## 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 '	
LOTA	IIAC

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 (Standard of Care): Universally applied best treatment practice in today's
- 2. To take a global perspective, and respect regional values
- 3. To foster intellectual curiosity and strategic
- 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.

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

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.

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.

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.

Thorough crisis and emergency management Article 9

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 Dailchi 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 GALS





















### 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

Daiichi Sankyo Group Value Report 2019

## Daiichi Sankyo's Value Creation Process

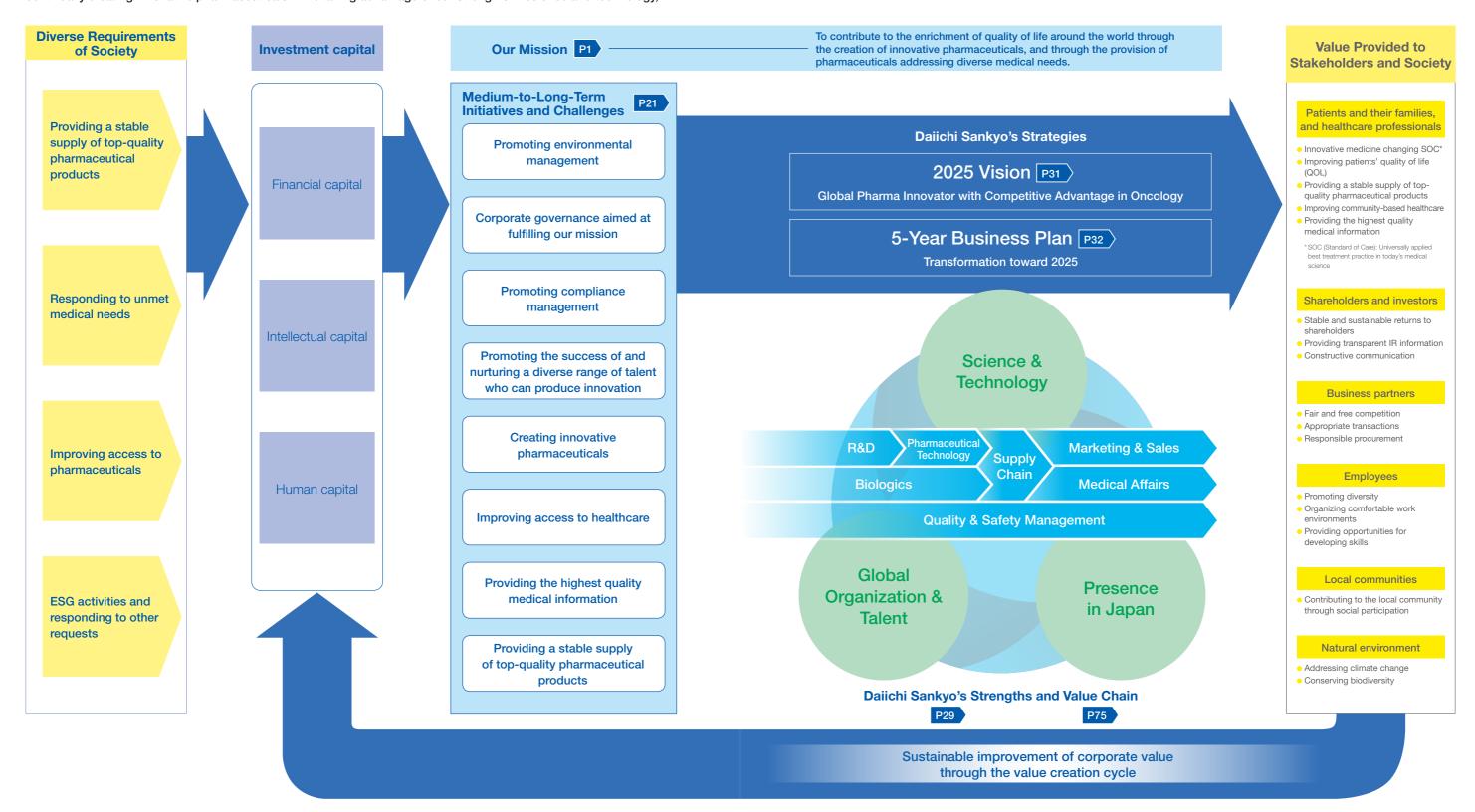
Daiichi Sankyo is requested from society for various needs including providing a stable supply of quality pharmaceuticals, responding to unmet medical needs\*1, improving access to pharmaceuticals\*2, and ESG activities. We engage in medium-to-long-term initiatives using our financial capital, intellectual 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.

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







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- ▶ Major R&D Pipeline



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▶ Road After the Merger

Ston

Creation

Medium-to-Long-Term Initiatives and Challenges

▶ Promoting Environmental Management

- ▶ Corporate Governance Aimed at Fulfilling Our Mission
- ▶ Promoting Compliance Management
- ▶ Promoting the Success and Development of a Diverse Range of Human Resources Who Can Produce Competitive Advantages
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**Business units** 

- ▶ Innovative Pharmaceuticals Business: Sales & Marketing Unit
- ▶ Generic Business: Daiichi Sankyo Espha Co., Ltd.
- ▶ Vaccine Business
- ▶ OTC Related Business: Daiichi Sankyo Healthcare Co., Ltd.
- ▶ Daiichi Sankyo, Inc. (DSUSB)
- American Regent, Inc.
- ▶ Daiichi Sankyo Europe GmbH
- ASCA Company

86 Functional units

- R&D Unit
- ▶ Biologics Unit
- ▶ Pharmaceutical Technology Unit
- ▶ Supply Chain Unit
- ▶ Medical Affairs Unit
- ▶ Quality & Safety Management Unit

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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 ▶P8, P21 and Challenges

Review of 5-Year Business Plan ▶P33 **R&D Pipeline** ▶P15

DS-8201 ▶P9, P45, P59

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### **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.



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 mediumto-long term corporate activities, and I would also like to give a brief description of these activities here.



## 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 companywide 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 copromotion 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

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

# Daiichi Sankyo's ADC Technology: Platform Technology

The ADC technology used for *DS-8201* allows for the creation of a new ADC by combining a different antibody with the same drug linker. Currently, R&D is underway for seven ADC projects all with the same linker and payload.

At the American Society of Clinical Oncology (ASCO) 2018, we exhibited the first ever clinical trial data on breast cancer with *U3-1402*, our second ADC following *DS-8201*. In ASCO 2019, we presented the first ever clinical trial data on lung cancer with *U3-1402* as well as with *DS-1062*, our third ADC. These results are still at an early stage, but the data shows potential efficacy in each ADC. We consider that both could have a similar potential as *DS-8201*, and we will make further investments in them going forward. We will also make considerations with a flexible approach regarding the optimal strategy for maximizing value in these projects.

In addition, we plan to start phase 1 trials for our new ADCs, *DS-7300* and *DS-6157*, during this fiscal year. We have more ADC projects scheduled after that as well.

The ADC projects produced with our ADC platform technology are successively going into clinics, and we plan to expand over a wide range of cancers and indications going forward. In this regard, I will need to make significant management decisions regarding when to increase our R&D expenses, personnel resources, production capacity, and other assets. I will make suitable management decisions, in order to deliver our innovative pharmaceuticals to more patients even earlier.

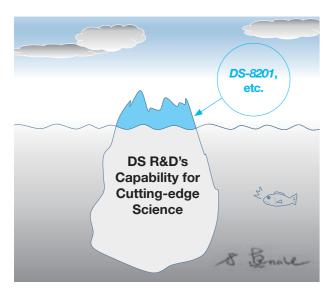
### ADC (Antibody Drug Conjugate) Pipeline

### Combinable with a wide range of antibodies

DS-8201		HER2
U3-1402	~~	HER3
DS-1062	**	TROP2
DS-7300		B7-H3

DS-6157	600	GPR20
DS-6000	60 %	Not disclosed
Project code pending		TA-MUC1

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

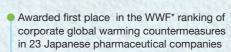
Fiscal 2019 marked the start of our oncology business, with plans to bring quizartinib and pexidartinib to the market as our first oncology products following our merger, as well as our work in submitting successive NDAs for DS-8201 in the U.S. and Japan. All employees will make a concerted effort to 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.

#### Introduction

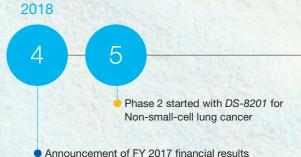
## At a glance

# **Annual Topics for Fiscal 2018**





- Included in the MSCI Japan Empowering Women (WIN) Select Index, one of the GPIF indices
- 13th Ordinary General Meeting of Shareholders
- Data presentation (DS-8201 Phase 1, U3-1402 Phase 1, and pexidartinib Phase 3) at the American Society of Clinical Oncology (ASCO)



- Selected for the DJSI "World Index" in the pharmaceutical sector for two consecutive years
- Entered into an agreement regarding a combined study of DS-8201 plus Keytruda (Merck in the U.S.)
  - Development alliance with the Roche Group for a HER2 low-expressing companion diagnostics
  - Filed NDA for Quizartinib (Europe, U.S.)



- Announced the transfer of 41 long-listed products in Japan
- Announcement of Q1 FY 2018 financial results
- Data presentation (DS-8201 Phase 1 and U3-1402 Phase 1) at the San Antonio Breast Cancer Symposium in the U.S.
- R&D Day

- Reconstruction support following the Great East Japan Earthquake: Coastal Forest Restoration Project (held 4 times in total)
- Announcement of Q2 FY 2018 financial results



2019

The Daiichi Sankyo Group Value Report 2018 received a Prize of Excellence in the 21st Nikkei Annual Report

Filed NDA for Pexidartinib (U.S.)

- Antihyperlipidemic agent introduced to Europe
- Acquired manufacturing and sales approval in Japan for the pain treatment Tarlige and the antihypertensive agent MINNEBRO
- Announced the transfer of the Takatsuki plant
- Announcement of Q3 FY 2018 financial results
- Initiated pivotal phase 3 trial of DS-8201 targeting HER2 low expressing breast cancer patients



- Selected for the 2019 Certified Health and Productivity Management Organization Recognition Program (Large Enterprise Category) - White 500: for two consecutive years
- Global development and Commercialization Collaboration with AstraZeneca regarding
- Accelerated BLA submission to U.S. FDA for DS-8201 targeting breast cancer

Daiichi Sankyo Group Value Report 2019 Daiichi Sankyo Group Value Report 2019

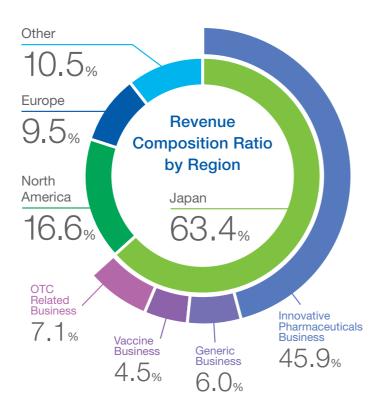
<sup>\*</sup> World Wide Fund for Nature

## At a glance

### **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	%	



### **Key Products**

Innovative Pharmaceuticals Business

117.7 billion



Anticoagulant LIXIANA/SAVAYSA Generic name Edoxaban

Generic Business

Olmetec/Benicar

Vaccine Business

¥105.9billi

Antihypertensive agent Generic name Olmesartan



Generic name Esomeprazole

Ulcer treatment

**NEXIUM** 



Antihypertensive agent Olmesartan (AG)

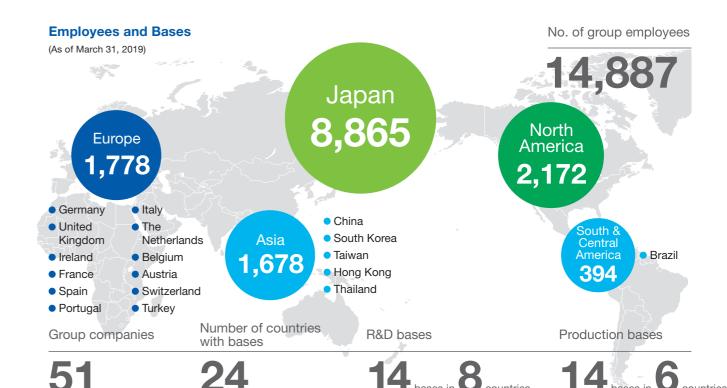
Seasonal influenza vaccine Influenza HA Vaccine



fiscal 2018:

¥**78.3**billion

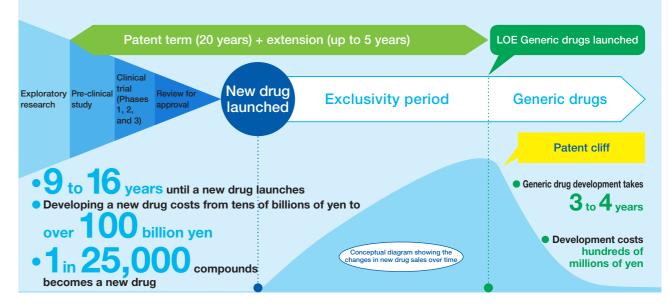
Antipyretic analgesics / Topical anti-inflammatory analgesics Loxonin S



## **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.



Daiichi Sankyo Group Value Report 2019

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
	hise  [fam-] Trastuzumab deruxtecan/ DS-8201/Anti-HER2-ADC	Breast cancer (HER2 positive post T-DM1)	JP/US/EU/ Asia	P2 🙀 P3	AstraZeneca
ADC		Breast cancer (HER2 positive vs. T-DM1)	JP/US/EU/ Asia	P3	AstraZeneca
Franchise		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 <i>nivolumab</i> )	US/EU	P1	BMS
	<i>U3-1402</i> /Anti-HER3-ADC	Breast cancer (HER3 expressing)	JP/US	P1	
	30 7 102/7 that 112 110 7120	EGFR-mutant non-small cell lung cancer	JP/US	P1	
	DS-1062/Anti-TROP2-ADC	Non-small cell lung cancer	JP/US	P1	
	Quizartinib/FLT3 inhibitor	Acute myeloid leukemia (relapsed/refractory)	EU/Asia	Submitted	
		Acute myeloid leukemia (first-line) 🐥	JP/US/EU/ Asia	P3	
AML Franchise	Milademetan/DS-3032/MDM2	Solid tumor (lyposarcoma 💂)	JP/US	P1	
	inhibitor	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	
	Axicabtagene ciloleucel/ Axi-Cel®/Anti-CD19 CAR-T cells	Acute myeloid leukemia	US	P1	
		B-cell lymphoma	JP	P2 🙎	Kite/Gilead
	Pexidartinib/CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor 💂	US/EU	Submitted	
Breakthrough Science	<i>DS-1647(G47∆)/</i> 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 <i>gefitinib</i> )	JP	P1	
	DO-1200/AAL IIIIIIDILUI	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
a	Edoxaban/Factor Xa inhibitor	Atrial fibrillation in very elderly patients	JP	P3/LCM*	
	Prasugrel/Anti-platelet agent	Ischemic stroke	JP	P3/LCM*	Ube Industries
Specialty medicine	Esaxerenone/MR antagonist	Diabetic nephropathy	JP	P3/LCM*	Exelixis
	DS-1040/TAFIa inhibitor	Acute ischemic stroke, acute pulmonary thromboembolism	JP/US/EU	P1	
	<i>Mirogabalin/</i> α2 <i>δ</i> 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	
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\* 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

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