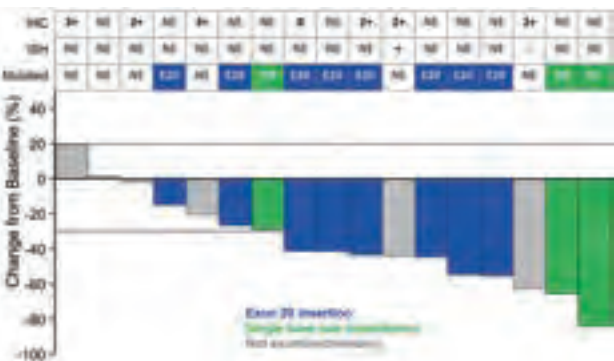
Source: Yoshino-T *et al.*, Abstract #563P, ESMO 2018

( 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

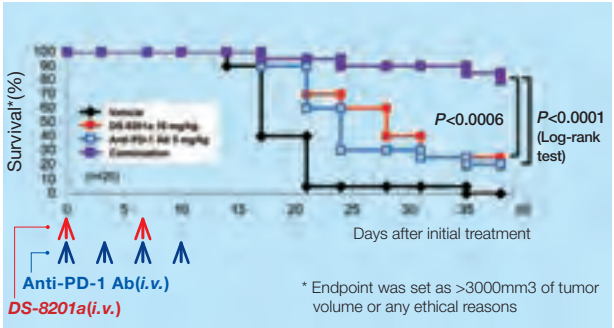
( 10 ) Progress of studies on combinations with immune checkpoint inhibitors

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

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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.

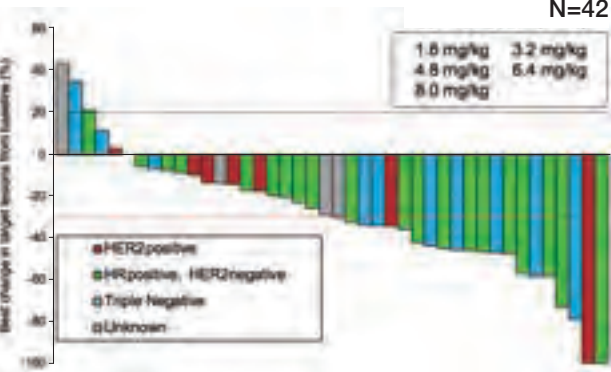
U3-1402 exerts its efficacy by binding to this HER3.

( 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.

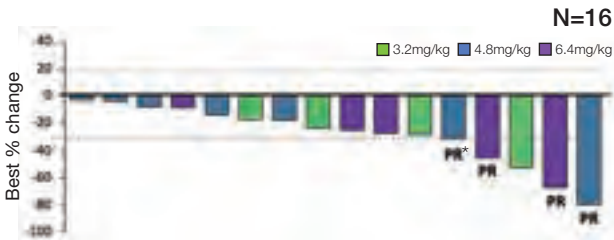
Currently, recommended dose for expansion was selected and the drug is undergoing the dose expansion part of the phase 1 study.

( 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.

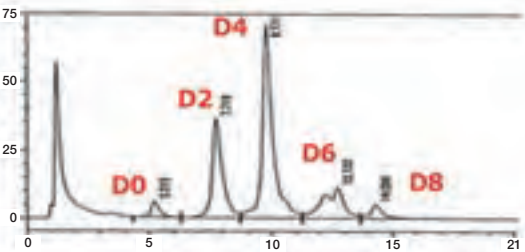
DS-1062 exerts its efficacy by binding to this TROP2.

( 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.

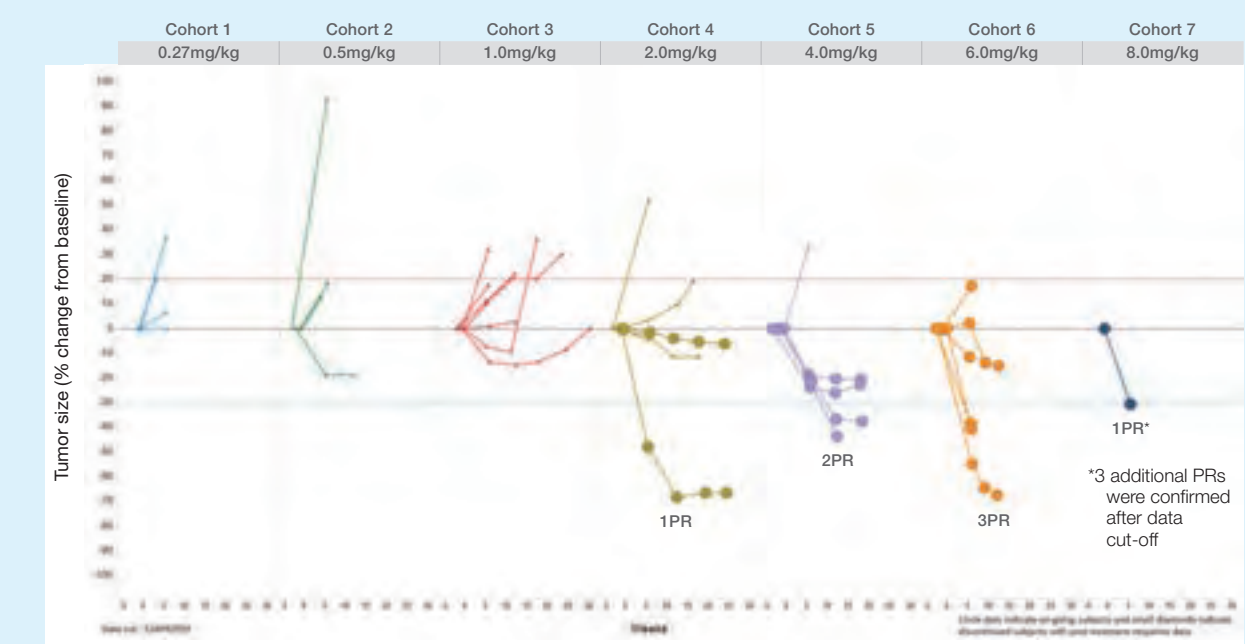
Since it is known that TROP2 is expressed in normal cells, such as skin cells, the number of payloads is controlled at four in order to maintain a better safety margin.

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

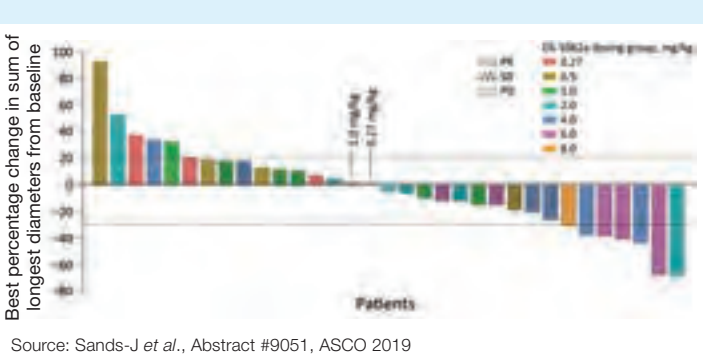
( 3 ) Progress of non-small-cell lung cancer clinical study

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

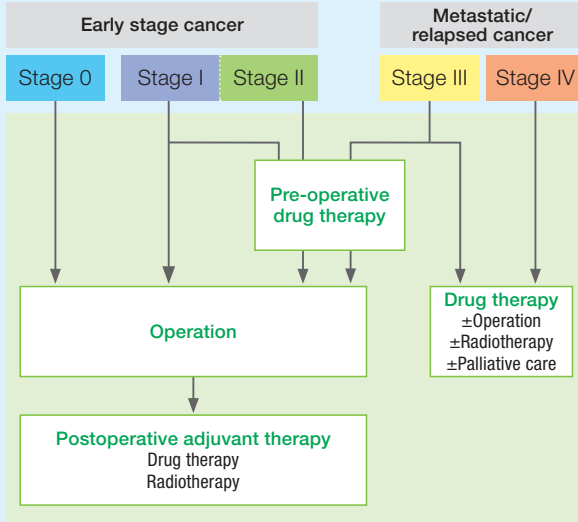
	Japan		U.S.		Europe	
	New	Recurrence	New	Recurrence	New	Recurrence
Stage 0	12	0.1	63	0.1	—	—
Stage I	40	0.1	133	2	121	1
Stage II	33	1	84	2	88	2
Stage III	7	1	26	3	35	4
Stage IV	2	9	16	27	16	30
Total	95	11	321	34	260	37

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

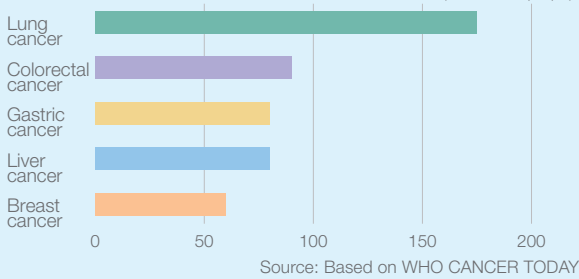
Lung cancer occurs when bronchi or lung cells become cancerous through a variety of factors, with smoking known to be the largest risk factor. Other risk factors include chronic obstructive pulmonary disease, the inhalation of asbestos, arsenic, chromium, or other carcinogens due to occupational exposure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

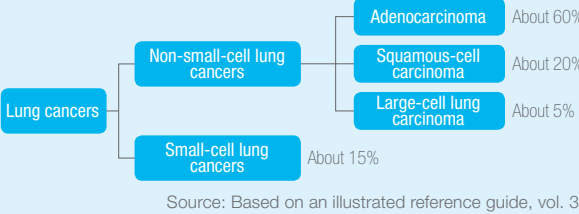
Lung cancers are classified into two groups based on their histological characteristics: small-cell lung cancers and non-small-cell lung cancers, with the latter accounting for about 85% of all cases.

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

Number of deaths related to different types of cancers (2018 estimates)



Organizational chart of lung cancers

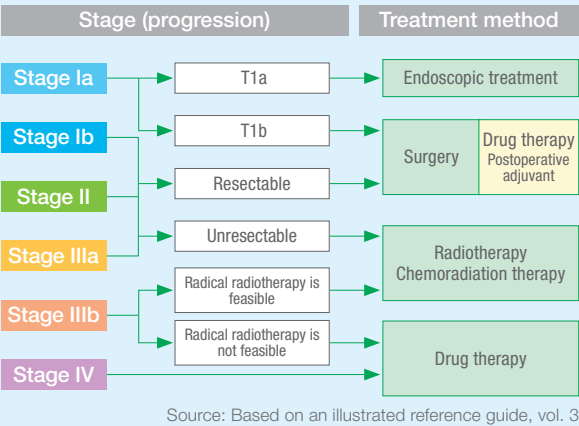


Lung cancer is categorized into stages I through IV based on a combination of the size and extension of infiltration of the tumor (T), the degree of metastases to nearby lymph nodes (N), and the presence of distant metastasis (M).

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.

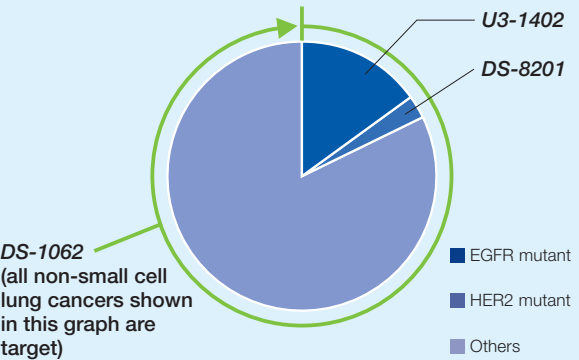
In drug therapy for non-small-cell lung cancers, different treatments are used depending on the stage. A platinum-based drug combination therapy was conventionally used for stages IIIb to IV, but recent methods of treatment involve selecting drugs after investigating the genetic mutations in the cancers.

In Daiichi Sankyo several clinical studies are underway for NSCLC; *DS-8201* for HER2-expressing or HER2 mutated NSCLC, *U3-1402* for EGFR-mutated NSCLC and *DS-1062* for NSCLC patients who are unresponsive or progressed with standard of therapy.



Stage	Treatment option (example)
I	Postoperative adjuvant chemotherapy
II-IIIa	Postoperative adjuvant chemotherapy (cisplatin and vinorelbine in combination)
IIIb-IV	Selecting molecular targeted drugs to use based on the results of genetic and PD-L1 testing

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



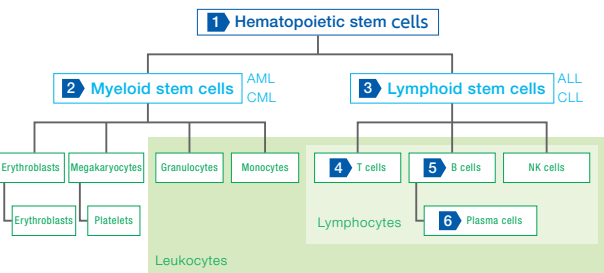
Daiichi Sankyo's AML Franchise

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.

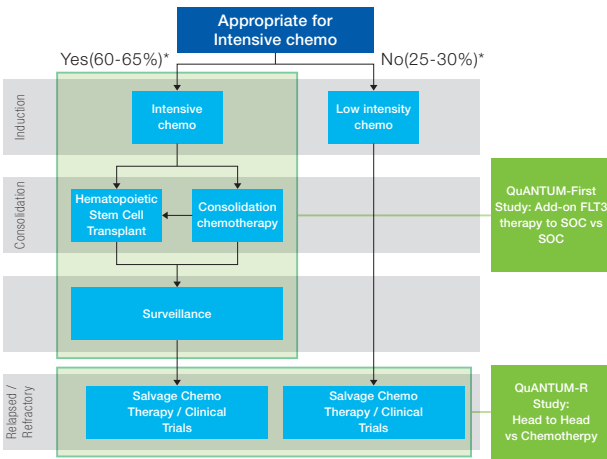
In Japan, the Ministry of Health, Labour and Welfare approved *quizartinib* for the treatment of relapsed/refractory FLT3-ITD AML in June 2019. We will launch it under the brand name *VANFLYTA*®.

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%)

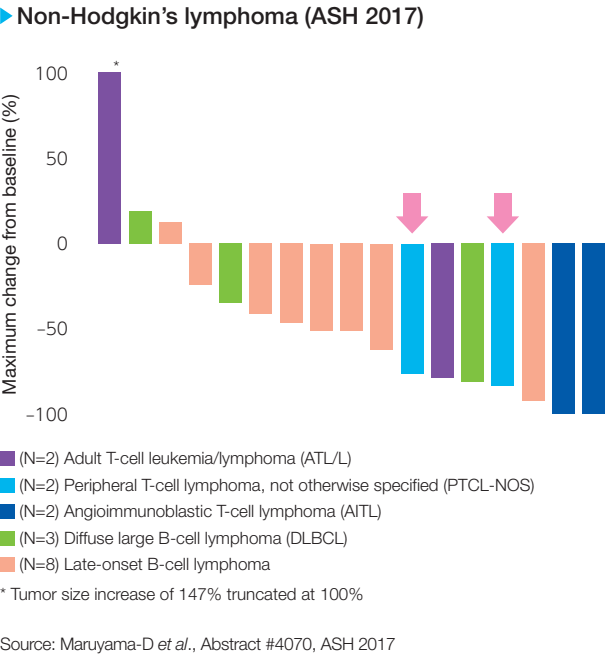
Overview and progress of 5-Year Business Plan: Establish Oncology Business

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.

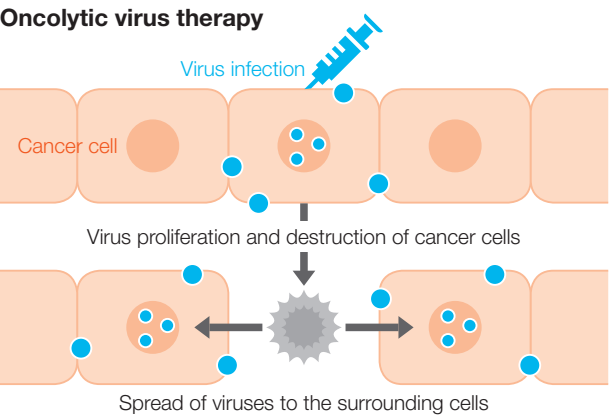


2 DS-1647 (oncolytic virus G47Δ)

*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

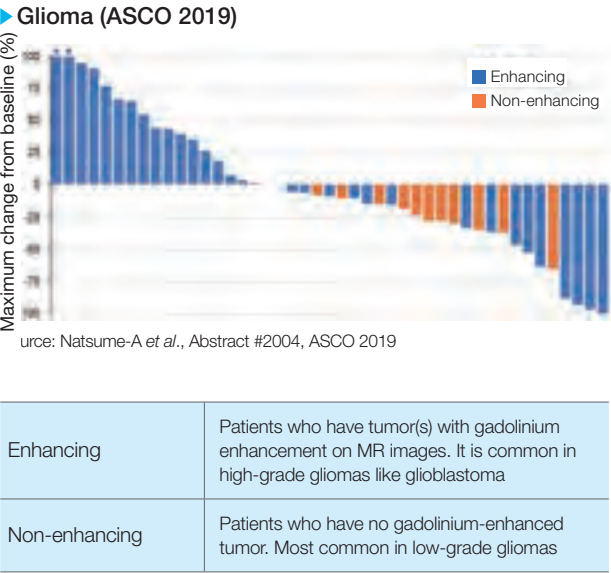
Classification of gliomas

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.



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

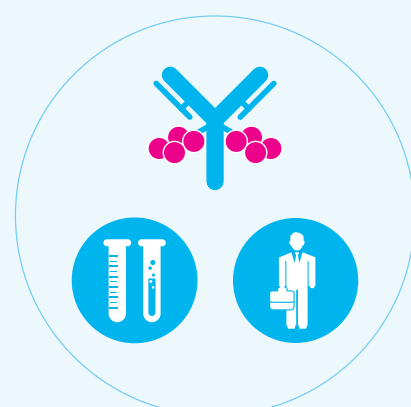
### Our collaborator:

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

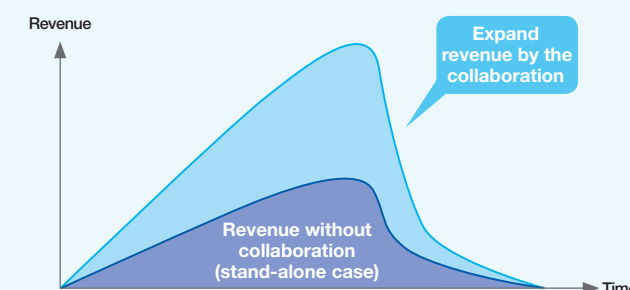
- ▶ Advancing development plans
- ▶ Further expansion of cancer types and indications

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.

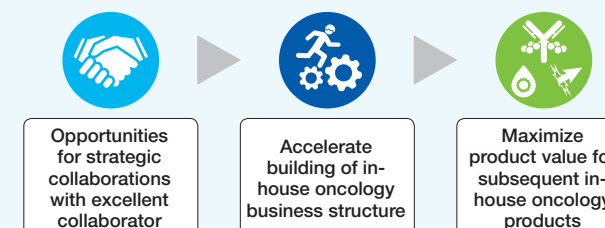
In addition, the product value of *DS-8201* is maximized with considerations such as the upfront payment and various milestones.

### Maximizing the product value of *DS-8201*



## The Significance of This Collaboration

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



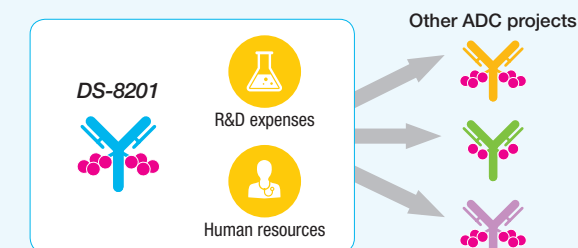
AstraZeneca has rich experience and resources in the global oncology area, and we will create various strategies in collaboration, assigning and sharing roles and executing the strategy. This will also accelerate the establishment of Daiichi Sankyo's oncology business infrastructure.

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 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)

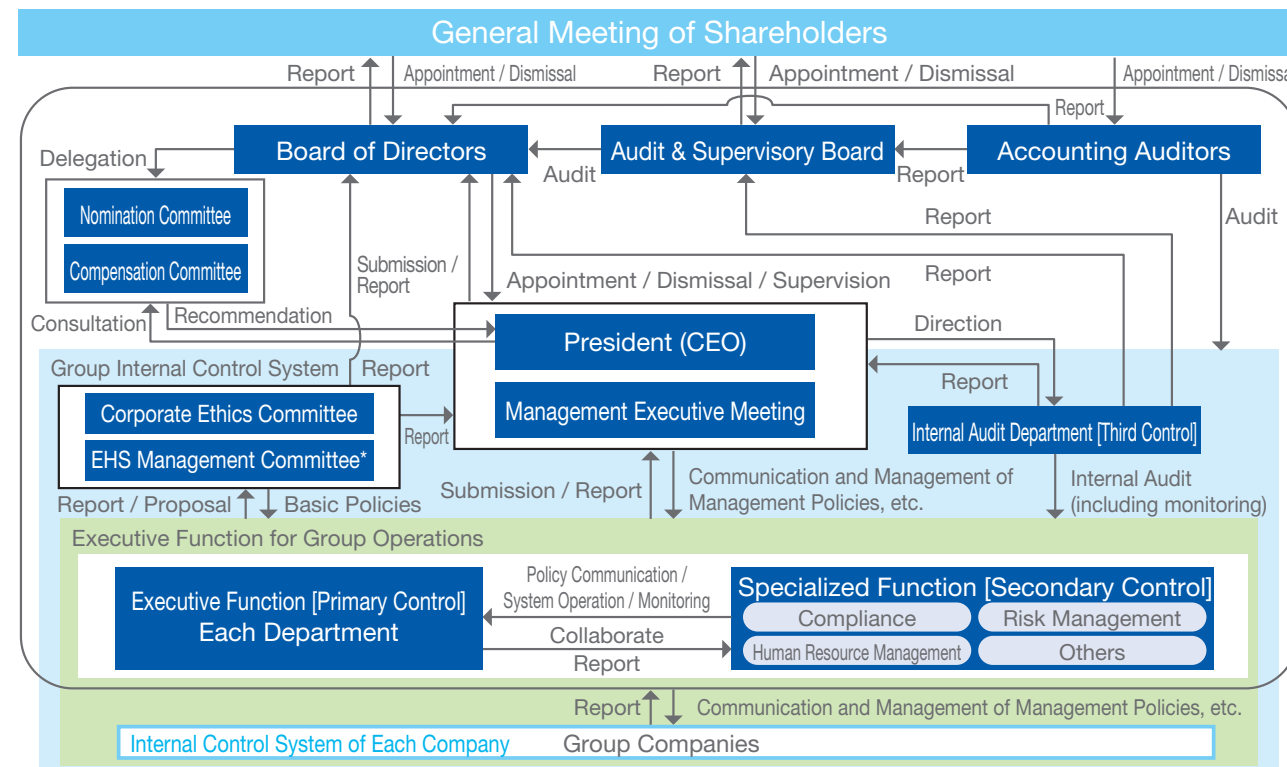
In order to ensure environmental conservation, health and safety in overall business activities at the Daiichi Sankyo Group and thereby to contribute to a sustainable society as well as to operate and promote management of the environment, health, and safety with a high likelihood of risk in an integrated 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.

## Overview of the corporate governance structure

(As of June 18, 2019)



\* EHS Management Committee: Environment, Health, Safety

## II Establishing internal control system that ensures proper operation under delegation of Board of Directors' authority

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.

### 1. Delegation of Board of Directors' authority to achieve proper and speedy management decision-making and the conduct of operations

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.

### 2. Establishment of internal control system

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

Corporate Function (Secondary Control), and internal audit including monitoring by the Internal Audit Department (Tertiary Control).

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.

## III System and measures that contribute to enhancing the effectiveness and function of the Board of Directors

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:

### 1. Terms of office and system for Members of the Board

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).

### 2. Evaluation of the Board of Directors

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

#### Results of the evaluation of the Board of Directors (Overview)

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.

### 3. Nomination Committee and Compensation Committee

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.

#### (1) Nomination Committee

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.

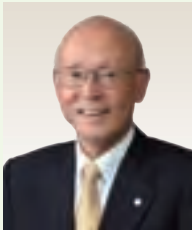
For candidates for Members of the Board, the Board of Directors appoints the candidates after they have been sufficiently verified by Nomination Committee. For candidates for Members of the Audit and Supervisory Board, the Board of Directors appoints the candidates after they have been verified by Nomination 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/Ghosn 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)



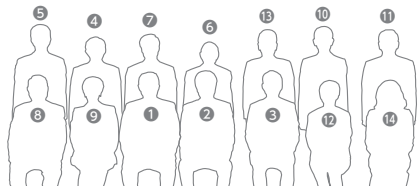
**Yukiko Imazu**  
Member of the Audit and  
Supervisory Board (Outside)  
(Independent Auditor)

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 Santory Limited ("Santory")  
2000 Director of Santory  
2002 President of Daiichi Santory Pharma Co., Ltd.  
2003 Resigned as Director of Santory  
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 NKJS 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

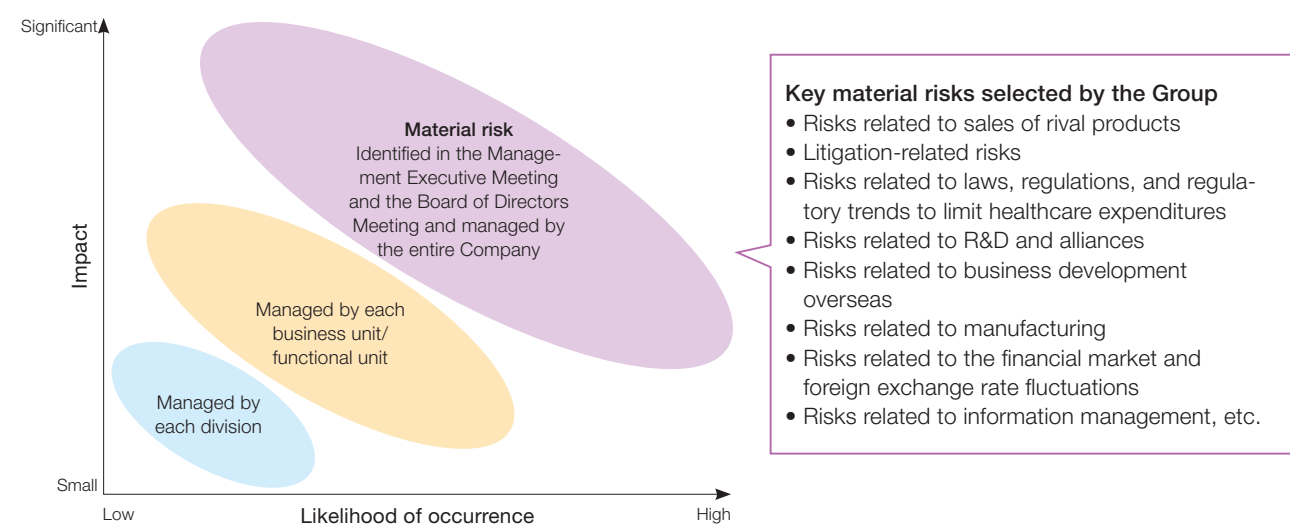
The chief financial officer (CFO) oversees Group-wide risk management as the risk management officer (RMO) and operates the risk management system in conjunction with an annual cycle of formulating and implementing business plans. In addition, the heads of each division autonomously manage risks to aid 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.

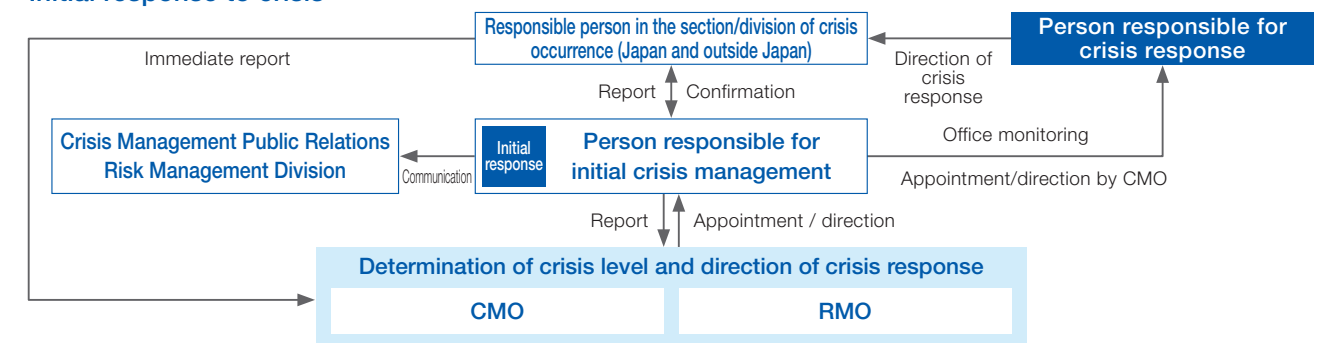
## Crisis Management

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





# Daiichi Sankyo Group's Value Chain and Organization

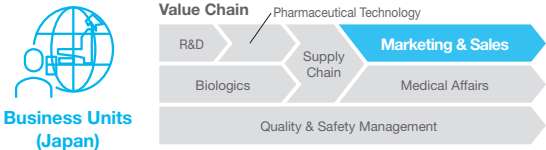
Daiichi Sankyo Group's value chain primarily encompasses research & development, biologics, pharmaceutical technologies, supply chain, marketing & sales, medical affairs, and quality & safety management. In conjunction with this value chain, we operate our organization independently while utilizing our unique strengths: Science & Technology, Global Organization & Talent, and Presence in Japan.



# Global Management Structure (As of June 18, 2019)



## Innovative Pharmaceuticals Business: Sales & Marketing Unit



The Sales & Marketing Unit delivers a wide range of high-quality innovative pharmaceuticals to patients, ranging from *Lixiana* and other primary areas\*<sup>1</sup> to specialty areas\*<sup>2</sup> centered on the oncology products. Taking the perspective of total care centered on patients, we aim to meet the needs of each customer and to contribute to healthcare in Japan by providing relevant information correctly, quickly, and carefully to all healthcare professionals who treat patients with diverse symptoms and conditions.

\*<sup>1</sup> Drugs mainly prescribed by general practitioners  
\*<sup>2</sup> Drugs mainly prescribed by hospitals/specialists

**Satoru Kimura** Head of Sales & Marketing Unit

### Toward a Trusted Medical Partner.

Based on the BRIDGE's\* activity concept, which wants to be a bridge between patients, their families and healthcare professionals by emphasizing the connection between people and providing proper information and providing products, we aim to be recognized as a reliable medical partner by everyone involved in healthcare. In addition to fostering MRs that can respond to a wide range of information needs that change on a daily basis, we are increasing the number of MRs with cancer-related expertise and raising the level of expertise. In addition, each employee strives to improve the correct understanding of dementia and cardiac diseases, and promotes to take training courses for supporters of dementia and to obtain a certification in lifesaving skills.

\* Bright Days Together

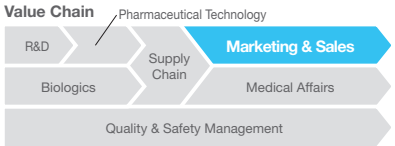


### Progress in Medium-Term Management Planning of Pharmaceutical Sales Units.

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Enhance Daiichi Sankyo's reputation as a trusted medical partner by improving information provision activities based on the BRIDGE concept	<b>MRs ranked No. 1 for the seven consecutive year</b> <ul style="list-style-type: none"><li>Ranked No. 1 in Japan in an overall assessment of MR activities in both the entire market and the hospital and general practice market categories in the survey conducted by an external organization*</li><li>In the entire market category, we have maintained the top ranking for seven consecutive years since fiscal 2012</li></ul> <small>* A survey by ANTERIO Inc. Evaluation of knowledge, information, humanity and responsiveness</small>	<b>Maintain MR No.1 ranking with high-quality information provision</b> <ul style="list-style-type: none"><li>Implement MR activities that contribute to the realization of medical care that all involved in medical care thinks by providing corrected information to patients, their families and medical personnel</li></ul>
	<b>All MRs passed the certificate test for the ninth consecutive year</b> <ul style="list-style-type: none"><li>All MRs have passed the certificate test for the ninth consecutive year since fiscal 2010 (Total pass rate in fiscal 2018: 75.9%)</li></ul>	<b>All MRs pass the certificate test for the tenth consecutive year</b> <ul style="list-style-type: none"><li>All MRs pass the test through the implementation of high-quality introductory training</li></ul>
Maximize revenue by promoting field and product strategies	<b>Domestic prescription drug share ranked No.1 for third consecutive year</b> <ul style="list-style-type: none"><li>Ranked No.1 in Japanese prescription drug share for three consecutive years due to expansion of <i>Lixiana</i> and other major products</li></ul>	<b>Expand major domestic products and early market penetration of new products</b> <ul style="list-style-type: none"><li>Achieve sustainable growth through further sales expansion of major products, mainly <i>Lixiana</i>, and early market penetration of new products</li></ul>
Construct systems and functions in response to environmental changes	<b>Established sales networks in the specialty care area</b> <ul style="list-style-type: none"><li>Established a domestic sales networks and information provision system to meet the market introduction of specialty products centered on cancer products, and the launch of new large-scale products such as Tarlige and Minnebro</li></ul>	<b>Establish an operating structure that can respond to total care</b> <ul style="list-style-type: none"><li>Establish an operating structure to further increase the level of expertise based on an internal oncology certification system and to respond to the total care of patients waiting for treatment</li></ul>
Promote a multichannel approach	<b>Utilized multichannel approach to meet individual needs</b> <ul style="list-style-type: none"><li>In response to the diverse needs of healthcare professionals, a multichannel approach using lectures, web seminars, internet, etc. through MRs gained a high evaluation (which is well retained in the memory of physicians) in the survey* on promotion by external organizations</li></ul> <small>* ANTERIO Inc.</small>	<b>Provide accurate information to all healthcare professionals</b> <ul style="list-style-type: none"><li>Build a multi-channel system that enables MRs to conduct activities in accordance with the needs of physicians, pharmacists, nurses, and other healthcare professionals in charge of team medical care, and provide accurate and quick information</li></ul>



# Generics Business: Daiichi Sankyo Espha Co., Ltd.



Daiichi Sankyo Espha takes pride in being as an innovator in the domestic generic pharmaceutical industry and provides authorized generics (AGs)\*, or a new standard for generics featuring formulation, labelling, and packaging innovations that are easy to swallow but hard to swallow accidentally based on the quality-level and stable supplies of Daiichi Sankyo groups. Through a promotion of the newly launched anticancer AG drug, we will create an environment where those who need generic drugs can use with peace of mind, while addressing various needs, in order to contribute to national medicine.

\* Authorized generic (AG): a generic drug manufactured after receiving approval from the brand-name pharmaceutical

Kentaro Murakawa Daiichi Sankyo Espha Co., Ltd. President

## Packaging that reduces the risk of accidental ingestion and can safely carry drugs

Daiichi Sankyo Espha is working on devises for formulation and packaging labels to prevent medical adverse events due to errors in taking drugs. Since there have been cases in which relatively high-risk drugs such as anticancer drugs are accidentally taken by families other than patients, especially small children, we have developed an external case for PTP sheets (named C-guard/child-guard) for the purpose of preventing children from taking the drugs by mistake and preventing drug miscontact and pop-out.



# Vaccine Business



In April 2019, the functions of Kitasato Daiichi Sankyo Vaccine (KDSV) like manufacturing and production technologies were transferred to Daiichi Sankyo Biotech, and the functions like R&D, quality & safety, and sales & marketing were transferred to Daiichi Sankyo. In addition, a portion of the Japan Vaccine business was transferred to Daiichi Sankyo to integrate dispersed vaccination functions. Daiichi Sankyo, as a manufacturer and distributor of vaccines, is more closely related to healthcare organizations and the government than ever before. By further improving stable supplies and quality levels, we aim to contribute more and more to the healthy lives and well-being of people.

Toshiaki Tojo, Ph.D. Head of the Vaccine Business

## Technical collaboration on MR-vaccine\* manufacture in Vietnam.

KDSV participated in the MR Vaccine Manufacturing Technology Transfer Project in JICA for five years until March 2018, and contributed to the domestic manufacturing and stable supplies in Vietnam by implementing manufacturing technology transfer to Vietnam's Vaccine Public. In October 2018, activities received the 14th JICA President's Award and the 70th Health and Cultural Award. We also donated these awards to Saitama Prefecture's National Midori Fund, where Daiichi Sankyo Biotech is located, to contribute to the conservation of surrounding natural environments. We also contributed to global medical activities by donating to medical institutions implementing medical activities in Vietnam.

\* Measles rubella combination vaccine



## Progress of Daiichi Sankyo Espha's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Strengthen the authorized generic (AG) lineup	<b>Launched AGs with 3 new active ingredients</b> <ul style="list-style-type: none"> <li>Launched <i>levofloxacin</i> intravenous infusion/infusion bag in June 2018 and <i>gefitinib</i> tablets and <i>siodosin</i> tablets/OD tablets in March 2019</li> <li>Expanded our product portfolio to 185 products portfolio with 73 active ingredients (product portfolio for AGs expanded to 25 products with 8 active ingredients)</li> </ul>	<b>Expand product portfolio focused on AGs</b> <ul style="list-style-type: none"> <li>Evolve from "Daiichi Sankyo Espha of AG" to "Daiichi Sankyo Espha of AG with competitive advantage in oncology"</li> <li>As AG portfolio for anticancer drugs, add 3 active ingredients: bicalutamide tablets/OD tablets, anastrozole tablets, and tamoxifen tablets</li> </ul>
Steadily launch AGs and other day-one generics* and gain market shares <small>* Day-one generics: Generic drugs launched on the first day that sales of a generic is possible</small>	<b>Expanded market share with new products, including AGs</b> <ul style="list-style-type: none"> <li>In addition to AG products launched in fiscal 2017, we also earned the top share in the target market for newly launched AG products</li> <li>5th position in the domestic generic pharmaceutical sales ranking</li> </ul>	<b>Promote anticancer AGs</b> <ul style="list-style-type: none"> <li>As AG leading company, expand market share by maximizing trust and expectations from patients, healthcare professionals, and the administration for AG and Daiichi Sankyo Espha through the promotion of anticancer AGs</li> </ul>
Step up coordination with partners in Japan and overseas	<b>Strengthen coordination with partner companies based on changes in the market environment</b> <ul style="list-style-type: none"> <li>Strengthened coordination with contract manufacturers and promoted cost reduction efforts by changing ingredients and streamlining manufacturing</li> </ul>	<b>Promote management efficiency in response to changes in the market environment</b> <ul style="list-style-type: none"> <li>Promote management efficiency through further efforts to reduce cost and reduce costs by strengthening cooperation with contract manufacturers in response to changes in the market environment</li> </ul>

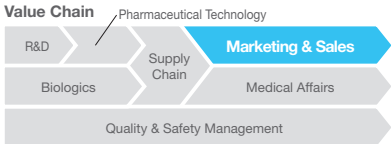
## Progress of the Vaccine Business's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Stable supply of vaccines  Establish a stable supply system  Awareness and dissemination of vaccines	<b>Stable supply of vaccines</b> <ul style="list-style-type: none"> <li>Supplied seasonal influenza vaccine before the influenza season by the effort to reduce lead time utilizing flexible shift production structure</li> </ul> <b>Building a stable supply base</b> <ul style="list-style-type: none"> <li>By improving the production method and establishing a system to increase production, a rapid supply system for MR vaccine is established in the event of an outbreak of measles rubella in response to the national measures for measles rubella</li> </ul>	<b>Stable supply of vaccines</b> <ul style="list-style-type: none"> <li>Supply the necessary and sufficient quantity of seasonal influenza vaccines before the influenza season by continuing measures for production efficiency and ensuring greater numbers of vaccines</li> <li>Supply MR vaccines in response to demand by utilizing the increased production system implemented in fiscal 2018</li> </ul> <b>Awareness and dissemination of vaccines</b> <ul style="list-style-type: none"> <li>Support for awareness and dissemination provided by healthcare professionals to ensure that children and families who are vaccinated are reassured</li> </ul>
Complete the establishment of a development and production system for pandemic influenza vaccines* and maintain production systems in preparation for future pandemics <small>* Open application project spearheaded by the Ministry of Health, Labour and Welfare to establish a production system and secure venues for supply</small>	<b>Establishment of a pandemic influenza vaccine production system</b> <ul style="list-style-type: none"> <li>Improved production methods for pandemic outbreaks were established, and the supply system for 40 million people within half a year could not be improved, but the public recruitment project was completed</li> <li>Conducted a training in preparation for pandemic outbreaks in established manufacturing methods</li> </ul>	<b>Maintenance of a pandemic influenza vaccine production system</b> <ul style="list-style-type: none"> <li>Establishment of a business system to prepare for pandemic outbreaks</li> <li>Education of personnel and development of action plans in the event of a pandemic</li> </ul>
Develop and encourage early market penetration of new influenza vaccines expected to be more effective and new, highly convenient combination vaccines	<b>Promotion of development themes</b> <ul style="list-style-type: none"> <li>Preparing for launch of nasal spray live attenuated influenza vaccine</li> <li>Started manufacturing of a convenient trivalent combination vaccine for measles, mumps, and rubella (MMR vaccine) for clinical trials and stability testing</li> </ul>	<b>Promotion of development themes</b> <ul style="list-style-type: none"> <li>Preparation for launch of nasal spray live attenuated influenza vaccine and establishment of supply system</li> <li>Accelerating development by transferring development of MMR-vaccines from Japan Vaccine to Daiichi Sankyo</li> </ul>

OTC Related Business:  
Daiichi Sankyo Healthcare  
Co., Ltd.



Business Units  
(Japan)



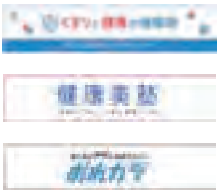
Daiichi Sankyo Healthcare handles a wide range of OTC drugs\*, including skin care cosmetics and oral care products. Among the Daiichi Sankyo groups, OTC is a unit that is closer to customers more broadly. By promoting self-medication and self-care through the contact and communication with customers, we will contribute to improving the quality of life (QOL) of many people who wish to be healthier and more attractive.

\* OTC drugs available in pharmacies, drug stores, etc.

Katsuhiko Yoshida Daiichi Sankyo Healthcare Co., Ltd. President

“Be more familiar with the use of medicines”  
A website that uses portals and is more familiar to consumers

With the evolution of digital environments, we provide an easy-to-understand introduction to the company website about signs of familiar symptoms, how to deal with self-care, and points to go to the hospital, in keeping with the era of solving daily questions and shopping on smartphones. We also provide a contact point for people who are unaware of their symptoms and who are encouraged to manage their health. (Drug and Health Information Office as a portal, Health and Beauty School for Women, and *Ore kara* for Men) The Store Search page allows you to search the nearest store that handles the desired product, and the Q&A allows you to check the detailed information about the product.



Progress of Daiichi Sankyo Healthcare's 5-Year Business Plan

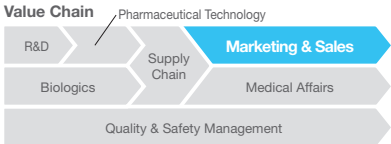
Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Improve product brand value in the OTC business	<b>Expansion of key brands</b> <ul style="list-style-type: none"><li>Expanded key brands, including <i>Lulu</i>, <i>Loxonin S</i>, and <i>Transino</i></li><li>Established a new brand <i>Breath Labo</i> (medicinal toothpaste) and added a new line such as <i>MINON Men</i> to address a wide range of lifestyle needs</li></ul>	<b>Accelerate growth of skin care and oral care business</b> <ul style="list-style-type: none"><li>Accelerate growth of <i>MINON</i>, <i>Transino</i>, <i>Clean Dental</i>, and <i>Breath Labo</i></li></ul> <b>Continue growth in the OTC business</b> <ul style="list-style-type: none"><li>Strengthen mainstay brands such as “<i>Lulu</i>” and “<i>Loxonin S</i>”</li></ul>
Accelerate the growth of the direct marketing business through leveraging synergies with Im Co., Ltd., in the direct marketing business	<b>Expansion of key brands</b> <ul style="list-style-type: none"><li>Breakthrough in the second year of launch of the female aging care brand BRIGHTAGE</li><li>Launched of Regain Triple Force</li></ul>	<b>Expansion of direct marketing business</b> <ul style="list-style-type: none"><li>Maximize the BRIGHTAGE branding power</li><li>Challenge to the new area</li><li>Further extension of the RICE FORCE</li></ul>
Achieve independent of overseas business	<b>Expanding the mainstay brand MINON Amino Moist</b> <ul style="list-style-type: none"><li>Expanded the number of sales stores in China</li><li>Launched in Hong Kong</li><li>Expanded sales during the second year of launch in Taiwan</li></ul>	<b>Strengthening operations in China, Hong Kong and Taiwan</b> <ul style="list-style-type: none"><li>Further expansion of the <i>MINON</i> brand as a whole</li><li>Increase the number of marketed products</li><li>Further promote by strengthening inbound efforts</li></ul>
Strengthen operating foundations to ensure responsiveness to market environment changes	<b>Strengthening the foundation to respond to changes in the needs of customers</b> <ul style="list-style-type: none"><li>Promoted continuous value creation based on perspectives originating from customers utilizing the functions of the CS* Department and the Product Strategy Department</li><li>Increased the number of site visitors by continuous improvement of Daiichi Sankyo Healthcare corporate website</li></ul> <p>* Abbreviation of Customer Satisfaction</p>	<b>Establishment of business infrastructure to respond to environmental change</b> <ul style="list-style-type: none"><li>Collect customer's voice and respond in timely manner in various ways</li><li>Streamline existing works by using AI and shift manpower to more creative works</li></ul>

Daiichi Sankyo, Inc. (DSUSB\*)

\* Daiichi Sankyo US Business



Business Units  
(United States)



The year 2018 was another successful year of transformation for Daiichi Sankyo, Inc. We have taken great strides toward our goal of becoming a leader in oncology in the U.S. by building new teams with deep and broad cancer expertise. Our new structure will allow us to maximize our in-line medicines as we prepare to launch our oncology portfolio. *Injectafer* stands out as our growth driver with increased sales across all customer types and continues as the #1 iron therapy in oncology clinics by dose volume and the fastest growing iron therapy in the U.S.

Ken Keller Daiichi Sankyo, Inc. President and CEO

Patient advocacy Initiatives

At Daiichi Sankyo, Inc., we believe our business extends beyond the discovery and development of therapies for unmet medical needs. It's our mission to make a positive difference in the communities where we live and work. Our philanthropic initiatives help people identify, prevent and manage illness. In 2018, examples include support for AmeriCares, World Cancer Day, Zufall Mobile Health Van, Myelodysplastic Syndromes Foundation, and the Leukemia & Lymphoma Society.



Daiichi Sankyo, Inc. employees at the 2018 "Light the Night" fundraiser for the Leukemia & Lymphoma Society

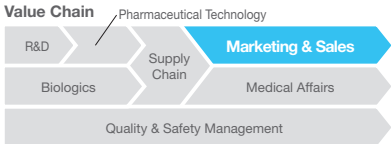
Daiichi Sankyo, Inc. 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Build and grow oncology capabilities	<b>Building awareness of our portfolio</b> <b>Injectafer</b> <ul style="list-style-type: none"><li>With new initiatives, <i>Injectafer</i> grew not only within the hematology/oncology market – where it is still the market leader – but also overall in new areas of patient need.</li><li>In 2018 we launched our first direct-to-patient promotional campaign driving thousands of new potential patients to speak with their HCPs about Iron Deficiency Anemia (IDA), including our Get Iron Informed campaign with celebrity IDA patient.</li></ul> <b>Oncology</b> <ul style="list-style-type: none"><li>Our medical teams have been incredibly responsive to healthcare providers seeking to learn about the mechanisms-of-action and data released to date for our oncology portfolio.</li><li>We have also recruited top talent into the organization to launch our new cancer therapies once approved, many with more than a decade of experience with leading oncology companies.</li></ul>	<b>2019 Is our inflection point</b> <b>Injectafer</b> <ul style="list-style-type: none"><li>We plan to grow <i>Injectafer</i> even further by building our share of voice to meet GI and Ob/Gyn customers' needs.</li></ul> <b>Oncology</b> <ul style="list-style-type: none"><li>Upon approval, we will launch <i>pexidartinib</i> offering certain TGCT patients with the first systemic therapy for this progressive and often debilitating disease.</li><li>With the planned filing of [fam] <i>trastuzumab deruxtecan (DS-8201)</i> BLA in 2019, we will prepare to successfully launch this medicine into the breast cancer space with our new collaborator, AstraZeneca.</li><li>We will focus on securing payer coverage and implement patient reimbursement support services for all of our medicines.</li></ul>
Grow pain business	<b>Tackling challenges head on</b> <ul style="list-style-type: none"><li>For <i>MorphaBond</i> and <i>Movantik</i> we maintained formulary coverage and access.</li><li>Our team remained resilient and adaptable to address challenges and to ensure all appropriate patients have access to our pain portfolio.</li><li>With the continued dialogue with the U.S. FDA regarding <i>RoxyBond</i>, our commercial organization continued focus on growing <i>Movantik</i> and <i>MorphaBond</i> ER.</li></ul>	<b>Offer abuse deterrent options</b> <ul style="list-style-type: none"><li>We will seek growth of both <i>Movantik</i> and <i>MorphaBond</i>.</li><li>In 2019 we plan to launch <i>RoxyBond</i> to offer an abuse deterrent formulation of a widely prescribed opioid and seek to be part of the solution to opioid misuse and abuse.</li></ul>
Maximize profit for mature products through LOE* timeframe <small>*Loss of exclusivity</small>	<b>Balancing investments</b> <ul style="list-style-type: none"><li>We maximized revenue for <i>Welchol</i> despite generic entry.</li><li>We have implemented innovative programs that reduce costs dedicated to our mature products while also ensuring our customers' needs are met.</li></ul>	<b>Maintain access and shift resources</b> <ul style="list-style-type: none"><li>We will continue to ensure patients have access to our mature medication while continuing to shift resources to our new portfolio.</li></ul>





Business Units  
(United States)



Ken Keller American Regent, Inc. President and CEO

Communication with community

At American Regent, Inc., we strive to make a positive impact in our communities. In FY2018, our company and our employees participated in numerous events to make a difference in the neighborhoods in which we work and live. Such examples include participating in Habitat for Humanity, which provide adequate and affordable housing, the Take Steps–Crohn's and Colitis Foundation walk, and our annual Holiday Adopt an Angel program.



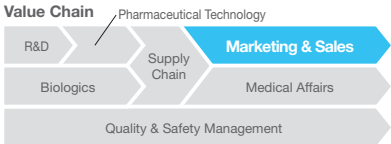
American Regent, Inc. employees at "Habitat for Humanity"

American Regent 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Build <i>Injectafer</i> into flagship product and market leader	<b>Secured market leader position</b> <ul style="list-style-type: none"><li>Our IV iron franchise is the #1 leader in the United States market, dominating market share with over 70% of all dollars in this category. Our two products, <i>Injectafer</i> and <i>Venofer</i>, are highly valued by our customers. We are focused on both protecting this business and expanding the appropriate use of IV iron into new therapeutic areas of iron deficiency in Heart Failure patients, as well as growing penetration into IDA in women's health and gastroenterology.</li></ul> <b>Achieved revenue target</b> <ul style="list-style-type: none"><li><i>Injectafer</i> achieved a record revenue level of \$399 million, an increase of 29% over the previous year. Continued collaboration between American Regent, Inc. and DSUSB was a main driver of the growth of <i>Injectafer</i> in spite of increasing competitive pressure.</li></ul>	<b>Continue market leadership for <i>injectafer</i></b> <ul style="list-style-type: none"><li><i>Injectafer</i> revenue target in FY2019 is \$418 million, +\$20M versus prior year despite increasing competitive threats. Growth drivers are;<ul style="list-style-type: none"><li>Increased share of voice to meet GI and OB/ GYN customer needs</li><li>Continued awareness among dissatisfied oral iron patients</li></ul></li></ul> <b>Accelerate life cycle management</b> <ul style="list-style-type: none"><li>HEART-FID clinical study is ongoing. Study will assess the efficacy and safety of iron therapy using <i>Injectafer</i> relative to <i>placebo</i> in treating patients with heart failure, iron deficiency, and a reduced ejection fraction.</li></ul>
Expand generic injectable portfolio with a variety of products to support customer needs	<b>Bring new products to market</b> <ul style="list-style-type: none"><li>American Regent successfully launched 7 new products in FY2018: <i>Neostigmine</i>, <i>Sterile Water</i>, <i>Hydroxyprogesterone Caproate</i>, <i>Fomepizole</i>, <i>Testosterone Cyprionate</i>, <i>Aminocaproic Acid</i> and <i>Droperidol</i>.</li></ul> <b>Achieved revenue target</b> <ul style="list-style-type: none"><li>FY2018 actual American Regent generic injectable portfolio revenue exceeded budget and continued to deliver year on year growth.</li></ul>	<b>Expand generics portfolio</b> <ul style="list-style-type: none"><li>American Regent plans to launch between 6 and 8 new products in FY2019. These product launches, coupled with American Regent's existing portfolio, will help to drive growth in the face of increasing competition in some key categories.</li><li>Continued focus and investment in product development and NDA/ANDA /505B2 filing efforts along with enhanced contracting strategies with GPOs and new evolving players entering the market will help to increase revenue going forward.</li></ul> <b>Capital expansion investment underway</b> <ul style="list-style-type: none"><li>American Regent's capital expansion investment of approximately \$200M across three manufacturing sites is underway and on-track. When completed, this investment will provide robust, state of the art manufacturing capabilities that will enable us to continue to meet the needs of our patients and customers.</li></ul>



Business Units  
(Europe)



FY2018 was a very successful year for Europe. *LIXIANA*® is continuously increasing its market share and we in-licensed *bempedoic acid* for patients who need additional LDL cholesterol lowering after maximum tolerated statin therapy. If authorized the new product will be a synergistic addition to our cardiovascular portfolio. We also established an effective commercial oncology organization to successfully launch our oncology products in Europe. For both business areas we continue to work on our aspiration to become the benchmark for customer centricity and have implemented many projects and processes to achieve this goal.

Jan Van Ruymbeke, MD. Daiichi Sankyo Europe GmbH Managing Director, CEO

Mycancertherapy.eu: Video portal for patients with cancer

Mycancertherapy.eu provides information in 16 different languages. It aims to help patients overcome barriers – often due to medical jargon, foreign language and a sense of being overwhelmed after a cancer diagnosis – in understanding their therapy journey. Leading HCPs answer the most frequent patient questions in their native tongue on the main aspects of cancer treatment, including side-effects or types of treatment. The website supports physicians in patient education as it enables patients to have the most important information about cancer explained to them by experts at home.



website: Mycancertherapy.eu

Daiichi Sankyo Europe 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Maximize <i>LIXIANA</i> 's potential	<b>Increasing market share</b> <ul style="list-style-type: none"><li>Since 2015 we launched <i>LIXIANA</i>® in all our European affiliates except for France and keep growing market shares.</li><li>As a result, our EU market share in March 2019 is more than 12% (exit share in DOT – days of treatment – for the month).</li><li>To leverage our cardiovascular success and heritage we have in-licensed <i>bempedoic acid</i> for patients who need additional LDL cholesterol lowering.</li></ul>	<b>Brand refinement</b> <ul style="list-style-type: none"><li>We have defined a new single-minded proposition for <i>LIXIANA</i>®: "Your choice for the elderly NVAf patients" is rolled-out across all European markets.</li><li>FY2019 is also the year we prepare for the launch of <i>bempedoic acid</i> foreseen in Q2 of FY2020. Launch preparations will build on the capabilities, synergies and learnings from the <i>LIXIANA</i>® introduction.</li></ul>
Establish oncology business	<b>Thorough preparation for launches</b> <ul style="list-style-type: none"><li>The European commercial organization is set up well to successfully launch our oncology products.</li><li>We have hired talented professionals for medical, market access, marketing, field force and other functions.</li><li>Our focus on customer centricity enables us to cater to the needs of the full set of stakeholders who contribute to patient care, among them oncologists and hematologists.</li></ul>	<b>Launching with excellence</b> <ul style="list-style-type: none"><li>Our focus this year is the successful launch of <i>VANFLYTA</i>® in early 2020. Together with our partner AstraZeneca we are also preparing for the launch of <i>DS-8201</i>.</li></ul>
Develop organization to further evolve into specialty care provider	<b>Adapt to upcoming oncology portfolio</b> <ul style="list-style-type: none"><li>With the build-out of our oncology division over the last years, we have set the ground for future launches.</li><li>At the same time we have further adapted our customer-facing roles to the needs of a specialty care environment.</li></ul>	<b>Focus on patients' and customers' needs</b> <ul style="list-style-type: none"><li>We are constantly evolving our organization to adapt to the changing healthcare environment.</li><li>In FY2019, we keep focusing on how to best meet patients' needs as well as provide our stakeholders – e.g. HCPs, payers – with solutions for their requirements in both the cardiovascular and oncology field.</li></ul>



The keywords concerning the growth of ASCA Company are “China”, “*LIXIANA*”, “Business Development” and “Oncology business”. In China, we aim to ensure growth and improve profitability by strengthening the business structure. For *LIXIANA*, we will take full advantage of the customer relationship that we have established for *Olmecartan* and synergize both products. Regarding Business Development, we will explore new markets by in-licensing local products and establishing DS own companies. We will also build a business infrastructure and prepare for launch in China, Brazil, and other countries with a large market for oncology products in order to quickly deliver promising new drugs in the future.

Hiroyuki Okuzawa ASCA Company President

### More women playing active roles in ASCA Company

ASCA Company has affiliates in Asia and South and Central America, and is operating its business there. ASCA Company, whose operation is supported by approximately 2,100 employees, has improved women’s empowerment; women comprise more than 50% of its workforce, and women occupy more than 40% of managerial positions. For example, in Daiichi Sankyo Taiwan, the President is a woman, and in addition, half of the senior members are women. We will make medical contributions matched to the specific needs of each country by promoting management based on Diversity and Inclusion, including women’s empowerment.



Daiichi Sankyo Taiwan senior members  
President Sheron Lin (third from left)

### Progress of ASCA Company's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Maintain and expand sales of existing products and quickly develop, launch, and expand sales of new products	<p><b>Achieved revenue of ¥87.7 billion (up 9.0% year on year)</b></p> <ul style="list-style-type: none"> <li>Existing mainstay products including <i>OLMETEC</i> and <i>CRAVIT</i> steadily grew in each country where they are marketed. In China, the revenue increased by 9% compared with the previous year, and challenges for optimizing alliance models with partners were extracted and countermeasures were implemented</li> <li><i>LIXIANA</i> grew to DOAC market share No.1 per month in South Korea, and Taiwan also continued to expand market share. In addition, it was launched in Brazil, and launched in Saudi Arabia and Indonesia through partners</li> <li>Launched <i>SEVIKAR</i> in China and <i>EFIENT</i> in Taiwan</li> </ul>	<p><b>Achieve revenue ¥100 billion (up 14.1% year on year)</b></p> <ul style="list-style-type: none"> <li>Implement strategies that maximize the potential of the Chinese business (expanding own marketing territories to increase profitability)</li> <li>Expand further revenue of <i>LIXIANA</i> in each country and implement initiatives in collaboration with various functions such as Marketing and Medical Affairs for launch and expansion in China</li> <li>Launch <i>LOXONIN TAPE</i> in Brazil</li> </ul>
Enhance portfolio of products matched to the specific needs of respective regions and countries	<p><b>Expanded the product pipelines</b></p> <ul style="list-style-type: none"> <li>Launched <i>LATUDA</i><sup>*1</sup> in Brazil</li> <li>In-licensed <i>PENTHROX</i><sup>*2</sup> in China, Thailand and Vietnam</li> <li>Started a promotion for <i>Omacor</i><sup>*3</sup> in South Korea</li> <li>Obtained a marketing approval for <i>LIXIANA</i> in China</li> </ul> <p><small>*1 Antipsychotic agent in-licensed from Sumitomo Dainippon Pharma *2 Non-opioid pain agent in-licensed from Medical Developments International *3 Treatment for dyslipidemia that has signed a co-promotion agreement with Kuhnle</small></p>	<p><b>Enrich product portfolio</b></p> <ul style="list-style-type: none"> <li>Promote preparations for commercialization of <i>PENTHROX</i></li> <li>Out-license <i>LIXIANA</i> in countries where we do not have affiliates and create business development opportunities</li> </ul>
Strengthen business foundation and implement measures targeting growth markets in fiscal 2021 and beyond	<p><b>Considered a plan to establish new own sales companies</b></p> <ul style="list-style-type: none"> <li>Considered establishment of bases in countries and regions that do not have our group’s own sales companies in line with the enrichment of the oncology pipeline</li> </ul>	<p><b>Further strengthen business foundation</b></p> <ul style="list-style-type: none"> <li>Design functions and organizations and promote talent acquisition for oncology business</li> <li>Continue to consider establishing own sales companies in ASEAN countries, Oceania, and Latin America in order to expand the oncology business and existing products such as <i>LIXIANA</i></li> </ul>



The R&D Unit developed “R&D2025” Vision at the end of 2017, which includes seven new compounds launches in the oncology area and five new compounds launches in the Specialty Medicine area by 2025, and has made every effort to achieve this vision. We will accelerate the development of *DS-8201* through co-development with AstraZeneca, and will make use of that experiences to development of the entire oncology area. We will also build new pillars to support us next to the oncology area by challenging the therapeutic applications of innovative and diverse modalities such as nucleic acid drugs and cell therapies, leading to generate innovative pharmaceuticals which will change SOC\*.

\* Standard of Care. The best and widely used treatment in modern medical.

Junichi Koga, Ph.D. Head of R&D Unit

### “COMPASS” navigator for drug discovery required by patients

The R&D division conducts activities called COMPASS, which links the R&D field to the medical field. The activity name, COMAPSS, is derived from the “Compassion for Patients Strategy” and is meant to be a “compass” for drug discovery based on patient needs. COMPASS develops three initiatives with the concepts of A (Alliance): know from activities in collaboration with patients’ organizations; B (Bedside): realize medical needs from experiences in healthcare settings; and C (Communication): learn from lectures and dialogue style conferences. We aim to achieve “patient-oriented drug discovery” through opinion exchanges with patient organizations and healthcare professionals, lectures, and hospital training to see the field of medical care.

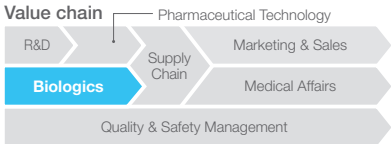


COMPASS C activity landscape

### Progress of the R&D Unit's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Become a leader of Antibody-drug conjugates	<p><b>DS-8201(HER2-ADC)</b></p> <ul style="list-style-type: none"> <li>HER2 positive metastatic breast cancer 3rd line <ul style="list-style-type: none"> <li>Completed pivotal phase 2 study enrollment</li> <li>Initiated phase 3 study</li> </ul> </li> <li>Initiated HER2 positive metastatic breast cancer 2nd-line vs T-DM1 phase 3 study</li> <li>Initiated HER2 low breast cancer phase 3 study</li> <li>Initiated lung cancer phase 2 study</li> <li>Initiated phase 1 study of combination with immune checkpoint inhibitor</li> </ul>	<p><b>DS-8201(HER2-ADC)</b></p> <ul style="list-style-type: none"> <li>Submit BLA/NDA (US/Japan): HER2 positive metastatic breast cancer 3rd-line</li> <li>Complete pivotal phase 2 study for gastric cancer (JP)</li> <li>Initiate phase 2 study for gastric cancer (US/EU)</li> </ul> <p><b>Other ADC franchises</b></p> <ul style="list-style-type: none"> <li>Prosecute <i>U3-1402</i> (HER3-ADC) phase 1 study</li> <li>Prosecute <i>DS-1062</i> (TROP2-ADC) phase 1 Study</li> <li>Initiate phase 1 studies for <i>DS-7300</i> (B7-H3-ADC) and <i>DS-6157</i> (GPR20-ADC)</li> </ul>
Establish a hematology cancer franchise	<p><b>Quizartinib (FLT3 inhibitor)</b></p> <ul style="list-style-type: none"> <li>Submitted NDA (JP/US/EU): relapsed/refractory AML</li> <li>Designated as breakthrough therapy (US) and as orphan drug (JP)</li> </ul>	<p><b>Quizartinib (FLT3 inhibitor)</b></p> <ul style="list-style-type: none"> <li>Obtain approval (JP/US/EU): relapsed/refractory AML</li> <li>[Obtained approval in June (JP), recieved complete response letter (CRL) in June (US)]</li> </ul>
Become a leader in breakthrough science in the oncology area	<ul style="list-style-type: none"> <li>Submitted NDA of <i>pexidartinib</i> (US/EU): tenosynovial giant cell tumor</li> <li>Initiated phase 2 study of <i>Axi-Cel</i><sup>®</sup> (CAR-T) (JP) and designated as orphan drug (JP)</li> <li>Initiated phase 1 study of <i>DS-1205</i> (AXL inhibitor)</li> <li>Completed phase 2 study of <i>DS-1647</i> (G47Δ) (JP)</li> </ul>	<ul style="list-style-type: none"> <li>Obtain approval for <i>pexidartinib</i> (US): tenosynovial giant cell tumor</li> <li>Submit NDA of <i>DS-1647</i> (G47Δ) (JP): Glioblastoma</li> <li>Prosecute phase 1 study of <i>DS-3201</i> (EZH1/2 Inhibitor) [SAKIGAKE designation in April (JP)]</li> </ul>
Maximize near-term revenue and grow future franchises in the specialty medicine area	<p><b>Maximize near-term revenue</b></p> <ul style="list-style-type: none"> <li>Obtained approval of <i>esaxerenone</i> (JP): hypertension</li> <li>Obtained approval of <i>mirogabalin</i> (JP): peripheral neuropathic pain</li> <li>Submitted NDA of <i>Inavir nebulizer</i> (JP): influenza virus infections</li> </ul>	<p><b>Maximize near-term revenue</b></p> <ul style="list-style-type: none"> <li>Prosecute phase 3 study of <i>mirogabalin</i> central neuropathic pain (JP)</li> <li>Obtain approval of <i>Inavir nebulizer</i> (JP): influenza virus infections</li> </ul> <p><b>Grow future franchises</b></p> <ul style="list-style-type: none"> <li>Prosecute phase 1/2 study of <i>DS-5141</i> (JP)</li> </ul>



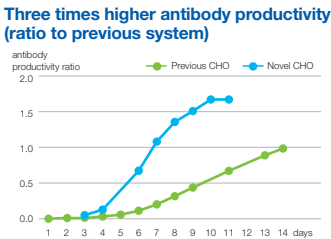


Masayuki Yabuta, Ph.D. Head of Biologics Unit

To develop highly productive expression systems in novel CHO cell line\*1

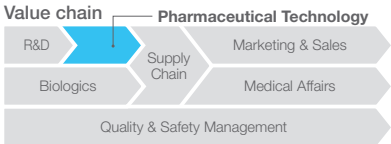
In the manufacture of antibody drugs, long-term cell culture is one of the high cost factors of antibody drugs. Daiichi Sankyo has participated in the Manufacturing Technology Association of Biologics, so-called MAB, supported by the(AMED<sup>2</sup> and MITT<sup>3</sup>), and successfully obtained novel CHO cell line with high growth performance. In addition, a new CHO cell expression system developed by combination with an in-house developed vector showed about three times higher antibody productivity than the previous system. In the future, we will achieve rapid and low-cost manufacturing by applying it to the production of biopharmaceuticals, and we hope that this cell will be widely used in other companies by the collaboration with MAB

\*1 Cell lines derived from Chinese hamster ovary cells. It is widely used in the manufacture of antibody drugs.  
\*2 Japan Agency of Medical Research and Development \*3 the Ministry of Economy, Trade, and Industry



Progress of the R&D Unit's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Contribute to accelerating the launch of DS-8201 and other ADC franchise drugs	<b>Establish commercial manufacturing process of antibodies for DS-8201</b> <ul style="list-style-type: none"><li>Established antibody manufacturing process for commercialization</li><li>Completed technology transfer to group companies responsible for commercial manufacturing</li><li>Started discussion on manufacturing process for large-scale manufacturing</li></ul>	<b>Establish commercial manufacturing process for DS-8201 and ADCs</b> <ul style="list-style-type: none"><li>Conduct actions for NDA of DS-8201</li><li>Continue discussion on manufacturing process for large-scale manufacturing</li><li>Develop manufacturing process for antibody part of ADC franchise</li></ul>
Develop manufacturing technologies and accelerate clinical development for biologics	<b>Develop cutting-edge technologies and apply them to development candidates</b> <ul style="list-style-type: none"><li>Developed in-house manufacturing technology (cell, culture medium, purification method, etc.)</li><li>Developed new biologics by in-house technology and developed manufacturing process</li></ul>	<b>Develop cutting-edge technologies and apply them to development candidates.</b> <ul style="list-style-type: none"><li>Develop antibody manufacturing process by using novel CHO cells.</li><li>Establish strategic antibody manufacturing alliance including group companies for clinical/commercial provision</li><li>Utilize in-house technology for the manufacture of various modalities</li></ul>
Discover innovative forms of modality* <small>*The foundation of drug development and therapeutic approaches such as protein drugs, nucleic acid medicine, cell medicine and regenerative medicine including low molecular compounds, peptide (middle molecule)</small>	<b>Create new modalities</b> <ul style="list-style-type: none"><li>Determined the development of nucleic acid pharmaceuticals with DDS (Drug Delivery System) functions</li><li>Determined the development of original protein scaffold as pharmaceuticals.</li><li>Expanded collaboration with Zymeworks on bispecific antibodies</li><li>Determined the development of lipid nanoparticle-mRNA (LNP-mRNA) for the novel immunotherapy against HPV-associated neoplasia/cancers.</li></ul>	<b>Create new modalities</b> <ul style="list-style-type: none"><li>Expand and optimize various modalities such as glycoengineered antibodies, cyclic peptides, and protein scaffolds and extend the application area</li><li>Build basic infrastructure for gene therapy research</li><li>Promote development of LNP-mRNA vaccines/immunotherapies</li></ul>
Construct and strengthen technologies and human resource infrastructure that support commercialization of biologics including cell therapies	<b>Promote cell therapy projects and R&amp;D</b> <ul style="list-style-type: none"><li>Conducted various actions for NDA of DS-1647 (G47Δ) by collaborating with partners</li><li>Conducted technology transfer of cell manufacturing methods in Axi-Cel® (CAR-T) projects</li></ul>	<b>Promote cell therapy projects and R&amp;D</b> <ul style="list-style-type: none"><li>Take actions for NDAs of DS-1647 (G47Δ) and Axi-Cel® (CAR-T)</li><li>Promote joint research with Tokyo Industrial University on the preparation methods of iPS cell-derived insulin-producing cells</li></ul> <b>Build and strengthen technology and human resource infrastructure</b> <ul style="list-style-type: none"><li>Develop biologics technologies and establish supply systems that make full use of in-group functions</li></ul>



Hiroto Kashiwase, DVM, Ph.D. Global Head of Pharmaceutical Technology Unit

Strengthening the supply system for investigational drug products

The Pharmaceutical Technology Unit develops new technologies and new application, such as ultra-low temperature cold chain technology, in order to deliver drug candidates, which consist of various modalities, as investigational drug products for clinical trials. We are working to deliver investigational drug products as soon as possible to patients who are waiting for a new treatment approach. We are also doing our best to address the demands from physicians and patients for compassionate use of investigational drug products, as well as supporting the ongoing extended access for patients after the completion of clinical trial. In addition, we are establishing a robust system for stable supply of investigational drug products.

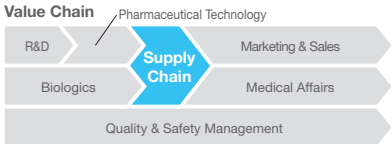


Investigational drugs used in clinical trials

Progress of the Pharmaceutical Technology Unit's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Accelerate and improve the efficiency of oncology development	<b>Steadily performed application-related work and technology transfer</b> <ul style="list-style-type: none"><li>Implemented process validation and prepared application dossiers in order to achieve acceleration of DS-8201 application</li><li>Implemented technology transfer for commercial manufacturing facilities for launch of DS-8201</li><li>Determined commercial manufacturing conditions for quizartinib and pexidartinib, which achieve good quality and productivity</li><li>Prepared application dossiers for quizartinib and pexidartinib</li></ul>	<b>Initiatives for DS-8201</b> <ul style="list-style-type: none"><li>Prepare for BLA/NDA submission in Japan and the US and respond to inquiries from regulatory reviews</li><li>Establish manufacturing and supply system for investigational drug products and commercial products considering collaboration with AstraZeneca,</li></ul> <b>Develop other oncology drugs</b> <ul style="list-style-type: none"><li>Ensure supply investigational drug products to support accelerated development even with rapid changes in the demands of investigational oncology products and comparator</li></ul>
Enhance fundamental technologies of biologics (ADCs)	<b>Enhance and deploy ADC-related technologies</b> <ul style="list-style-type: none"><li>Developed new formulations by using ADC-platform technologies (e.g., DS-6157 and DS-6000)</li><li>Developed ADC analysis technology that enables precise control of impurities</li></ul> <b>Prepare for the next generation ADCs</b> <ul style="list-style-type: none"><li>Developed efficiently next-generation ADCs based on the experience of existing ADCs</li></ul>	<b>Promotion of next-generation ADC development</b> <ul style="list-style-type: none"><li>Develop high-speed analytical technology that shortens the research and development period for biopharmaceuticals</li><li>Establish investigational product manufacturing and supply system for next-generation ADCs</li></ul>
Develop high-value-added products, reduce costs, and establish new manufacturing processes	<b>Develop high-value-added products</b> <ul style="list-style-type: none"><li>Prepared application dossiers for Inavir nebulizer* formulation</li><li>Designed of a package capable of preventing exposure to oncology drugs</li></ul> <small>* Devices for nebulizing drug solutions through the mouth and nose</small>	<b>Develop technologies that address a variety of modalities</b> <ul style="list-style-type: none"><li>Establish ultra-low-temperature cold chain* that supports cell therapy and regenerative medicine</li><li>Establish manufacturing process of nucleic acid drugs to reduce cost</li></ul> <small>* Logistics method that maintains uninterrupted low temperatures between manufacturing , transportation and consumer activities</small>

Supply Chain Unit



The Supply Chain Unit is rapidly transforming its organizational functions with the aim of a “supply chain with competitive advantages in oncology and biotechnology”. In particular, for the launch of *DS-8201*, we are strengthening our stable production and supply system by investments in biopharmaceuticals manufacturing facilities, addition of contract manufacturers worldwide and continuing development of biotech personnel capabilities. In the meantime, we are working to achieve stable supply and reduce product cost in response to the growing demand in *edoxaban*, which supports our growth. We will continue to contribute to the creation of group profits by transforming and strengthening supply chain functions.

Junichi Fukute Head of Supply Chain Unit

Toward a production system that utilizes environmentally friendly equipment

Daiichi Sankyo Propharma Co., Ltd., a subsidiary company belongs to the Supply Chain Unit, has used an environmentally focused gas co-generation system since 2012 after the earthquake, and efficiently uses energy such as heat and steam generated by its operation. Furthermore, this system can supply power even in an emergency such as power failure. In FY2018, this system contributed to the reduction of environmental impact by reducing approximately 2,000t of CO<sub>2</sub>. The effect is on the rise year by year, and we aim to make a more environmentally focused production system by using it continuously.

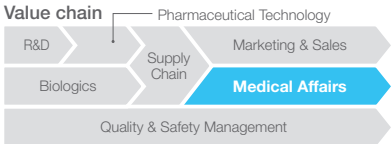


A power generator that takes development environments into account

Progress of Supply Chain Unit's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Transform and rebuild supply chain structures adapted to changes in the product mix	<b>Established a manufacturing system for anticancer drugs and biologics</b> <ul style="list-style-type: none"><li>Established manufacturing facilities for drug substances and formulations in accordance with the development plan of the ADC franchise</li><li>Secured and developed human resources in accordance with the human resources developing roadmap in biologics field</li><li>Promoted preparations/considerations on initiatives for a stable supply globally in accordance with the mid-to-long term supply plan</li></ul>	<b>Strengthen a manufacturing system for anticancer drugs and biologics</b> <ul style="list-style-type: none"><li>Strengthen the global manufacturing and supply system for anticancer drugs and biologics, including investigational drugs</li><li>Secure manufacturing and analysis personnel based on the human resources developing roadmap in biologics field</li><li>Promote capital investment plan based on our future vision</li><li>Establish new logistics functions in response to environmental changes</li></ul>
Construct a supply system in response to the growth of existing and new products and respond to new technologies	<b>Established a global supply system for edoxaban</b> <ul style="list-style-type: none"><li>Established a stable supply system by reviewing mid-to-long term supply system in response to the expansion of approved countries</li></ul> <b>Established a manufacturing and supply system for cutting-edge pharmaceutical products</b> <ul style="list-style-type: none"><li>Promoted an establishment of production system and cold chain* tailored to individual product characteristics of regenerative medical products, such as <i>Axi-Cel</i><sup>®</sup> (CAR-T) and <i>DS-1647</i> (G47Δ)</li></ul> <p>* A logistics that maintains uninterrupted low temperatures from manufacturing to consumers</p>	<b>Establish and promote a supply system in accordance with development and launch schedules</b> <ul style="list-style-type: none"><li>Prepare for launch of new products on schedule and achieve a stable supply after launch</li><li>Achieve a stable supply of <i>edoxaban</i> in response to growing demand in Japan and Europe</li></ul> <b>Establish a reliable supply system for ADC and cutting-edge pharmaceutical products and study mid-to-long term stable supply measures</b> <ul style="list-style-type: none"><li>Promote mid-to-long term stable supply measures to increase production of <i>DS-8201</i></li><li>Establish a manufacturing and supply system for <i>Axi-Cel</i><sup>®</sup> and <i>DS-1647</i> (G47Δ)</li></ul>
Promote cost reduction activities and attain results globally	<b>Reinforcing continuous profit generation by cost reductions</b> <ul style="list-style-type: none"><li>Achieved manufacturing cost reduction as planned by cost reduction approaches from various viewpoints including procurement and manufacturing process</li></ul>	<b>Contribute to the group profits by promoting cost reduction measures</b> <ul style="list-style-type: none"><li>Promote cost reduction of <i>edoxaban</i> drug substance by adding new supply sources</li><li>Optimize capital investments, Reduce procurement costs for facility.</li></ul>

Medical Affairs Unit



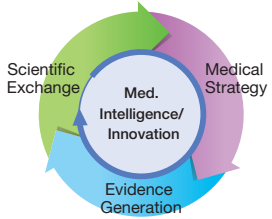
The Medical Affairs (MA) Unit will accelerate activity which has been working since fiscal 2018 to further prepare the MA system for the launch of new oncology products. In particular, for *DS-8201*, we will establish a collaborative relationship with its strategic partners, AstraZeneca, to ensure that high-quality evidence is delivered to healthcare professionals and patients as soon as possible. In Japan, new products other than oncology have been launched, and we aim to build evidence to answer clinical questions in the medical community. In addition, we are enriching product information functions and enhancing the quality of the response to our client.

Yoshikazu Fukuchi Head of Medical Affairs Unit

Initiatives for the dissemination of latest information to healthcare professionals and patients in the oncology field

Novel cancer drugs provide new benefits to patients who failed conventional therapies, but they also could carry a variety of side effect risk. We will provide benefits to patients by finding new knowledge on efficacy and safety from various clinical studies and disseminating them to healthcare professionals and patients as soon as possible. To this end, we will strengthen our MSL\* functions and also strengthen and maximize oncology and pipeline knowledge of our call-centers.

\* Position responsible for collecting clinical evidence and identifying and answering clinical questions by engaging in medical and scientific discussions with healthcare professionals and researchers and by promoting clinical research and academic activities



Progress of Medical Affairs (MA) Unit's 5-year business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Generate and disseminate scientific evidence on <i>edoxaban</i>	<b>Generate scientific evidence on edoxaban</b> <ul style="list-style-type: none"><li>Presented ELIMINATE trial * results at scientific conferences</li><li>Presented patient background data from a large-scale registry study in Japan at scientific conferences</li></ul> <p>* Study in patients with atrial fibrillation who underwent catheter ablation</p>	<b>Accelerate dissemination of edoxaban evidence</b> <ul style="list-style-type: none"><li>Disseminate information from multiple Japanese and foreign clinical studies through presentations at scientific conferences and publications</li><li>Promote research toward the end of various clinical research</li></ul>
Generate and disseminate scientific evidence in the oncology field	<b>Established launch readiness for oncology products</b> <ul style="list-style-type: none"><li>Established a medical plan* to prepare for the launch of <i>quizartinib</i> and <i>DS-8201</i></li><li>Deployed oncology MSL in Japan</li></ul> <p>* Evidence generation and dissemination plan to contribute to medical practice</p>	<b>Generate and disseminate scientific evidence in the oncology field</b> <ul style="list-style-type: none"><li>Establish a new Oncology Medical Science Department</li><li>Implement a medical plan for <i>quizartinib</i> and create evidence through an investigator-initiated study of <i>DS-8201</i></li></ul>
Generate and disseminate scientific evidence on other priority products	<b>MA activities for esaxerenone and mirogabalin</b> <ul style="list-style-type: none"><li>Developed activity plan for creation and dissemination of evidence for new products</li><li>Data lock for <i>prasugrel</i> PENDULUM study*</li></ul> <p>* Investigation of thrombotic events, bleeding events, and platelet aggregation inhibition by antiplatelet therapy in patients undergoing PCI</p>	<b>Generate and disseminate evidence on other priority products</b> <ul style="list-style-type: none"><li>Start clinical research studies of <i>esaxerenone</i> and <i>mirogabalin</i></li><li>Present at a conference and publish paper on the results of a PENDULUM study</li><li>Information gathering through advisory meetings</li></ul>
Sophisticate MA operation in response to environmental changes	<b>Reinforce infrastructures for the global MA operation</b> <ul style="list-style-type: none"><li>Realized stable operation of the global MA (GMA) activities</li><li>Developed GMA future plans and started initiatives to achieve MA Unit 2025 Vision</li></ul>	<b>Reinforce the Global MA activities in the oncology field</b> <ul style="list-style-type: none"><li>Further strengthen GMA functions, mainly in the oncology field</li><li>Sophisticate information generation and dissemination activities through deepening collaboration with relevant departments, such as R&amp;D and market access</li></ul>
Improve customer satisfaction, enhance medical information, and entrench practice of utilizing Voice of Customer (VOC)	<b>Ranked No.1 for 4 consecutive years</b> <ul style="list-style-type: none"><li>Our call center was ranked No.1 among pharmacists in health insurance pharmacies for 4 consecutive years based on a survey conducted by outside research company on DI centers</li><li>Started inquiry response operations activities using AI for the first time in industry</li><li>Established a dedicated line for inquiries about oncology field</li></ul>	<b>Create more sophisticated medical information's functions</b> <ul style="list-style-type: none"><li>Aim to continue to be ranked No.1 among pharmacists in health insurance pharmacies for 5 consecutive years and also aim to be ranked No.1 among pharmacist in hospitals</li><li>Comply with Guidelines for Sales Information Provision Activities</li><li>Propose clinical questions by gathering, analyzing, and evaluating the voice of customers</li></ul>



Quality & Safety Management Unit



The Quality & Safety Management Unit is responsible for quality assurance and safety management of pharmaceuticals throughout the life cycle using global standards. We will establish a safety management system to ensure the reliability of not only small molecule pharmaceuticals but also antibodies and new modality products, as well as a safety management system that can respond to the shift toward the cancer area. In addition, by ensuring to monitor adverse reactions and disseminate various information on proper use and safety management that enable to contribute to patient's safety and security, we will be able to treat patients with high risk of side effects, and aim to suppress adverse reactions and diseases to become severe.

Miyuki Arai Head of the Quality & Safety Management Unit

Aiming to promote further diversity

In fiscal 2019, the percentage of women in The Quality & Safety division's 305 employees is 42% and the percentage of women in management positions is 28%. Many employees have returned to work after maternity leave. We have a team system that allows us to follow each other, so we are able to flexibly utilizes flex-time, home-based work, and short working hour system to make balance of both work and private including childcare and nursing care. We also provide career change opportunities for senior employees to work that leverages their past experiences. We aim to promote further diversity in the future in order to foster a corporate culture in which everyone can work lively and be active in a variety of ways.



Progress of the Quality & Safety Management Unit's 5-Year Business Plan

Target	Major Achievements in Fiscal 2018	Initiatives for Fiscal 2019
Continue the post-marketing surveillance on <i>LIXIANA</i> and <i>Effient</i> to create additional evidence	<b>Prosecuted post-marketing surveillance on mainstay products and created additional evidence</b> <ul style="list-style-type: none"><li>Published <i>LIXIANA</i>'s latest evidence and shared with healthcare professionals</li><li>Presented data on <i>Effient</i>'s large-scale real-world data on dosages suitable for the Japanese at the late breaking session of the Japanese Circulation Society for two consecutive years</li></ul>	<b>Promote post-marketing surveillance on mainstay products and create additional evidence</b> <ul style="list-style-type: none"><li>Continue to prosecute large-scale studies on <i>LIXIANA</i> and <i>Effient</i> and present efficacy and safety information at major academic conferences, etc.</li><li>Start specific use results survey for new products such as <i>Tarlige</i> and <i>Minnebro</i> and plan database survey</li></ul>
Introduce quality risk analysis and evaluation systems for new fields and new technologies	<b>Established a quality assurance system for products in new areas</b> <ul style="list-style-type: none"><li>Ensured the reliability of manufacturing sites for <i>DS-8201</i> and prepared for regulatory inspections</li><li>Supported problem solution at the contract manufactures for NDA of <i>DS-1647 (G47Δ)</i></li><li>Established a quality-assurance system for commercialization of <i>Axi-Cel® (CAR-T)</i> and clarified challenges and risks</li></ul>	<b>Establish a quality assurance system for products in new areas</b> <ul style="list-style-type: none"><li>Promote reliability assurance of <i>DS-8201</i> BLA/ NDA data and response to regulatory inspections, and establish a manufacturing site control system including CMO*</li><li>Complete NDA of <i>DS-1647 (G47Δ)</i> and <i>Axi-Cel® (CAR-T)</i> as planned and respond to regulatory review</li></ul> <p>* CMO: Contract Manufacturing Organization</p>
Strengthen safety monitoring measures and verify the effectiveness of safety measures	<b>Reinforced safety measures for new and mainstay products</b> <ul style="list-style-type: none"><li>Practiced integrated risk management and thorough safety measures in the global clinical trial of <i>DS-8201</i></li><li>Built a framework that facilitates prompt communication with healthcare professionals on the safety information of oncology products</li><li>Improved productivity by automating routine tasks with RPA* implementation</li></ul> <p>*Robotics Process Automation</p>	<b>Reinforce safety measures for new and mainstay products</b> <ul style="list-style-type: none"><li>Continue <i>DS-8201</i> clinical trial safety measures, prepare package inserts and RMP* for approval, and establish a system to collect and provide information after launch</li><li>Contribute to the safety and security of patients by promoting a framework that facilitates prompt communication with healthcare professionals on the safety information of oncology products</li></ul> <p>* RMP: Risk Management Plan</p>

Business Activities

Initiatives Aimed at Realizing a Sustainable Society

The Daiichi Sankyo Group is working to address many issues related to sustainability as part of our medium-to-long-term initiatives and challenges. We fulfill our corporate social responsibility (CSR) by addressing to resolve social challenges through business activities and enacting improvements for corporate value based on the DAIICHI SANKYO Group Corporate Conduct Charter, which is the basis of its business activities. The following introduce the Group's initiatives aimed at realizing a sustainable society.

For details, refer to page 21.

Daiichi Sankyo Group's Initiatives for SDGs

The Daiichi Sankyo Group is working to address business and sustainability issues based on the DAIICHI SANKYO Group Corporate Conduct Charter.

In light of the Sustainable Development Goals (SDGs) and other international frameworks, the Group has made revisions to the DAIICHI SANKYO Group Corporate Conduct Charter in April 2019 and has declared that it will contribute to the realization of a sustainable society.

With a philosophy of "Leave no one behind," 17 Goals and 169 Targets to be accomplished by 2030 were established as SDGs to resolve global social issues for realizing a sustainable, diverse and inclusive society. This idea is in line with the philosophy of the Group, "to contribute to the enrichment of quality of life around the world."

For "Goal 3: Ensure healthy lives and promote well-being for all at all ages" the Group is especially working to resolve unmet medical needs, such as cancer and other non-communicable diseases, rare diseases, malaria, tuberculosis, and neglected tropical diseases through innovation (Goal 9). To address climate change (Goal 13), the Group is

working to reduce the environmental impact and risks in all its business activities and to effectively use resources. As for partnership (Goal 17), the Group is working together with various partners in the fields of industry, academia and government for the above initiatives.

[https://www.daiichisankyo.com/about\\_us/responsibility/csr/sdgs/index.html#gc\\_list](https://www.daiichisankyo.com/about_us/responsibility/csr/sdgs/index.html#gc_list)

\* The SDGs are a set of goals for 2030 to address the key issues facing the world, and have been adopted by the member states of the United Nations. Seventeen goals to be accomplished by 2030 have 169 targets.

SUSTAINABLE DEVELOPMENT GOALS



3 Ensure healthy lives and promote well-being for all at all ages

The Group will contribute to ensuring healthy lives and promoting well-being for all by working to resolve unmet medical needs, such as cancer and other non-communicable diseases, rare diseases, malaria, tuberculosis, and neglected tropical diseases.

Innovation

The Group will promote human resource development and an organization that creates innovation, thereby contributing to fulfilling its mission through creating innovative pharmaceuticals.

Climate Change

The Group promotes the realization of a sustainable society through working to reduce environmental impact and risks in all its business activities and to effectively use resources.

Partnership

The Group addresses issues in research and development of medicines and access barriers to essential healthcare through diverse partnerships with industry, academia, government, and others.

Initiatives Aimed at Realizing a Sustainable Society

Initiatives for Sustainability Issues

The Daiichi Sankyo Group is working to address many CSR issues related to sustainability. So far, we have identified CSR issues based on international frameworks such as the Ten Principles of the United Nations Global Compact (UNGC) and the TCFD\* and rankings by Access to Medicine Index, which evaluate practices and contributions to improving availability of pharmaceuticals in developing countries. We further categorizes these issues into six priority areas for activities (promoting compliance management, mutual growth of employees and the Company, enhancing communication with stakeholders, promoting environmental management, improving access to healthcare, and social contribution activities).

In addition, among these six activity areas, we have set “promoting environmental management”, “promoting compliance management”, and “improving access to healthcare” as the medium-to-long-term initiatives in order to realize a sustainable society and to improve the corporate values in the medium-to-long-term.

For details, refer to page 21.




\* 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.

Organizing Sustainability Issues

For our initiatives for Sustainability issues, we need to periodically conduct self-assessments and revise them according to the progress in resolving issues and changing requirements from stakeholders and society. In fiscal 2018, the third year of our 5-year business plan, we organized CSR issues for the purpose of appropriately responding to requirements and expectations found from assessment results by ESG rating agencies and through stakeholder communication. As a result of these efforts we established new issues to be addressed, consolidated issues, and lowered the priorities of issues that we determined have sufficiently been addressed. The result of this activity was discussed during a meeting of the Global Management Committee (GMC) in December 2018 and the issues were organized into 21 issues as shown in the table below.

Please refer to the Daiichi Sankyo website for the organized 21 CSR issues (list).  
[https://www.daiichisankyo.com/about\\_us/responsibility/csr/management/csr\\_manage/index.html](https://www.daiichisankyo.com/about_us/responsibility/csr/management/csr_manage/index.html)

Initiatives for CSR issues organized into six priority areas for activities

Priority areas for activities	Issues (21 items)	Examples of initiatives
<b>Promoting Compliance Management</b>   	<b>Observe group-wide codes of conduct and thorough prevention of corruption</b>	<ul style="list-style-type: none"><li>Continued operation of the compliance system</li><li>Implementation of a Compliance Awareness Survey</li><li>Spread of a Global Marketing Code of Conduct</li><li>Dissemination of the ICP</li><li>Compliance training and educational activities</li><li>Response to thorough information (cyber) security</li><li>Spread of Global Policies Related to Preventing Bribery and Corruption</li></ul>
	<b>Consideration for R&amp;D ethics, bioethics, and genetic resources</b>	<ul style="list-style-type: none"><li>GCP and other development-related training</li><li>Thorough R&amp;D ethics</li><li>Fair utilization of genetic resources</li></ul>
	<b>Maintaining reliability for ensuring product quality and safety</b>	<ul style="list-style-type: none"><li>Safety-related training (GVP training)</li><li>Quality audit of raw material and other suppliers</li><li>Product recall information</li></ul>
	<b>Ethical marketing practices</b>	<ul style="list-style-type: none"><li>Compliance with the Guidelines on Providing Sales Information</li><li>Strengthening the review system for sales promotion materials</li><li>Proper advertisement</li><li>MR accreditation test results</li></ul>
	<b>Sustainable procurement</b>	<ul style="list-style-type: none"><li>Thorough compliance in procurement</li><li>Implementation of self-CSR examinations</li><li>Codes of conduct of business partners</li></ul>
	<b>Report on breach of laws and legal cases</b>	<ul style="list-style-type: none"><li>Disclosure of business and other risks</li></ul>
	<b>Respect for rights of all people involved in business activities</b>	<ul style="list-style-type: none"><li>Initiatives for promoting respect for human rights</li><li>Training related to the UNGC</li></ul>

Priority areas for activities	Issues (21 items)	Examples of initiatives
<b>Mutual Growth of Employees and the Company</b>   	<b>Develop human resources / Acquire and retain talented individuals</b>	<ul style="list-style-type: none"><li>Group talent management</li><li>Create Our Future (COF) project</li><li>Recruitment activities</li><li>Development of entry- and mid-level employees</li><li>Cultivation of line managers (organization heads)</li><li>Daiichi Sankyo Human Resources Management Philosophy</li></ul>
	<b>Diversity &amp; Inclusion</b>	<ul style="list-style-type: none"><li>Acquisition of the Highest Level of Eruboshi Certification based on the Act on Promotion of Women's Participation and Advancement in the Workplace</li><li>Development of environment for balancing life events and work</li><li>Support for The Women's Empowerment Principles (WEPs)</li><li>Participation in IkuBoss Alliance</li><li>Support for the Career Development and Work Styles of Diverse Employees</li><li>Support for the career development of employees in Japan</li><li>Initiatives Based on Action Plan for Empowering Women</li><li>Acquisition of the Kurumin certification</li><li>Promotion of the employment of individuals with disabilities</li><li>Systems and measures to support diverse work styles (Japan)</li></ul>
	<b>Policy of equal pay for equal jobs</b>	<ul style="list-style-type: none"><li>Training related to the UNGC</li></ul>
	<b>Work-life cycle</b>	<ul style="list-style-type: none"><li>Promotion of the "Work-Life Cycle" (Japan)</li></ul>
	<b>Prevent occupational accidents</b>	<ul style="list-style-type: none"><li>Promotion of occupational health and safety</li><li>Systems and initiatives for supporting occupational health and safety (Japan)</li><li>2018 Certified Health and Productivity Management Organization Recognition Program (Large Enterprise Category)—White 500</li></ul>
<b>Enhancement of Communication with Stakeholders</b>  	<b>Stakeholder engagement</b>	<ul style="list-style-type: none"><li>Stakeholder dialog</li><li>Communication with healthcare professionals and patients</li><li>Communication with shareholders and investors</li><li>Communication with employees</li><li>Communication with local communities</li><li>Communication with ESG rating agencies</li><li>Communication with labor unions</li></ul>
	<b>Reliable external reports</b>	<ul style="list-style-type: none"><li>External verification of environmental reports</li></ul>
<b>Promoting Environmental Management</b>    	<b>Response to climate change and consideration for biodiversity</b>	<ul style="list-style-type: none"><li>Endorsement of the TCFD</li><li>Initiatives toward energy conservation and prevention of global warming</li><li>CO<sub>2</sub> emissions reduction targets and performance</li><li>CO<sub>2</sub> emissions reduction initiatives</li><li>Biodiversity initiatives</li></ul>
	<b>Response to environmental risks and hazardous substance management</b>	<ul style="list-style-type: none"><li>Usage reduction and emission and transfer control of chemical substances</li></ul>
	<b>Waste and water resource management aimed at recycling-oriented economy</b>	<ul style="list-style-type: none"><li>Response to water risk</li><li>Appropriate use of water resources</li><li>Environmental audit</li><li>Waste reduction targets and performance</li><li>Promotion of compliance for waste management</li></ul>
<b>Improving Access to Healthcare</b>   	<b>Address global health issues</b>	<ul style="list-style-type: none"><li>Participation in the Access Accelerated</li><li>Participation in the GHIT Fund</li><li>Initiatives targeting rare diseases</li><li>Mobile Healthcare Field Clinic Services in Tanzania</li><li>Cultivation of healthcare workers in China</li><li>Technical cooperation related to manufacturing the combined measles-rubella vaccine (MR vaccine) in Vietnam</li><li>Clinical trials to be conducted from a humanitarian viewpoint</li><li>Participation in the Manufacturing Technology Association of Biologics</li><li>OiDE project</li></ul>
	<b>Measures to combat counterfeit medicines</b>	<ul style="list-style-type: none"><li>Measures to combat counterfeit medicines</li></ul>
	<b>Supply of affordable pharmaceutical products</b>	<ul style="list-style-type: none"><li>Realization of pricing measures that take the situation of each country and region into consideration</li><li>Patient Assistance Programs (United States)</li></ul>
<b>Social Contribution Activities</b>  	<b>Social contribution activities appropriate for the Daiichi Sankyo Group</b>	<ul style="list-style-type: none"><li>Support for cancer patients and their families</li><li>Reconstruction support following the Great East Japan Earthquake</li><li>Support for mobile healthcare clinics (United States)</li><li>Awareness raising activities on heart disease and strokes (Spain)</li><li>Activities that promote good health in senior citizens (Taiwan)</li><li>Advancement of medicine and pharmacology (scholarships, etc.)</li><li>Social welfare (Table for Two, etc.)</li><li>Environmental preservation activities (cleanup activities around operating sites, etc.)</li><li>Youth development (science and pharmacology seminars for high school students, etc.)</li></ul>



Initiatives Aimed at Realizing a Sustainable Society

CSR Management

The Daiichi Sankyo Group is working on CSR issues through its business under the global management structure. By establishing and continuing to promote a CSR management cycle which includes extracting and reviewing issues to be addressed based on requirements and expectations from society, addressing issues in cooperating with related divisions, and conducting self-assessment through stakeholder communication, we will improve corporate value in the long term.

Extracting CSR issues

Issues are extracted based on expectations and needs identified through stakeholder communications or investigations done by ESG rating agencies and various CSR initiatives, and these are shared with related divisions and group companies.

Stakeholder communication

We conduct self-assessment based on stakeholder communication such as investigations by ESG rating agencies and disclosure of responses regarding issues.

The progress on addressing issues is reported during a meeting of the Global Management Committee (GMC) and other meetings along with evaluation from stakeholders, etc. By continuing to conduct these activities and thereby improving external CSR/ESG evaluations and increasing awareness of employees, we improve long term cooperate value as a result.

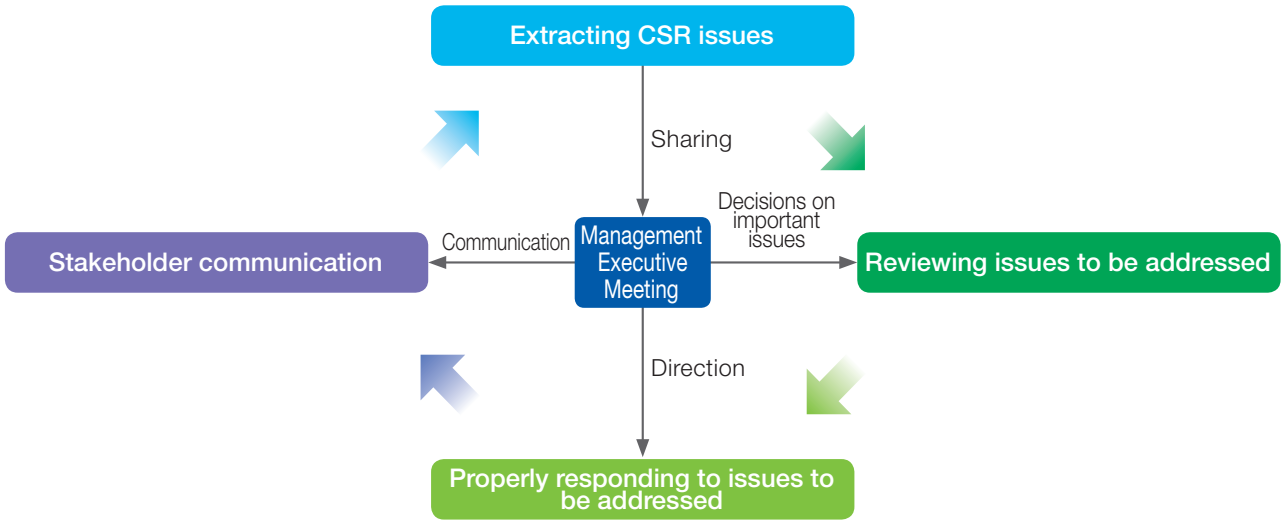
Reviewing issues to be addressed

Issues that need attention are reviewed based on business strategies and requests from stakeholders, etc.

Properly responding to issues to be addressed

Addressing issues is promoted in cooperation with related sections.


The CSR management cycle



Inclusion in ESG Indices in Reflection of External CSR and ESG Evaluations

To address sustainability issues, we pursue ongoing improvements to our corporate values. These efforts have been highly appreciated, resulting in the Group being selected for the following ESG indices as of June 2019.


Selected for the “World Index” in the pharmaceutical sector for two consecutive years



The DJSI is jointly managed by S&P Dow Jones Indices LLC of the United States and RobecoSAM AG of Switzerland. This ESG index evaluates the sustainability of a company and provides important criterion for investors to select investment targets. The Company has been included in the DJSI World Index for two consecutive years since last year and the DJSI Asia/Pacific for nine consecutive years. The Group was selected for the DJSI World Index as the first Japanese corporation in the pharmaceutical sector last year as is being selected as the only Japanese company among the seven companies selected for the pharmaceutical sector.


Environmental aspects	• Environmental efficiency in operation
Social aspects	• Corporate citizenship and social contribution • Occupational health and safety

Selected consecutively for eleven years/three years



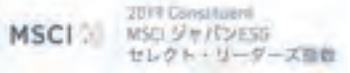
The FTSE4Good Index Series and the FTSE Blossom Japan Index are indices that reflect the performance of corporations that excel in environmental, society, and governance (ESG) factors, established by FTSE Russell, a global index provider and wholly-owned subsidiary of the London Stock Exchange. The Company has been selected for eleven consecutive years as a component of the FTSE4Good Global Index from 2009 and for three consecutive years as a component of the FTSE Blossom Japan Index from 2017. This index is one of four indices selected by the Government Pension Investment Fund (GPIF) as an ESG Index in Japanese stocks.

Selected consecutively for two years




The MSCI Japan Empowering Women (WIN) Select Index is an index of MSCI in the U.S. that assesses gender diversity in corporations such as the percentage of females among new recruits, employees, average work years and the percentage of female executives, and comprises corporations that excel in these factors. The Company has been included in this index for two consecutive years from 2018. This index is one of four indices selected by the Government Pension Investment Fund (GPIF) as an ESG Index in Japanese stock.

Selected for the first time



The MSCI Japan ESG Select Leaders Index is an index of MSCI in the U.S. that comprises corporations among corporations included in the MSCI Japan IMI Top 700 Index that are highly assessed in ESG (environment, society, and governance) evaluations. In June 2019, the Company was included in this index for the first time. This index is one of four indices selected by the Government Pension Investment Fund (GPIF) as an ESG Index in Japanese stock.

Selected consecutively for four years



The SNAM Sustainability Index is an SRI fund managed by Sompo Japan Nipponkoa Asset Management Co., Ltd., aimed at pension funds and institutional investors that invest in a wide range of companies highly rated in terms of ESG factors (environment, society, governance). The Company has been included in this index for four consecutive years.

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(As of June 2019)

10-Year Financial Summary

Japanese GAAP				
	FY2009	FY2010	FY2011	FY2012
Financial Results				
Net sales	952.1	967.3	938.6	997.8
Overseas sales	482.3	489.7	469.0	486.6
Ratio of overseas sales to net sales (%)	50.7	50.6	50.0	48.8
Operating income	95.5	122.1	98.2	100.5
Ratio of operating income to net sales (%)	10.0	12.6	10.5	10.1
Net income (loss)	41.8	70.1	10.3	66.6
Research and development expenses	196.8	194.3	185.0	183.0
Ratio of research and development expenses to net sales (%)	20.7	20.1	19.7	18.3
Depreciation and amortization	45.9	43.9	46.3	41.4
Capital expenditure	29.7	37.3	62.9	65.1
Financial Position				
Total assets	1,489.5	1,480.2	1,518.4	1,644.0
Net assets	889.5	887.7	832.7	915.7
Cash Flows				
Net increase (decrease) in cash and cash equivalents	81.4	43.2	(89.7)	(21.8)
Free cash flows*	172.8	78.1	(32.5)	19.9
Per Share Information				
Basic net income (loss) per share (yen)	59.45	99.62	14.75	94.64
Net assets per share (yen)	1,215.62	1,206.12	1,143.52	1,253.86
Annual dividends per share (yen)	60	60	60	60
Main Financial Indicators				
Return on equity (ROE) (%)	4.9	8.2	1.3	7.9
Equity ratio (%)	57.4	57.4	53.0	53.7
Dividend on equity (DOE) (%)	4.9	5.0	5.1	5.0
Price-earnings ratio (PER)	29.5	16.1	102.2	19.2
Stock price at the end of the year	1,751	1,606	1,508	1,815
Market capitalization	12,326	11,304	10,692	12,777
Average exchange rates (USD/JPY)	92.86	85.72	79.07	83.11
(EUR/JPY)	131.16	113.13	108.96	107.15
Number of Employees				
Japan	29,825	30,488	31,929	32,229
North America	8,892	9,002	9,308	9,251
Europe	3,580	3,410	3,737	3,331
Others	2,516	2,576	2,624	2,556
	14,837	15,500	16,260	17,091

\* Cash flows from operating activities + Cash flows from investing activities

(Billions of yen)							
IFRS							
	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
Financial Results							
Revenue	994.7	1,118.2	919.4	986.4	955.1	960.2	929.7
Overseas revenue	483.2	584.5	392.4	430.7	375.2	341.9	333.8
Ratio of overseas revenue to revenue (%)	48.6	52.3	42.7	43.7	39.3	35.6	35.9
Operating profit	98.7	111.6	74.4	130.4	88.9	76.3	83.7
Ratio of operating profit to revenue (%)	9.9	10.0	8.1	13.2	9.3	7.9	9.0
Profit attributable to owners of the Company	64.0	60.9	322.1	82.3	53.5	60.3	93.4
Research and development expenses	184.4	191.2	190.7	208.7	214.3	236.0	203.7
Ratio of research and development expenses to revenue (%)	18.5	17.1	20.7	21.2	22.4	24.6	21.9
Depreciation and amortization	45.3	51.5	42.0	44.3	47.4	46.7	46.2
Capital expenditure	65.1	49.2	36.3	23.3	23.9	26.9	38.3
Financial Position							
Total assets	1,684.9	1,854.0	1,982.3	1,900.5	1,915.0	1,897.8	2,088.1
Total equity	938.5	1,007.5	1,307.0	1,233.5	1,171.4	1,133.0	1,249.7
Cash Flows							
Net increase (decrease) in cash and cash equivalents	(37.8)	(23.7)	(10.7)	45.4	24.4	115.2	(116.7)
Free cash flows	20.4	(124.1)	121.5	168.3	39.4	217.0	(50.5)
Per Share Information							
Basic earnings per share (yen)	90.96	86.57	457.56	119.37	79.63	91.31	144.20
Equity per share attributable to owners of the Company (yen)	1,287.94	1,392.03	1,852.28	1,801.90	1,772.99	1,749.33	1,928.80
Annual dividends per share (yen)	60	60	60	70	70	70	70
Main Financial Indicators							
Return on equity attributable to owners of the Company (ROE) (%)	7.4	6.5	28.2	6.5	4.4	5.2	7.8
Ratio of equity attributable to owners of the Company to total assets (%)	53.8	52.9	65.8	64.8	61.4	59.7	59.8
Ratio of dividends to equity attributable to owners of the Company (%) (DOE) (%)	4.9	4.5	3.7	3.8	3.9	4.0	3.8
Price-earnings ratio (PER)	20.0	20.1	4.2	21.0	31.5	38.6	35.4
Stock price at the end of the year	1,815	1,738	1,907	2,502	2,507	3,526	5,100
Market capitalization	12,777	12,235	13,426	17,102	16,627	22,837	33,042
Average exchange rates (USD/JPY)	83.11	100.24	109.94	120.14	108.42	110.86	110.91
(EUR/JPY)	107.15	134.38	138.78	132.57	118.84	129.70	128.40
Number of Employees							
Japan	32,229	32,791	16,428	15,249	14,670	14,446	14,887
North America	9,251	9,145	8,543	8,589	8,648	8,765	8,865
Europe	3,331	3,402	3,322	2,321	2,464	2,191	2,172
Others	2,556	2,226	2,094	1,997	1,578	1,582	1,778
	17,091	18,018	2,469	2,342	1,980	1,908	2,072

Note: Results for FY2012 in compliance with IFRS are shown for comparison purposes.



# Financial Results and Financial Analysis

## Consolidated Financial Results for Fiscal 2018

Consolidated Financial Results				
	FY2017 Results	FY2018 Results	YoY	
Revenue	960.2	929.7	-30.5	(-3.2%)
Cost of sales	346.0	364.6	+18.6	
SG&A expenses	301.8	277.7	-24.2	
R&D expenses	236.0	203.7	-32.3	
Operating profit	76.3	83.7	+7.4	(+9.7%)
Profit before tax	81.0	85.8	+4.8	(+5.9%)
Profit attributable to owners of the Company	60.3	93.4	+33.1	(+55.0%)

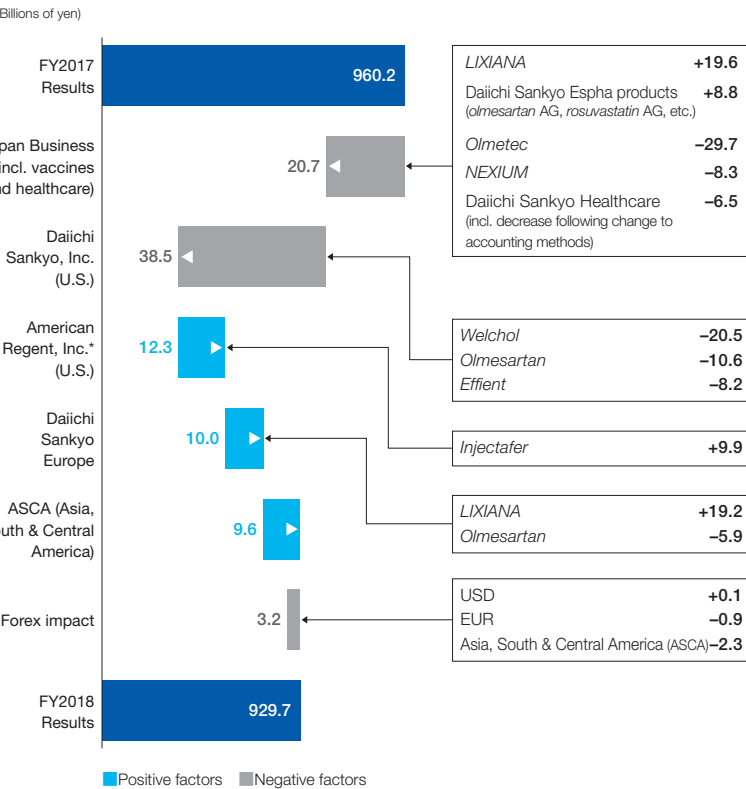
Yen Exchange Rates for Major Currencies (Annual Average Rate)			
	FY2017 Results	FY2018 Results	YoY
USD/JPY	110.86	110.91	+0.05
EUR/JPY	129.70	128.40	-1.30

### 1. Revenue

Consolidated revenue in fiscal 2018 decreased by ¥30.5 billion, or 3.2% year on year, to ¥929.7 billion. The impacts of yen appreciation placed downward pressure on revenue to the extent of ¥3.2 billion. When the impacts of foreign exchange influences are excluded, revenue was down ¥27.3 billion year on year.

#### Revenue

**Decreased by ¥30.5 billion** (Decreased by ¥27.3 billion excl. forex impact)



\* Formerly Luitpold Pharmaceuticals, Inc.

In the Japan Business, *LIXIANA* and Daiichi Sankyo Espha products enjoyed an increase in revenue, but *Olmetec* experienced a significant decrease in revenue owing to the impact of the increased number of generic drugs. In addition, *NEXIUM* experienced a decrease in revenue due to the impact of price revisions, and Daiichi Sankyo Healthcare saw a reduction in revenue following a change to our accounting methods. These factors among others resulted in an overall decrease of ¥20.7 billion.

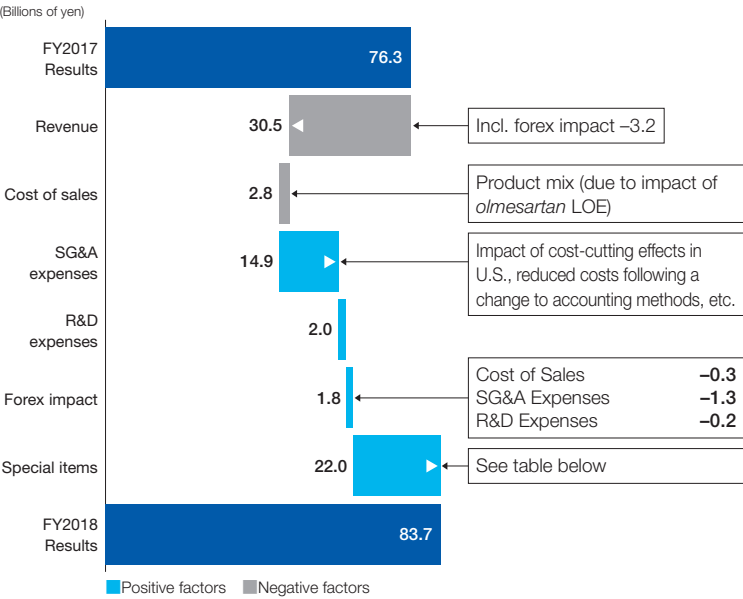
In the United States, revenue from Daiichi Sankyo, Inc. declined ¥38.5 billion year on year following a decrease in revenue from *Welchol*, *olmesartan*, and *Effient* among other factors. Meanwhile, American Regent, Inc. saw a revenue increase of ¥12.3 billion year on year following higher sales of *Injectafer*. Revenue at Daiichi Sankyo Europe GmbH increased ¥10.0 billion year on year due to a large increase in *LIXIANA* sales, despite decreases in sales from *olmesartan*. In the Company's operations in ASCA, Asia and South & Central America, revenue was up ¥9.6 billion year on year, with results chiefly seen in China and Korea.

### 2. Operating Profit

Operating profit in fiscal 2018 increased ¥7.4 billion, or 9.7% year on year, to ¥83.7 billion. When the impacts of foreign exchange influences and special items are excluded, the actual decrease in operating profit was ¥13.2 billion.

#### Operating profit

**Increased by ¥7.4 billion**  
(Decreased by ¥13.2 billion excl. forex impact and special items)



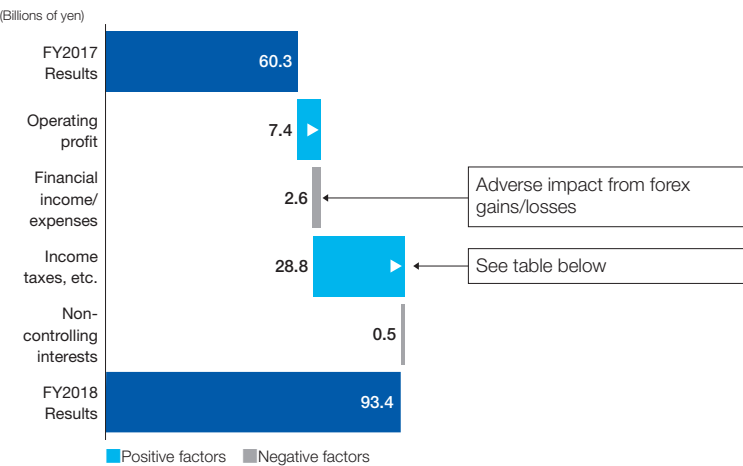
Special items					(Billions of yen)
FY2017 Results			FY2018 Results	YoY	
Cost of sales	Gain on Sales of fixed assets	-1.0	Impairment loss (intangible assets)**	15.1	+16.1
SG&A expenses	Restructuring costs in the U.S.	4.5	Gain on Sales of fixed assets	-3.5	-7.9
R&D expenses	Impairment loss (intangible assets)*	30.2			-30.2
Total		33.6		11.6	-22.0
* CL-108, etc.			** Zelnoraf and MOVANTIK		

### 3. Profit Attributable to Owners of the Company

Profit attributable to owners of the Company increased ¥33.1 billion, or 55.0% year on year, to ¥93.4 billion.

#### Profit attributable to owners of the Company

**Increased by ¥33.1 billion**



Income taxes, etc.			
	FY2017 Results	FY2018 Results	YoY
Profit before tax	81.0	85.8	+4.8
Income taxes, etc.	21.2	-7.6	-28.8
Tax rate	26.2%	-8.8%	-35.0%

Consolidated revenue in fiscal 2018 decreased ¥30.5 billion, including impact from foreign exchange to the extent of ¥3.2 billion.

Cost of sales was up ¥2.8 billion year on year as the ratio of cost of sales to revenue increased due to the impact of LOE of *olmesartan*.

SG&A expenses decreased ¥14.9 billion year on year, owing to effects from cost reductions in the U.S. as well as decreased costs following a change to accounting methods at Daiichi Sankyo Healthcare. R&D expenses dropped ¥2.0 billion year on year.

Foreign exchange influences caused a total decrease of ¥1.8 billion in expenses.

Special items in fiscal 2017 included impairment loss in intangible assets related to *CL-108*, and restructuring expenses in the U.S. Business, causing a total increase of ¥33.6 billion in expenses. Special items in fiscal 2018 included impairment loss in intangible assets related to *Zelnoraf* and *MOVANTIK*, resulting in a total increase of ¥11.6 billion in expenses, and a decrease of ¥22.0 billion in expenses year on year.

Operating profit increased ¥7.4 billion year on year including foreign exchange influences and special items.

Financial income and expenses increased ¥2.6 billion year on year due to the adverse impact from foreign exchange losses following due to the strong yen, among other factors.

Income taxes decreased ¥28.8 billion year on year as a result of the fact that we could include additional deferred tax assets due to a significant increase in the amount of our future taxable income through the strategic collaboration with AstraZeneca for *DS-8201*, among other factors.

Regarding non-controlling interests, we experienced a negative impact to profit, to the amount of ¥0.5 billion.

As a result of the above, the profit attributable to owners of the Company came to ¥93.4 billion.

Financial Results and Financial Analysis

Financial Position

1. Assets, Liabilities, and Equity

Assets

Total assets at the end of fiscal 2018 amounted to ¥2,088.1 billion. Trade and other receivables increased (¥188.1 billion year on year) among other factors, ultimately leading to an increase of ¥190.3 billion compared to the end of fiscal 2017.

Liabilities

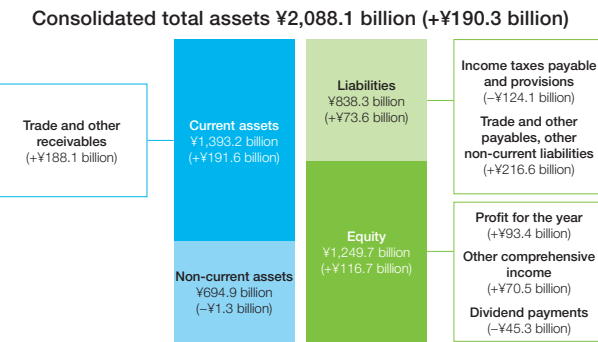
Total liabilities at the end of fiscal 2018 amounted to ¥838.3 billion. Income taxes payable and provisions decreased (¥124.1 billion year on year), while trade and other payables as well as other non-current liabilities increased (¥216.6 billion year on year) among other factors, ultimately leading to an increase of ¥73.6 billion compared to the end of fiscal 2017.

Equity

Total equity at the end of fiscal 2018 amounted to ¥1,249.7 billion. Dividend payments (¥45.3 billion) contributed to a decrease, while profit attributable to owners of the Company (¥93.4 billion) and other comprehensive income (¥70.5 billion) recorded for the year among other factors ultimately led to an increase of ¥116.7 billion compared to the end of fiscal 2017.

Summary of consolidated statement of financial position

As of March 31, 2019: parentheses ( ) indicate comparison to March 31, 2018



Ratio of equity attributable to owners of the Company to total assets (equity ratio) was 59.8% (¥1,249.7 billion ÷ ¥2,088.1 billion), which was an increase of 0.1% compared to the end of fiscal 2017.

3. Capital Expenditure

In fiscal 2018, we focused capital expenditure on production facilities for Daiichi Sankyo Chemical Pharma and Daiichi Sankyo Propharma. Especially, capital expenditure increased for our oncology business with a focus on the ADC franchise, and the total capital expenditure amounted to ¥38.3 billion.

	FY2017 Results	FY2018 Results	YoY
Capital expenditure	26.9	38.3	11.5
Depreciation (Property, plant and equipment)	27.4	26.0	-1.4

2. Cash Flows

Cash and cash equivalents at the end of fiscal 2018 decreased by ¥114.5 billion year on year to ¥243.2 billion.

Cash flows from operating activities

Cash inflows from operating activities were ¥92.0 billion (¥108.4 billion in the previous fiscal year) due to a decrease in cash caused by a profit before tax amounting to ¥85.8 billion, depreciation and amortization amounting to ¥46.2 billion, impairment loss amounting to ¥15.2 billion, and other non-cash items, as well as income tax payments and other factors.

Cash flows from investing activities

Cash outflows due to investing activities were ¥142.5 billion (+¥108.6 billion in the previous fiscal year) due to payments into time deposits, as well as capital expenditure and acquisitions of intangible assets, among other factors.

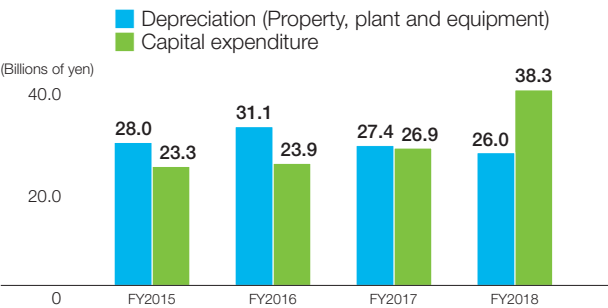
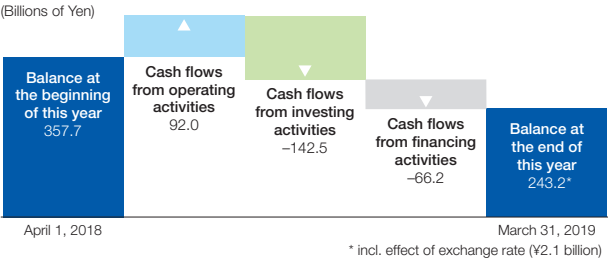
Cash flows from financing activities

Cash outflows due to financing activities were ¥66.2 billion (¥101.8 billion in the previous fiscal year) due to dividend payments, repayments of borrowings, and other factors.

	FY2017 Results	FY2018 Results	YoY
Cash flows from operating activities	108.4	92.0	-16.4
Cash flows from investing activities	108.6	-142.5	-251.1
Cash flows from financing activities	-101.8	-66.2	35.6
Net increase in cash and cash equivalents	115.2	-116.7	-231.9
Effect of exchange rate change on cash and cash equivalents	-3.6	2.1	5.7
Cash and cash equivalents at the end of the year	357.7	243.2	-114.5
Free cash flows*	217.0	-50.5	-267.5

\* Free cash flows = Cash flows from operating activities + Cash flows from investing activities

Summary of consolidated statement of cash flows



Financial Results Forecasts for Fiscal 2019

Sales revenues are projected to increase 1.1% year on year to ¥940.0 billion, due to part of the contractual lump-sum payment from our strategic collaboration for *DS-8201* being incorporated into the recognized sales amount (¥10.0 billion) for year ending March 2020.

Operating profit is projected to increase 19.5% year on year to ¥100.0 billion due to continued cost reductions, as well as recording profit from selling the Takatsuki Plant (¥19.0 billion) and real estate (¥10.6 billion) among other factors, despite the fact that cost increases are expected as a result of investments centered on the oncology business.

Profit attributable to owners of the Company is expected to decrease 22.9% year on year to ¥72.0 billion, due to income taxes going back to the regular tax rate in the year ending March 2020 despite temporarily being set at a negative rate in the previous year following our strategic collaboration for *DS-8201* among other factors.

The impact following our strategic collaboration for *DS-8201* only includes the amount recognized for this fiscal year in terms of the contractual lump-sum payment attributed to deferred revenue.

Forecasts are based on an assumption of foreign exchange rates at ¥110 to the U.S. dollar and ¥130 to the euro.

Consolidated financial results forecast for fiscal 2019

	FY2018 Results	FY2019 Results	YoY
Revenue	929.7	940.0	+10.3 (+1.1%)
Operating profit	83.7	100.0	+16.3 (+19.5%)
Profit before tax	85.8	100.0	+14.2
Profit attributable to owners of the Company	93.4	72.0	-21.4 (-22.9%)

Yen exchange rates for major currencies (Annual average rate)

	FY2018 Results	FY2019 Results
USD/JPY	110.91	110.00
EUR/JPY	128.40	130.00

Shareholder Returns

In order to achieve sustainable growth in corporate value, the basic policy of management is to decide profit distributions based on a comprehensive evaluation of the investments essential for implementing the growth strategy and profit returns to shareholders.

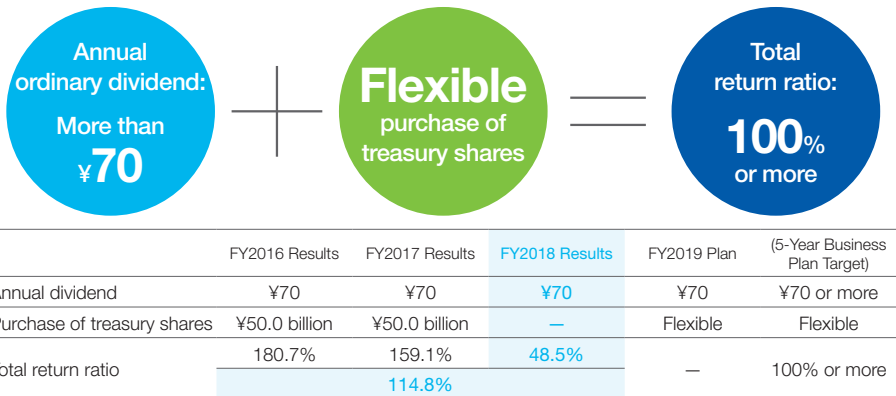
Our shareholder return policy calls for a total return ratio\* of 100% or more for the fiscal 2016 through fiscal 2022, and annual ordinary dividend payments of ¥70 per share or more. On the basis of this policy, Daiichi Sankyo intends to pay stable dividends while flexibly acquiring shares of its own stock.

Under this basic policy, Daiichi Sankyo achieved ordinary dividend payments of ¥70 per share in fiscal 2018. As a result, the total return ratio was 48.5% for one year and 114.8% cumulatively over three years.

The Company plans to issue annual dividends per share of ¥70 in fiscal 2019.

\* Total return ratio = (Total dividends + Total acquisition costs of own shares) / Profit attributable to owners of the Company

Shareholder returns policy during 5YBP (Target)





# Consolidated Financial Statements

## Consolidated Statement of Profit or Loss

	(Millions of yen)	
	FY2017 (For the year ended March 31, 2018)	FY2018 (For the year ended March 31, 2019)
Revenue	960,195	929,717
Cost of sales	346,021	364,605
Gross profit	614,173	565,112
Selling, general and administrative expenses	301,845	277,695
Research and development expenses	236,046	203,711
Operating profit	76,282	83,705
Financial income	8,642	8,141
Financial expenses	4,223	5,910
Share of profit (loss) of investments accounted for using the equity method	320	(105)
Profit before tax	81,021	85,831
Income taxes	21,210	(7,591)
Profit for the year	59,811	93,422
Profit attributable to:		
Owners of the Company	60,282	93,409
Non-controlling interests	(471)	12
Profit for the year	59,811	93,422
Earnings per share		
Basic earnings per share (yen)	91.31	144.20
Diluted earnings per share (yen)	91.10	143.88

## Consolidated Statement of Comprehensive Income

	(Millions of yen)	
	FY2017 (For the year ended March 31, 2018)	FY2018 (For the year ended March 31, 2019)
Profit for the year	59,811	93,422
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	10,688	60,976
Remeasurements of defined benefit plans	1,616	205
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(10,229)	9,289
Share of other comprehensive income of investments accounted for using the equity method	3	—
Other comprehensive income (loss) for the year	2,078	70,471
Total comprehensive income for the year	61,890	163,893
Total comprehensive income attributable to:		
Owners of the Company	62,361	163,881
Non-controlling interests	(471)	12
Total comprehensive income for the year	61,890	163,893

## Consolidated Statement of Financial Position

	(Millions of yen)	
	FY2017 (As of March 31, 2018)	FY2018 (As of March 31, 2019)
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	357,702	243,155
Trade and other receivables	231,529	419,609
Other financial assets	429,380	536,880
Inventories	172,586	176,067
Other current assets	10,347	15,471
Subtotal	1,201,545	1,391,183
Assets held for sale	—	2,000
Total current assets	1,201,545	1,393,184
Non-current assets		
Property, plant and equipment	217,946	229,085
Goodwill	75,479	77,851
Intangible assets	173,537	169,472
Investments accounted for using the equity method	1,693	2,200
Other financial assets	179,177	114,895
Deferred tax assets	40,339	94,809
Other non-current assets	8,035	6,551
Total non-current assets	696,209	694,866
Total assets	1,897,754	2,088,051
<b>LIABILITIES AND EQUITY</b>		
Current liabilities		
Trade and other payables	226,164	312,660
Bonds and borrowings	20,000	40,000
Other financial liabilities	516	530
Income taxes payable	64,609	10,451
Provisions	34,015	7,837
Other current liabilities	7,800	12,715
Subtotal	353,105	384,195
Liabilities directly associated with assets held for sale	—	349
Total current liabilities	353,105	384,544
Non-current liabilities		
Bonds and borrowings	260,564	220,585
Other financial liabilities	8,155	5,680
Post-employment benefit liabilities	10,547	10,384
Provisions	48,752	4,985
Deferred tax liabilities	18,676	17,166
Other non-current liabilities	64,911	195,000
Total non-current liabilities	411,608	453,802
Total liabilities	764,713	838,346
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	94,633	94,633
Treasury shares	(163,531)	(162,964)
Other components of equity	120,504	115,166
Retained earnings	1,031,376	1,152,806
Total equity attributable to owners of the Company	1,132,982	1,249,642
Non-controlling interests		
Non-controlling interests	58	62
Total equity	1,133,041	1,249,705
Total liabilities and equity	1,897,754	2,088,051

# Consolidated Financial Statements

## Consolidated Statement of Changes in Equity

(Millions of yen)

	Equity attributable to owners of the Company					
				Other components of equity		
	Share capital	Capital surplus	Treasury shares	Subscription rights to shares	Exchange differences on translation of foreign operations	Financial assets measured at fair value through other comprehensive income
Balance as of April 1, 2017	50,000	103,750	(113,952)	2,067	67,568	54,853
Profit for the year	—	—	—	—	—	—
Other comprehensive income (loss) for the year	—	—	—	—	(10,229)	10,688
Total comprehensive income (loss) for the year	—	—	—	—	(10,229)	10,688
Purchase of treasury shares	—	(51)	(50,033)	—	—	—
Cancellation of treasury shares	—	—	453	(74)	—	—
Dividends	—	—	—	—	—	—
Acquisition of non-controlling interests	—	(9,064)	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	—	—	(4,369)
Others	—	—	—	—	—	—
Total transactions with owners of the Company	—	(9,116)	(49,579)	(74)	—	(4,369)
Balance as of April 1, 2018	50,000	94,633	(163,531)	1,993	57,339	61,171
Changes in accounting policies	—	—	—	—	—	—
Adjusted balance as of April 1, 2018	50,000	94,633	(163,531)	1,993	57,339	61,171
Profit for the year	—	—	—	—	—	—
Other comprehensive income (loss) for the year	—	—	—	—	9,289	60,976
Total comprehensive income (loss) for the year	—	—	—	—	9,289	60,976
Purchase of treasury shares	—	—	(45)	—	—	—
Cancellation of treasury shares	—	—	612	(187)	—	—
Dividends	—	—	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	—	—	(75,415)
Others	—	—	—	—	—	—
Total transactions with owners of the Company	—	—	567	(187)	—	(75,415)
Balance as of March 31, 2019	50,000	94,633	(162,964)	1,805	66,628	46,732

(Millions of yen)

	Equity attributable to owners of the Company					
	Other components of equity					
	Remeasurements of defined benefit plans	Total for other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2017	—	124,489	1,011,610	1,175,897	(4,469)	1,171,428
Profit for the year	—	—	60,282	60,282	(471)	59,811
Other comprehensive income (loss) for the year	1,620	2,078	—	2,078	—	2,078
Total comprehensive income (loss) for the year	1,620	2,078	60,282	62,361	(471)	61,890
Purchase of treasury shares	—	—	—	(50,085)	—	(50,085)
Cancellation of treasury shares	—	(74)	(75)	304	—	304
Dividends	—	—	(46,430)	(46,430)	—	(46,430)
Acquisition of non-controlling interests	—	—	—	(9,064)	5,007	(4,057)
Transfer from other components of equity to retained earnings	(1,620)	(5,989)	5,989	—	—	—
Others	—	—	—	—	(8)	(8)
Total transactions with owners of the Company	(1,620)	(6,063)	(40,516)	(105,276)	4,998	(100,277)
Balance as of April 1, 2018	—	120,504	1,031,376	1,132,982	58	1,133,041
Changes in accounting policies	—	—	(530)	(530)	—	(530)
Adjusted balance as of April 1, 2018	—	120,504	1,030,846	1,132,452	58	1,132,510
Profit for the year	—	—	93,409	93,409	12	93,422
Other comprehensive income (loss) for the year	205	70,471	—	70,471	—	70,471
Total comprehensive income (loss) for the year	205	70,471	93,409	163,881	12	163,893
Purchase of treasury shares	—	—	—	(45)	—	(45)
Cancellation of treasury shares	—	(187)	(115)	310	—	310
Dividends	—	—	(45,340)	(45,340)	—	(45,340)
Transfer from other components of equity to retained earnings	(205)	(75,621)	74,006	(1,615)	—	(1,615)
Others	—	—	—	—	(8)	(8)
Total transactions with owners of the Company	(205)	(75,808)	28,550	(46,691)	(8)	(46,699)
Balance as of March 31, 2019	—	115,166	1,152,806	1,249,642	62	1,249,705

## Consolidated Statement of Cash Flows

(Millions of yen)

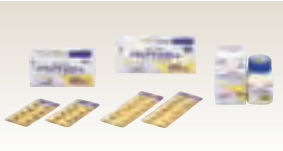
	FY2017 (For the year ended March 31, 2018)	FY2018 (For the year ended March 31, 2019)
Cash flows from operating activities		
Profit before tax	81,021	85,831
Depreciation and amortization	46,680	46,169
Impairment loss	36,672	15,194
Financial income	(8,642)	(8,141)
Financial expenses	4,223	5,910
Share of (profit) loss of investments accounted for using the equity method	(320)	105
(Gain) loss on sale and disposal of non-current assets	(5,125)	(7,562)
(Increase) decrease in trade and other receivables	2,535	(187,792)
(Increase) decrease in inventories	(19,394)	(4,018)
Increase (decrease) in trade and other payables	238	60,419
Others, net	(9,755)	118,395
Subtotal	128,134	124,510
Interest and dividends received	4,516	5,437
Interest paid	(2,038)	(1,768)
Income taxes paid	(22,173)	(36,146)
Net cash flows from (used in) operating activities	108,439	92,033
Cash flows from investing activities		
Payments into time deposits	(388,376)	(452,338)
Proceeds from maturities of time deposits	488,576	378,448
Acquisition of securities	(128,492)	(149,672)
Proceeds from sale of securities	165,458	136,858
Acquisitions of property, plant and equipment	(23,399)	(36,108)
Proceeds from sale of property, plant and equipment	139	1,901
Acquisition of intangible assets	(14,609)	(30,505)
Proceeds from sale of subsidiary	—	752
Payments for loans receivable	(982)	(548)
Proceeds from collection of loans receivable	753	839
Others, net	9,501	7,852
Net cash flows from (used in) investing activities	108,568	(142,520)
Cash flows from financing activities		
Repayments of bonds and borrowings	—	(20,000)
Purchase of treasury shares	(50,085)	(45)
Proceeds from sale of treasury shares	1	0
Dividends paid	(46,420)	(45,339)
Others, net	(5,262)	(819)
Net cash flows from (used in) financing activities	(101,766)	(66,203)
Net increase (decrease) in cash and cash equivalents	115,241	(116,689)
Cash and cash equivalents at the beginning of the year	246,050	357,702
Effect of exchange rate change on cash and cash equivalents	(3,590)	2,143
Cash and cash equivalents at the end of the year	357,702	243,155



Major Products

Innovative Pharmaceuticals Business

Brand Name (Generic Name)		Efficacy	Launched	Remarks
Japan [Daiichi Sankyo Co., Ltd.]				
CANALIA	(teneligliptin / canagliflozin)	Type 2 diabetes mellitus treatment	2017	A first combination drug of the DPP-4 inhibitor <i>teneligliptin</i> and the SGLT2 inhibitor <i>canagliflozin</i> approved in Japan, which demonstrates blood glucose-lowering activity through a complementary pharmacological effect.
VIMPAT	(lacosamide)	Anti-epileptic agent	2016	Sodium channel blocker. Suppresses the excessive excitation of nerves in the brain, and reduces the occurrence of epileptic seizures.
Effient	(prasugrel)	Antiplatelet agent	2014	ADP receptor inhibitor. Inhibits platelet aggregation and reduces the incidence of artery stenosis and occlusion due to thrombosis.
PRALIA	(denosumab)	Treatment for osteoporosis / inhibitor for rheumatoid arthritis-induced progression of bone erosion	2013	Human monoclonal anti-RANKL antibody. Subcutaneous formulation which controls bone resorption and bone destruction by specifically inhibiting RANKL.
TENELIA	(teneligliptin)	Type 2 diabetes mellitus treatment	2012	DPP-4 inhibitor. The agent facilitates glucose-dependent insulin release and inhibits glucagon release, thereby demonstrating the blood glucose-lowering activity.
RANMARK	(denosumab)	Treatment for bone disorders caused by bone metastases from tumors	2012	Human monoclonal anti-RANKL antibody. This controls abnormal bone destruction caused by osteoclasts, and reduces the occurrence of fractures and other skeletal related events (SRE). Approved for the indication of giant cell tumors of bone in 2014 and was designated as an orphan drug.
LIXIANA	(edoxaban)	Anticoagulant	2011	Orally active Factor Xa inhibitor. Prevents the formation of blood clots by specifically, reversibly and directly inhibiting the enzyme, Factor Xa, a clotting factor in the blood.
NEXIUM	(esomeprazole)	Ulcer treatment	2011	Proton pump inhibitor. This can be used for a wide range of ages, from infants to adults. It suppresses excessive gastric acid secretion.
Memary	(memantine)	Alzheimer's disease treatment	2011	N-methyl-D-aspartate (NMDA) receptor antagonist. Memantine slows down progression of dementia symptoms in patients with moderate to severe Alzheimer's disease.
Inavir	(laninamivir)	Anti-influenza treatment	2010	Neuraminidase inhibitor that inhibits influenza viral proliferation. Treatment is completed with a single inhaled dosage.
Olmetec	(olmesartan)	Antihypertensive agent	2004	Angiotensin II receptor blocker. This suppresses the vasoconstriction effects of angiotensin II, and thereby demonstrates the effect of lowering blood pressure.
Rezaltas			2010	A combination drug of two antihypertensive agents: an angiotensin II receptor blocker, <i>olmesartan medoxomil</i> , and a calcium ion antagonist, <i>azelnidipine</i> . This combination demonstrates the effect of decreasing blood pressure through a complementary pharmacological effect.
Cravit	(levofloxacin)	Synthetic antibacterial agent	1993	New quinolone antibacterial agent offering strong antibacterial action and a broad antibacterial spectrum.
Mevalotin	(pravastatin)	Hypercholesterolemia treatment	1989	HMG-CoA reductase inhibitor (statin) that lowers blood cholesterol levels by inhibiting cholesterol synthesis in the liver.
Omnipaque	(iohexol)	Contrast medium	1987	Nonionic contrast medium. This is used to add contrast to images or highlight specific tissues in images that are difficult to read under normal diagnostic conditions.
Loxonin	(loxoprofen)	Anti-inflammatory analgesic	1986	Nonsteroidal anti-inflammatory analgesic. Suppresses the production of prostaglandin associated with inflammation, and thereby demonstrates an analgesic effect. Also available as transdermal agents (poultice, gel, tape).



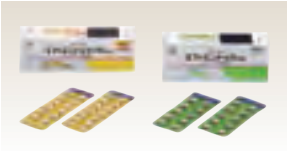
LIXIANA (Japan)



Memary (Japan)



TENELIA, CANALIA (Japan)



Effient (Japan)



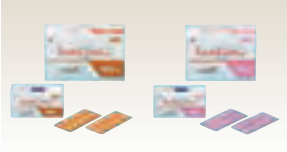
NEXIUM (Japan)



PRALIA (Japan)



RANMARK (Japan)



VIMPAT (Japan)

Innovative Pharmaceuticals Business

Brand Name (Generic Name)		Efficacy	Launched	Remarks
US [Daiichi Sankyo Inc.]				
MOVANTI	(naloxegol)	Opioid-induced constipation treatment	2015	First once-daily oral product approved by the FDA for the treatment of opioid-induced constipation (OIC) for adults with chronic non-cancer pain.
SAVAYSA	(edoxaban)	Anticoagulant	2015	Orally active Factor Xa inhibitor. It is an anticoagulant that specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood. Approved for indications to reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF) and for the treatment of venous thromboembolism (VTE) (deep vein thrombosis (DVT) and pulmonary embolism (PE)).
Effient	(prasugrel)	Antiplatelet agent	2009	Inhibits platelet aggregation and reduces the incidence of artery stenosis and occlusion.
Benicar	(olmesartan)	Antihypertensive agent	2002	Benicar: Olmesartan
Benicar HCT			2003	Benicar HCT: A combination drug of olmesartan medoxomil and hydrochlorothiazide (diuretic)
AZOR			2007	AZOR: A combination drug of olmesartan medoxomil and amlodipine besylate (calcium channel blocker)
TRIBENZOR	(olmesartan)	Antihypertensive agent	2010	TRIBENZOR: A triple combination drug of olmesartan medoxomil, hydrochlorothiazide, and amlodipine besylate
Welchol			2000	Bile acid sequestrant. Marketed as a drug for treatment of hypercholesterolemia. Gained approval also for type 2 diabetes mellitus indication as part of life-cycle management.
US [American Regent, Inc.]				
Injectafer	(ferric carboxymaltose injection)	Iron deficiency anemia treatment	2013	Effective for patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-dialysis-dependent chronic kidney disease.
Venofer	(iron sucrose injection)	Iron deficiency anemia treatment	2000	Iron replacement product. Effective for treatment of iron deficiency anemia in dialysis patients, etc.
Europe [Daiichi Sankyo Europe GmbH]				
LIXIANA	(edoxaban)	Anticoagulant	2015	Orally active Factor Xa inhibitor. It is an anticoagulant that specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood. Approved for indications for the prevention of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF) and for the treatment and prevention of recurrent venous thromboembolism (VTE) (deep vein thrombosis (DVT) and pulmonary embolism (PE)).
Effient	(prasugrel)	Antiplatelet agent	2009	Inhibits platelet aggregation and reduces the incidence of artery stenosis and occlusion.
Olmetec	(olmesartan)	Antihypertensive agent	2002	Olmetec: Olmesartan
Olmetec Plus			2005	Olmetec Plus: A combination drug of olmesartan medoxomil and hydrochlorothiazide (diuretic)
Sevikar			2009	Sevikar: A combination drug of olmesartan medoxomil and amlodipine besylate (calcium channel blocker)
Sevikar HCT	(olmesartan)	Antihypertensive agent	2010	Sevikar HCT: A triple combination drug of olmesartan medoxomil, hydrochlorothiazide, and amlodipine besylate

Generic Business

Brand Name (Efficacy)
Japan [Daiichi Sankyo Espha Co., Ltd.]
Olmesartan (Antihypertensive agent)
Rosuvastatin (Hypercholesterolemia treatment)
Telmisartan (Antihypertensive agent)
Silodosin (Treatment for dysuria)
Gefitinib (Treatment for malignant tumors)



Injectafer (US)



Gefitinib (Generic Drugs)



Lulu (OTC Related Drugs)



Breath Labo (OTC Related Drugs)



LIXIANA (Europe)



Silodosin (Generic Drugs)



MINON series (OTC Related Drugs)



Influenza HA Vaccine (Vaccines)

Vaccine Business

Brand Name
Japan [Daiichi Sankyo Co., Ltd.]
Influenza HA Vaccine
Live Attenuated Measles-Rubella Combined Vaccine
Live Attenuated Mumps Vaccine
Squarekids (4-valent combination vaccine for the prevention of pertussis, diphtheria, tetanus, and poliomyelitis (polio))

# Corporate Profile / Main Group Companies

## Corporate Profile

(As of April 1, 2019)

Company name DAIICHI SANKYO CO., LTD.  
Established September 28, 2005  
Business Research and development, manufacturing, import, sales, and marketing of pharmaceutical products  
Share capital ¥50,000 million  
Headquarters 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan  
Branches Sapporo, Tohoku, Tokyo, Chiba, Saitama, Yokohama, Kanetsu, Tokai, Kyoto, Osaka, Kobe, Chugoku, Shikoku, and Kyushu

Sales Manufacturing Research and development

## U.S.A.

Daiichi Sankyo, Inc.  
American Regent, Inc.  
Plexxikon Inc.

Revenue	(Billions of yen)		
	FY2017 Results	FY2018 Results	YoY
Daiichi Sankyo, Inc.	74.8	36.3	-38.5
Olmesartan	21.3	10.7	-10.6
Welchol	33.9	13.4	-20.5
Effient	10.7	2.4	-8.2
SAVAYSA	2.2	2.3	+0.1
MOVANTIK	4.7	4.2	-0.5
American Regent, Inc.	105.4	117.8	+12.4
Venofor	31.0	28.9	-2.0
Injectafer	34.3	44.2	+9.9

## Europe

Daiichi Sankyo Europe GmbH  
Daiichi Sankyo Deutschland GmbH  
Daiichi Sankyo France SAS  
Daiichi Sankyo Italia S.p.A.  
Daiichi Sankyo España, S.A.  
Daiichi Sankyo UK Ltd.  
Daiichi Sankyo (Schweiz) AG  
Daiichi Sankyo Portugal, Unipessoal Lda.  
Daiichi Sankyo Austria GmbH  
Daiichi Sankyo Belgium N.V.-S.A.  
Daiichi Sankyo Nederland B.V.  
Daiichi Sankyo Ilac Ticaret Ltd. Şti.  
Daiichi Sankyo Ireland Ltd.  
Daiichi Sankyo Altkirch Sarl

Revenue	(Billions of yen)		
	FY2017 Results	FY2018 Results	YoY
Daiichi Sankyo Europe	79.4	88.6	+9.1
Olmesartan	33.5	27.4	-6.1
Effient	8.0	5.7	-2.3
LIXIANA	27.0	45.8	+18.8

## Japan

Daiichi Sankyo Espha Co., Ltd.  
Daiichi Sankyo Healthcare Co., Ltd.  
Daiichi Sankyo Propharma Co., Ltd.  
Daiichi Sankyo Chemical Pharma Co., Ltd.  
Daiichi Sankyo Biotech Co., Ltd.  
Daiichi Sankyo RD Novare Co., Ltd.  
Daiichi Sankyo Business Associe Co., Ltd.  
Daiichi Sankyo Happiness Co., Ltd.

Revenue	(Billions of yen)		
	FY2017 Results	FY2018 Results	YoY
Domestic Prescription Drug and Vaccine Business	540.0	523.3	-16.7
NEXIUM	86.5	78.3	-8.3
LIXIANA	45.3	64.9	+19.6
Memary	48.6	50.2	+1.7
Loxonin	36.5	30.5	-6.0
PRALIA	23.2	27.4	+4.2
TENELIA	26.3	25.3	-1.0
Inavir	25.3	18.2	-7.1
Olmotec	44.6	14.9	-29.7
RANMARK	15.4	16.4	+1.0
Effient	12.8	13.9	+1.1
Rezaltas	16.8	15.5	-1.3
Urief	11.1	10.3	-0.9
Omnipaque	14.0	12.0	-2.0
CANALIA	2.7	9.2	+6.5
VIMPAT	2.6	6.6	+3.9
Daiichi Sankyo Healthcare (OTC Related)	72.9	66.4	-6.5

## ASCA\*

Daiichi Sankyo (China) Holdings Co., Ltd.  
Daiichi Sankyo Taiwan Ltd.  
Daiichi Sankyo Korea Co., Ltd.  
Daiichi Sankyo (Thailand) Ltd.  
Daiichi Sankyo Hong Kong Ltd.  
Daiichi Sankyo Brasil Farmaceutica LTDA.

\* Asia, South & Central America

Revenue	(Billions of yen)		
	FY2017 Results	FY2018 Results	YoY
Asia, South & Central America (ASCA)	80.4	87.7	+7.3
Daiichi Sankyo China	35.3	38.5	+3.2
Daiichi Sankyo Taiwan	6.6	7.1	+0.5
Daiichi Sankyo Korea	11.8	15.7	+3.9
Daiichi Sankyo Thailand	2.9	3.3	+0.3
Daiichi Sankyo Brasil	10.1	10.0	-0.1



ESG (Environmental, Social, and Governance) Data

Environmental

Promoting Environmental Management

Aspect	Classification	Item	Scope*1	Unit	FY2016	FY2017	FY2018	
CO <sub>2</sub>	CO <sub>2</sub> emissions		In Japan	t-CO <sub>2</sub>	<div><div></div></div> 176,732	<div><div></div></div> 165,933	<div><div></div></div> 156,323	
			Global	t-CO <sub>2</sub>	236,162	224,826	211,560	
	CO <sub>2</sub> emissions by Greenhouse Gas Protocol		Scope 1	In Japan	t-CO <sub>2</sub>	<div><div></div></div> 91,662	<div><div></div></div> 84,283	<div><div></div></div> 79,505
				Global	t-CO <sub>2</sub>	115,474	108,106	100,503
			Scope 2	In Japan	t-CO <sub>2</sub>	<div><div></div></div> 90,182	<div><div></div></div> 85,382	<div><div></div></div> 79,901
				Global	t-CO <sub>2</sub>	125,799	120,451	114,140
Water resources	Water used	In Japan	1,000m <sup>3</sup>	<div><div></div></div> 10,986	<div><div></div></div> 10,311	<div><div></div></div> 9,867		
		Global	1,000m <sup>3</sup>	11,534	10,828	10,393		
	Wastewater	In Japan	1,000m <sup>3</sup>	<div><div></div></div> 9,934	<div><div></div></div> 9,856	<div><div></div></div> 9,476		
		Global	1,000m <sup>3</sup>	10,370	10,283	9,809		
	Effective water usage volume*2		Global	1,000m <sup>3</sup>	1,163	545	583	
	Waste	Waste generated	In Japan	t	<div><div></div></div> 20,588	<div><div></div></div> 14,682	<div><div></div></div> 14,684	
Global			t	22,788	18,514	17,044		
Final disposal rate		In Japan	%	0.69	0.43	0.51		
Amount of office paper consumed		In Japan	Million sheets	5,355	5,360	5,109		

Information with this mark is verified by SGS Japan Inc.  
Information with this mark is assured by SGS Japan Inc.

Social


Promoting Compliance Management

Aspect	Classification	Item	Scope*1	Unit	FY2016	FY2017	FY2018
Compliance	Training on Daiichi Sankyo Group Individual Conduct Principles	Number of employees participating in e-learning and group training	In Japan	Persons	—	—	9,248
			Outside Japan	Persons	—	—	Approx. 6,100
	Compliance training based on Corporate Integrity Agreement*3 in the United States		In Japan	Persons	125	147	170
			Outside Japan	Persons	2,001	2,074	1,837
	GVP*4 compliance training	Ratio of GVP-related employees undergoing training	Non-consolidated	%	100	100	100
		Ratio of all employees (excluding GVP-related employees) undergoing training	Non-consolidated	%	99.8	99.9	99.9
	Development-related training (including GCP)		Non-consolidated	Times	93	93	86

Compliance Data for FY2018 (Global)

- Number of allegations received (excluding through monitoring): 248
- Categories of allegations: Financial and competitive integrity, Workplace standards, Marketing and promotional activities, Conflicts of interest, Other
- Measures: Out of all allegations received we appropriately investigated cases that we determined as requiring investigation. For cases that were recognized as compliance violations among them, we took necessary disciplinary action including dismissing the violators.

Note: The results included in this information for FY2018 were calculated by each DS affiliate based on the individual criteria, as impacted by regional differences in laws, employment practices, and local policies & procedures. Accordingly, this information has been aggregated and the discrepancies impact the overall meaning and categorization of the figures.



The Company updates its corporate website with other ESG data.

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

Mutual Growth of Employees and the Company

Aspect	Classification	Item	Scope*1	Unit	FY2016	FY2017	FY2018	
Employees	Number of employees by region*5		In Japan	Persons	8,648	8,765	8,865	
			Outside Japan	Persons	6,022	5,681	6,022	
			Global	Persons	14,670	14,446	14,887	
	Employee data*5	Number of male employees	In Japan	Persons	6,643	6,663	6,695	
			Outside Japan	Persons	3,088	2,888	3,076	
		Number of female employees	In Japan	Persons	2,005	2,102	2,170	
			Outside Japan	Persons	2,934	2,793	2,946	
		Average years of service	In Japan	Male	Persons	19.5	19.9	20.1
				Female	Persons	15.8	15.8	15.5
				All	Persons	18.7	18.9	19.0
	Diversity*5	Percentage of female employees	In Japan		%	23.2	24.0	24.5
			Global		%	33.7	33.9	34.4
		Percentage of women in managerial positions	In Japan		%	5.4	6.0	6.5
			Global		%	22.6	21.3	22.5
		Percentage of women in senior managerial positions*6	In Japan		%	—	—	2.1
			Global		%	—	—	22.5
		Employment rate of people with physical or mental disabilities	In Japan		%	2.44	2.45	2.43
	Human resources development	Number of company-wide award winners*7	In Japan		Persons	47	41	44
		Employee turnover rate*8	Global		%	5.3	6.0	6.0

Information with this mark is assured by KPMG AZSA Sustainability Co., Ltd.

Enhancement of Communication with Stakeholders

Aspect	Classification	Item	Scope*1	Unit	FY2016	FY2017	FY2018
Patients and medical professionals	Evaluation of corporate stance and MR activities	MRs rated (all responding physicians)*9	In Japan	Rank	First	First	First
		MRs rated (hospital doctors)*9	In Japan	Rank	First	First	First
		MRs rated (private-practice physicians)*9	In Japan	Rank	First	First	First
	Number of inquiries our Medical Information Center received from outside the Company (pharmaceutical products)		In Japan	1,000 cases	99	101	89
Shareholders	Dividends per share	Interim	Non-consolidated	Yen	35	35	35
		Year-end	Non-consolidated	Yen	35	35	35
		Total	Non-consolidated	Yen	70	70	70

Improvement of Access to Healthcare

Aspect	Classification	Item	Scope	Unit	FY2016	FY2017	FY2018
Social	Number of mobile healthcare field clinics	Number of activities (January-December)	In Tanzania	Times	102	521	1,090
	Number of development projects conducted through the GHIT Fund*10		In Japan		5	5	4

Social Contribution Activities

Aspect	Classification	Item	Scope*1	Unit	FY2016	FY2017	FY2018
Social	Amount of contributions		Non-consolidated	Millions of yen	2,003	1,671	1,532
	Number of visitors to our laboratories/factories		In Japan	Persons	1,200	1,100	849
	Number of visitors to Kusuri Museum		Non-consolidated	Persons	14,793	22,137	24,362
Employees	Acquisition of volunteer leave		In Japan	Persons	9	18	17

Governance

Aspect	Classification	Item	Scope	Unit	FY2016	FY2017	FY2018
Governance	Structure of Board of Directors	Number of directors	Non-consolidated	Persons	10	9	9
		Number of outside directors	Non-consolidated	Persons	4	4	4
		Number of female directors	Non-consolidated	Persons	0	0	1
	Structure of Audit & Supervisory Board	Number of Audit & Supervisory Board members	Non-consolidated	Persons	4	5	5
		Number of Outside Audit & Supervisory Board members	Non-consolidated	Persons	2	3	3
		Number of Outside Audit & Supervisory Board members (female)	Non-consolidated	Persons	1	2	2
	Remuneration of Directors	Total	Non-consolidated	Millions of yen	578	609	650
	Remuneration of Audit & Supervisory Board members	Total	Non-consolidated	Millions of yen	105	117	120

\*1 In Japan: Daiichi Sankyo (non-consolidated) and consolidated subsidiaries in Japan. Outside Japan: consolidated overseas subsidiaries. Global: Daiichi Sankyo (non-consolidated) and all its consolidated subsidiaries.

\*2 Water intake-Water waste

\*3 Corporate Integrity Agreement: An agreement regarding legal compliance

\*4 Good Vigilance Practice: Standard for post-marketing safety control of pharmaceuticals

\*5 Number of employees as of the settlement date of each Group company (as of March 31, 2019 for FY2018). However, employees accepted from outside the Group to the Group are excluded. Figures for the average years of service are current as of April 1 of the following fiscal year.

\*6 Percentage of women who are in positions equivalent to division heads or higher positions


\*7 Total number of employees who received prize from culture-building and achievement awards

\*8 Rate of employees retiring for personal reasons

\*9 Conducted by ANTERIO Inc. (FY2016-FY2018)


\*10 Global Health Innovative Technology Fund

Independent Assurance Report for Social Indicators



### Independent Assurance Report

To the President and COO of Daiichi Sankyo Co, Ltd.

We were engaged by Daiichi Sankyo Co., Ltd. (the “Company”) to undertake a limited assurance engagement of the social performance indicators marked with  (the “Indicators”) for the period from April 1, 2018 to March 31, 2019 included in its Value Report 2019 (the “Report”) for the fiscal year ended March 31, 2019.

#### The Company's Responsibility

The Company is responsible for the preparation of the Indicators in accordance with its own reporting criteria (the “Company’s reporting criteria”), as described in the Report.

#### Our Responsibility

Our responsibility is to express a limited assurance conclusion on the Indicators based on the procedures we have performed. We conducted our engagement in accordance with the ‘International Standard on Assurance Engagements (ISAE) 3000, Assurance Engagements other than Audits or Reviews of Historical Financial Information’ issued by the International Auditing and Assurance Standards Board. The limited assurance engagement consisted of making inquiries, primarily of persons responsible for the preparation of information presented in the Report, and applying analytical and other procedures, and the procedures performed vary in nature from, and are less in extent than for, a reasonable assurance engagement. The level of assurance provided is thus not as high as that provided by a reasonable assurance engagement. Our assurance procedures included:


- Interviewing the Company’s responsible personnel to obtain an understanding of its policy for preparing the Report and reviewing the Company’s reporting criteria.
- Inquiring about the design of the systems and methods used to collect and process the Indicators.
- Performing analytical procedures on the Indicators.
- Examining, on a test basis, evidence supporting the generation, aggregation and reporting of the Indicators in conformity with the Company’s reporting criteria, and recalculating the Indicators.
- Evaluating the overall presentation of the Indicators.

#### Conclusion

Based on the procedures performed, as described above, nothing has come to our attention that causes us to believe that the Indicators in the Report are not prepared, in all material respects, in accordance with the Company’s reporting criteria as described in the Report.

#### Our Independence and Quality Control

We have complied with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants, which includes independence and other requirements founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior. In accordance with International Standard on Quality Control 1, we maintain a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.



KPMG AZSA Sustainability Co., Ltd.  
Tokyo, Japan  
September 13, 2019

Shareholders’ Information

#### Common Stock

(As of March 31, 2019)

Number of shares authorized	2,800,000,000
Number of shares issued	709,011,343
Number of shareholders	74,272

#### Share Registrar

Mitsubishi UFJ Trust and Banking Corporation

**Mailing address and telephone number:**  
Mitsubishi UFJ Trust and Banking Corporation  
Corporate Agency Division  
Shin-TOKYO Post Office post office box No.29,  
137-8081, Japan  
Tel: 0120-232-711 (toll free within Japan)

#### Major Shareholders

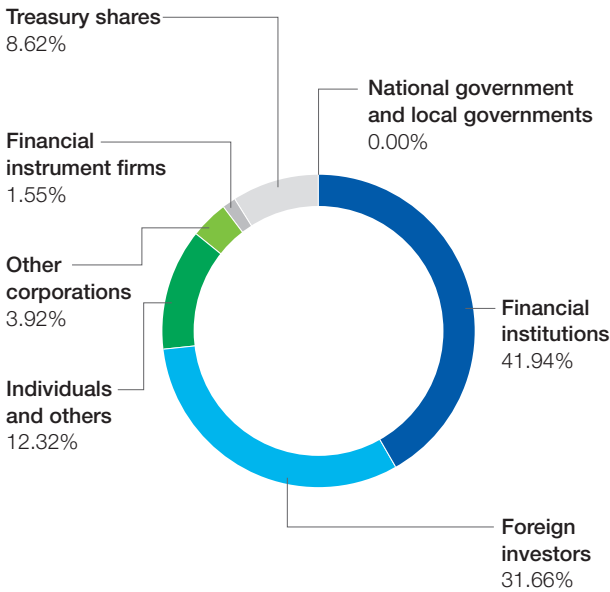
(As of March 31, 2019)

Name	Number of Shares Held (Thousands of shares)	Ratio (%)
The Master Trust Bank of Japan, Ltd. (trust account)	62,797	9.69
JP MORGAN CHASE BANK 380055	55,009	8.49
Japan Trustee Services Bank, Ltd. (trust account)	53,972	8.33
Nippon Life Insurance Company	35,776	5.52
SSBTC CLIENT OMNIBUS ACCOUNT	20,224	3.12
Trust & Custody Services Bank, Ltd. as trustee for Mizuho Bank, Ltd. Retirement Benefit Trust Account re-entrusted by Mizuho Trust and Banking Co., Ltd.	14,402	2.22
The Shizuoka Bank, Ltd.	11,390	1.76
Japan Trustee Services Bank, Ltd. (trust account 5)	11,230	1.73
Japan Trustee Services Bank, Ltd. (trust account 7)	10,099	1.56
JP MORGAN CHASE BANK 385151	9,861	1.52

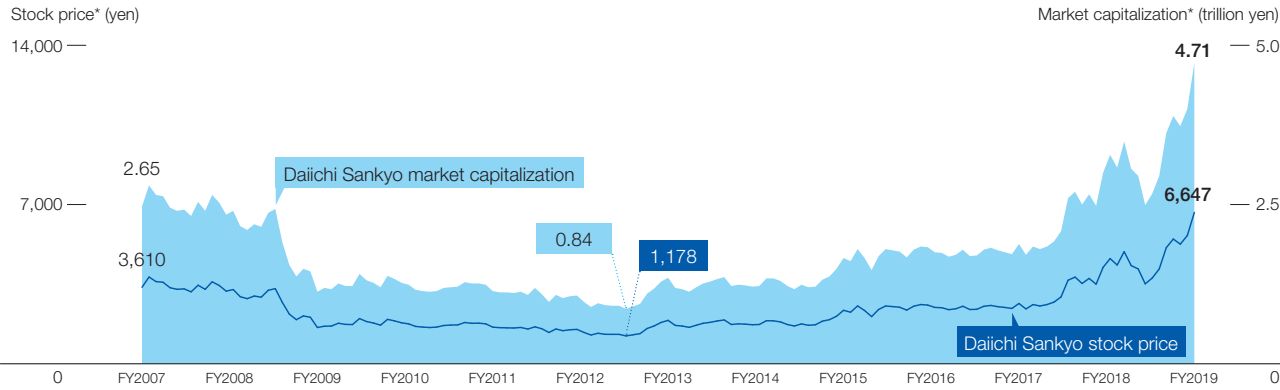
Notes: 1. The Company holds 61,124,702 treasury shares, which are excluded from the above list.  
2. Treasury shares are not included in the computing of equity stake.

#### Distribution of Shareholders

(As of March 31, 2019)



#### Market Capitalization and Changes in Stock Price



\* Stock prices and market capitalization are based on values for the end of March 2007 to the end of July 2019. Market capitalization includes treasury shares.





MSCI Japan Empowering Women Select Index

THE INCLUSION OF DAIICHI SANKYO CO.,LTD. IN ANY MSCI INDEX, AND THE USE OF MSCI LOGOS, TRADEMARKS, SERVICE MARKS OR INDEX NAMES HEREIN, DO NOT CONSTITUTE A SPONSORSHIP, ENDORSEMENT OR PROMOTION OF DAIICHI SANKYO CO.,LTD. BY MSCI OR ANY OF ITS AFFILIATES. THE MSCI INDEXES ARE THE EXCLUSIVE PROPERTY OF MSCI. MSCI AND THE MSCI INDEX NAMES AND LOGOS ARE TRADEMARKS OR SERVICE MARKS OF MSCI OR ITS AFFILIATES.



"Eruboshi" Certification Mark



"Kurumin" Certification Mark



Logo given to Certified Health and Productivity Management Organization (White500)



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CSR Department  
Tel: +81-3-6225-1067

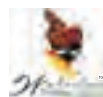
<https://www.daiichisankyo.com/>



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