# Activity Report

## **Sustainability Activities**

P67 Communication with Stakeholders

P69 Improvement of Access to Healthcare

P79 **Respect for Human Rights** 

P71 **Promoting Compliance** Management

P75 Promoting the Success and Development of a Diverse Range of People Who Create Our Competitive Advantages

Value Chain Activities

P81 Japan Business Unit

P85 American Regent Unit

P89 Pharmaceutical Technology Unit

P82 **Oncology Business Unit** 

P86 Daiichi Sankyo Healthcare Unit

P90 Supply Chain Unit P83 EU Specialty Business Unit

P87 Research & **Development Unit** 

P91

Quality Assurance & Regulatory Affairs Unit

P73 Promoting Environmental Management

P84 **ASCA Business Unit** 

P88 **Biologics Unit** 

P92 Clinical Safety & Pharmacovigilance Unit

## Communication with Stakeholders

The Daiichi Sankyo Group responds to a wide range of requirements from society, including those for responding to unmet medical needs. To respond to requests from society that are constantly changing along with rapid changes in economic, geopolitical and global environmental changes, we believe that, for sustainable corporate activities, it is crucial to timely understand the changes through dialogues with various stakeholders.

#### Basic Policy

The Group specifies "We maintain productive, positive and professional relationships with our stakeholders" in Article 2 of the Daiichi Sankyo Group Corporate Conduct Charter, and "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" in Article 3.

Furthermore, the Group specifies "We actively, effectively and fairly disclose Company information to the public and engage in an open and constructive dialogue with a wide range of stakeholders" in Chapter 2 "Society" of the Daiichi Sankyo Group Employee Code of Conduct.

#### Relationship with Stakeholders

In order for the Group to sustainably grow and create corporate value in the mid-to-long-term in society, we recognize that it is important to communicate with various stakeholders, including patients and their families, healthcare professionals, shareholders and investors, business partners, employees, local communities and the natural environment.

In the current 5-year business plan, we aim to "Create Shared Value with Stakeholders" as the fourth strategic pillar. We will promote initiatives for creating shared value with patients, shareholders and investors, society and employees.





#### Stakeholde

Patients and The

and Healthcare Professionals

Shareholders an

Business Partne

Employees

Jatural Environn

ers	S
	<ul> <li>Information provision activities aiming to Through medical representatives (MRs) activities on our pharmaceuticals to and for various health information, we provide accurate, timely and wel pharmaceuticals including useful information for</li> </ul>
Families	<ul> <li>Response to inquiries from patients and We receive approx. 6,000 inquiries per month a patients and healthcare professionals in Japan. accurate information in a timely manner by usin</li> </ul>
	<ul> <li>Communication with patients and health COMPASS ("Compassion for Patients" Strategy in Japan with opportunities for direct communic as bedside visits at hospitals and lectures to co</li> </ul>
	<ul> <li>Creation of high quality information</li> <li>We aim to be a partner of our stakeholders that medicinal value of our pharmaceuticals and disc</li> </ul>
	<ul> <li>Medication support aiming for patients' We have provided medication support such as which treatment continuation rate is said to be taking a medicine by inhaleing.</li> </ul>
	Stable supply of investigational drugs th the pandemic We have also engaged in new initiatives such a patients can receive or be administered investig facilities through collaboration with medical inst
	• Formulation, labeling and packaging sch medication errors We have improved the distinguishability of table increased efforts to prevent medication errors b preventing patient's family members, especially medicines such as anticancer drugs.
Investors	<ul> <li>Active IR activities         In addition to quarterly held financial results pre (R&amp;D briefing), we proactively hold seminars for     </li> </ul>
Investors	<ul> <li>ESG dialogues with investors</li> <li>We hold dialogues with institutional investors or (integrated reports).</li> </ul>
	<ul> <li>Promotion of sustainable procurement</li> <li>We request our key business partners to conduct their understanding of our Group's view on sustained</li> </ul>
	<ul> <li>Issuance of internal newsletters</li> <li>We issue our internal newsletter "Patio" four time and information to foster a sense of unity groups</li> </ul>
	<ul> <li>A series of town hall meetings hosted by Our CEO engages in direct and interactive comm Company's visions and a medium-term business</li> </ul>
	<ul> <li>Individual development plan</li> <li>We conduct an "individual development plan" in themselves and confirm future careers over the r subordinates</li> </ul>
s	<ul> <li>Operation of Daiichi Sankyo Kusuri Muse We opened the Daiichi Sankyo Kusuri Museum importance of medicine and drug discovery act revitalization of the Nihonbashi area, the number</li> </ul>
	• Efforts for promoting correct understand We are striving to contribute to the enrichment understanding of each of our employees about
at	<ul> <li>Various training on environment</li> <li>We have endeavored to improve employees' aw changes impact on the environment e-learning p employees to increase environment awareness a Japan. In addition, we have also conducted prof and laboratories.</li> </ul>

Low carbon society action plan information with other industries

#### Specific Initiatives

#### be a reliable medical partner

in Japan, we have provided, collected and communicated information ncare professionals, including physicians and pharmacists. In providing Il-balanced information on the safety and effectiveness of our the enrichment of quality of life of patients and their families.

#### healthcare professionals

and approx. 70,000 inquiries per year about our products from We respond to such inquiries with the utmost respect while delivering ng a call center support system utilizing Al.

#### ncare professionals through COMPASS

y) in the Japan R&D Division has planned and provided our employees ation with patients and healthcare professionals through events such ontribute to realizing "life with smile" around the world.

delivers the best medical solution by generating evidence of high seminating them widely to society.

#### safe and secure medication

a "medication reminder alarm system" for treatment for osteoporosis elatively low, and a "whistle" to check the strength of inhalation when

#### hrough collaboration with medical institutions during

as the establishment of a "Direct to Patients" system under which pational drugs at home or a nearby hospital without visiting clinical trial titutions during the COVID-19 pandemic.

#### nemes for easier-to-swallow medication and prevention of

ets by printing the drug name on both sides of the tablets and by developing outer packaging for PTP sheets for the purpose of small children from accidentally ingesting relatively high risk

sentations or conference calls by the management, and an R&D Day institutional investors after major academic conferences

n ESG topics and meetings with investors using our Value Reports

ct a CSR Self-Assessment Survey every three years in order to deepen ainable procurement and strengthen communication with them.

es a year addressing various topics, such as management information vide.

#### y top management

munication with all employees in Japan and overseas, explaining the plan

Japan to cultivate consciousness of career development by employees mid-to-long-term through dialogues between supervisors and their

#### eum

n in 2012 for the purpose of providing the opportunities to learn the tivities while having fun and for the purpose of contributing to the er of visitors has exceeded more about 140 thousand cumulatively.

#### ling of diseases and disease awareness activities of quality of life of the local community with improved correct

diseases and through disease awareness activities.

areness of the environment through actions such as providing climate programs and holding a contest for artwork open to all the group and providing the COOL CHOICE program for all the employees in essional training for the person in charge of environment in our plants

We have participated in the Environment Committee of the Federation and Low Carbon Society Action Plan Working Group of Pharmaceutical Manufactures' Associations of Japan, promoted its industry-wide initiatives for carbon neutrality, such as planning of industry target, planning and conducting the environment seminar and exchanging

## Improvement of Access to Healthcare

Based on the "Daiichi Sankyo Group Policy on Access to Healthcare," the Daiichi Sankyo Group works to expand access to healthcare with the three activity pillars of "Research & Development," "Availability," and "Capacity Building", and contributes to achieving Goal 3 of the SDGs, "Good health and well-being."





### Reinforcement of Healthcare Foundations in Developing Countries

In developing countries, access to healthcare is restricted due to various factors such as the absence of health insurance systems and healthcare infrastructure, lack of healthcare professionals, and physical distance to medical institutions. The Daiichi Sankyo Group engages in activities to improve access to healthcare in developing countries by understanding the local needs well and working in partnership with Non-governmental organizations (NGOs) with a solid base for local activities.

Capacity Building

https://www.daiichisankyo.com//sustainability/access to healthcare/capability/

### • Mobile healthcare field clinic services in Myanmar

(FY2019-FY2022)

In Myanmar where child and maternal mortality rates are high, we are providing mobile clinic services in collaboration with Plan International Japan, with KPIs such as reducing the under-five mortality rate and improving the maternal checkup rate.



### • Breast cancer and cervical cancer screening camp project in Nepal

(FY2021-FY2023)

In Nepal, where breast and cervical cancers are the most common cancers among women, accounting for 30% of all cancer-related mortality. We are working with AMDA Multisectoral and Integrated Development Services to increase the number of people who receive cancer screening and early detection through the screening camp and educational activities.

### • Capacity building for SRHR and breast cancer/cervical cancer in Zimbabwe (FY2021-FY2024)

In cooperation with Plan International Japan, we are working to improve women's rights and access to cancer screening through educational activities for SRHR\* and breast/cervical cancers and trainings of healthcare professionals.

\* Sexual and Reproductive Health and Rights







## **Continued Initiatives Targeting Rare Diseases**

Daiichi Sankyo works actively on the development of pharmaceuticals for rare diseases with significant social needs, where the number of patients is small and effective treatment is not available.

DS-5141, a nucleic acid drug based on Daiichi Sankyo's proprietary nucleic acid modification technology, is being examined for the treatment of Duchenne muscular dystrophy in phase 1/2 clinical trials in Japan. DS-4108, a drug using the same technology, targets glycogen storage disease type la

\* Tissue non-specific alkaline phosphatase. A membrane-bound enzyme that degrades pyrophosphate.

#### Initiatves to Prevent Antimicrobial Resistance (AMR)

The emergence and spread of antimicrobial-resistant bacteria is a significant global public health issue. It is estimated that the number of deaths due to antimicrobial-resistant (AMR) bacteria will reach approximately 10 million every year between now and 2050 if appropriate countermeasures are not taken now. The Daiichi Sankyo Group has taken measures against AMR bacteria by partnering with external organizations in utilizing its assets acquired through activities in the field of infectious diseases.

In 2019, Daiichi Sankyo signed an agreement to participate in the AMR Screening Consortium led by the GARDP\*. Daiichi Sankyo is the third Japanese company to participate in the

\* Global Antibiotic Research and Development Partnership

## 🔊 Initiatives for Malaria, Tuberculosis, and Neglected Tropical Diseases (NTDs) through Partnerships

The Daiichi Sankyo Group makes the best use of its accumulated scientific findings and global network and promotes partnership-based drug discovery. Collaboration with partners possessing leading edge scientific knowledge around the world brings synergies to initiatives that cannot be completed by the Group alone. This initiative contributes to Goal 17: "Partnerships for the Goals" of SDGs adopted by the United Nations member states.

Daiichi Sankyo has contributed to the Global Health Innovative Technology (GHIT) Fund since its establishment in April 2013. The GHIT Fund is a public-private partnership

## VOICE



Kousei Shimada

Medicinal Chemistry Research Laboratories, Reseach Function

### To Protect People from Infectious Diseases

In response to the spread of COVID-19, we have launched a task force to promote research and development of vaccines and therapeutic agents on a Group-wide scale. In the meantime, we re-recognized the need for a system which can quickly respond to new pandemics and AMR (Antimicrobial Resistance) issues that are expected to occur in the future. To further activate research & development of anti-infective agents, we established the Emerging and Re-emerging Infectious Diseases Research Special Team (EReDS) in April 2021 and started activities. Creating novel drugs is a unique contribution that pharmaceutical companies can make. We will contribute to the development of sustainable society by maintaining the foundation of infectious disease research, passing on internal knowledge and knowhow, and creating novel drugs in the field of infectious diseases while leveraging our group's strength in drug discovery and promoting industrygovernment-academia cooperation.

(GSDIa) and is undergoing pre-clinical studies. The TNAP\* inhibitor DS-1211, which targets pseudoxanthoma elasticum, has been evaluated in phase 1 clinical trials in the United States. A phase 1 clinical trial of DS-6016 (anti-ALK2 antibody) is ongoing in Japan, with fibrodysplasia ossificans progressiva as the target disease.

In the field of rare diseases, we will continue our quest to create innovative pharmaceuticals by using the Company's strength in Science and Technology.

Consortium, which aims to acquire novel compounds with antibacterial activity by using the chemical libraries of the respective companies.

In July 2020, Daiichi Sankyo decided to participate in and contribute US\$20 million to the AMR Action Fund, which was established to support the clinical development of new antibiotics and to realize a sustainable antibiotics market. Through the participation in the Fund, we will promote the development of innovative antibiotics and contribute to the prompt resolution of AMR issues around the world.

originating in Japan and aims to achieve drug discovery for combating infectious diseases in developing countries.

The Group companies are utilizing the partnership through the GHIT Fund structure to undertake a number of projects, including one to explore clinical candidate compounds for the treatment of Chagas disease, which is considered to be one of neglected tropical diseases (NTDs), and another to explore candidate anti-tuberculosis drugs from natural products. In addition to these activities, we have launched two screening projects for therapeutic drugs for malaria.

# Promoting Compliance Management

Thorough compliance is essential for the sustainable growth of a company. Daiichi Sankyo Group is committed to conducting all of its business operations based on the understanding that compliance is more than just adhering to laws, regulations and rules; it involves acting with high ethical standardsand social consciousness appropriate for a life science-oriented company.

#### Compliance Training and Educational Activities

Ongoing compliance trainings and educational activities are indispensable parts of promoting our compliance programs.

In order to promote understanding of compliance, encourage high ethical standards, and cultivate an open workplace environment, we have been conducting small group discussion-type trainings (interactive training) using original training materials in the Company and Group companies in Japan.

Furthermore, we conduct compliance trainings by external specialists on a regular basis for the board members, Members of the Audit and Supervisory Board, Corporate Officers of the Company, and various employees of Group companies in Japan, such as presidents and compliance officers. We also conduct compliance trainings annually for new employees of the Company and Group companies in Japan and newlyappointed managers for each respective position. Employees at Group companies outside of Japan are also conducting compliance training using case studies and e-learning

programs, depending on the circumstances in each region. Furthermore, we are also working on raising compliance awareness throughout the Group, as part of educational activities. For example, we periodically send messages of the Company's CEO regarding the importance of compliance to all the Group companies globally in order to further raise awareness of compliance.



## Using a Compliance Reporting System

From May 2021, we have newly introduced the global hotline as a group-wide reporting channel managed by an outside vendor. While we previously established and operated a compliance reporting system according to the circumstances in each region, we believe that integrating external reporting channels contributes to identifying a breach of compliance throughout the Group better than before and developing more appropriate measures, which results in establishing an open workplace environment.

The global hotline accepts reports and consultation of compliance-related matters 24 hours a day, 7 days a week available in languages of countries and regions where the Group companies are located. We also receive reports and consultation from the outside of the companies as well as from employees on each the Group's websites.

Furthermore, the Company and each group companies in Japan provides reporting channels such as a hotline and/or e-mail system. There are also harassment consultation contact persons for Japan Daiichi Sankyo Group employees in the Human Resources Department, in each business function, and in external organizations.

We have also introduced and operated a system where a compliance officer of an group companies outside of Japan who discovers alleged misconduct of Senior Executive of the company may directly report to and consult with the Company's General Counsel (SEMRP:Senior Executive Misconduct Reporting Procedure).

### Employee Survey on Ethical Culture in Japan

We conduct Employee Survey on Ethical Culture for executives and employees in the Company and Group companies in Japan periodically. In FY2020, approximately 9,500 individuals participated in the survey. We were able to identify the Company and Group companies' in Japan strengths and areas for improvement through this survey by analyzing factors such

### Establishment of Daiichi Sankyo Group Quality Policy

Pharmaceutical companies all over the world have experienced incidents where they have lost their reliability due to quality and/ or compliance issues, which have given a tremendous impact on their management. The Daiichi Sankyo Group has also faced such incident before.

Now that the countries and partners to be managed by Daiichi Sankyo have been rapidly expanding and getting more complicated due to globalization of value chain, increase in number of alliance partners and subcontractors etc., it is necessary to foster a culture of "Quality First" in the Daiichi Sankyo Group and enhance our quality management throughout the Daiichi Sankyo Group to develop a strong organizational base. We established the "Daiichi Sankyo Group Quality Policy" as a superior global policy for all the Daiichi Sankyo Group companies

## Ethical Marketing Practices

In addition to establishing our code in the Company and group companies in Japan and group companies outside of Japan in accordance with the industry code of each country and territory in which we operate based on the International Federation of Pharmaceutical Manufacturers & Associations Code of Practice ("IFPMA Code"), we established the "Daiichi Sankyo Group Global Marketing Code of Conduct" on October 1, 2016, as a global policy with the aim of maintaining a high level of standard when interacting with healthcare professionals, medical institutions, and patient organizations as well as promoting pharmaceutical products.

In this policy, we clearly state that relationships between the Company and each Group company and healthcare professionals must be maintained for the purpose of improving

## VOICE

### Introduction of Global Hotline



The Daiichi Sankyo Group operates the hotline (a reporting channel) to foster an ethical culture in which all employees are encouraged to openly discuss what is right and what is wrong at their workplace.t. The global hotline newly introduced is available to persons outside the Daiichi Sankyo Group as well as employees of the Group companies in Japan and overseas for reporting and consultation in 19 languages, including Japanese and English. The global hotline also centrally manages consultations and inquiries regarding compliance on a global basis, through which we believe that we can identify allegations at the Daiichi Sankyo Group more comprehensively and take appropriate measures. However, we understand that introducing the global hotline cannot be achieved the intended purpose without employees' understanding the importance and fully utilizing it. We will continue our efforts to effectively operate the global hotline by communicating the protection of reporters and consulters as well as the purpose and importance of it to employees.

as the level of comprehension of their mission and compliancerelated policies, compliance implementation, and development of internal systems. We will be conducting such employee survey on a regular basis, and based on the results, we aim to enhance our compliance programs at the Company and Group companies in Japan.

for the purpose of building a system to be transmitted quality information to all levels of the organization in a timely and accurate manner, and to commit management and/or all employees to consistently address quality and compliance issues. By strengthening quality governance and the quality mindset, we will promote that every single employee including executives recognize the responsibility for quality and act autonomously, as well as maintain and continuously improve an effective quality system throughout the lifecycle of pharmaceutical products, from the development stage to launch and termination., which will contribute to the Daiichi Sankyo Group's materiality "Providing a stable supply of top-quality pharmaceutical products," "Providing the highest quality medical information" and "Promoting Compliance Management."

the quality of healthcare, with a focus on providing information on pharmaceutical products to healthcare professionals, providing scientific and educational information, and supporting medical research and education.

In line with the revision of the IFPMA Code in January 2019, we revised the policy, prohibiting the provision of gifts and promotional aids to healthcare professionals, etc. We also prohibit the provision of entertainment, cash, and other personal gifts and stipulates stricter terms and conditions of contract in cases where we pay remuneration to healthcare professionals as well as the appropriateness of the remuneration. In this way, we promote appropriate marketing practices in accordance with the IFPMA Code.

# Promoting Environmental Management

The Daiichi Sankyo Group recognizes that environmental issues, including global warming and extreme weather, are worldwide issues which have impacts on our work and life, and we also understand that climate change is a risk that may affect our long-term business foundations such as, for example, a stable supply of pharmaceuticals. We work to promote environmental management based on these and we believe that doing so contributes to a resilient and sustainable society and helps build long-term corporate business foundations.

### Measures for Climate Change

The EHS Management Policy (FY2021–FY2025) states that we should "Lower the environmental impact of the entire supply chain by conserving energy and resources, or reducing greenhouse gas emissions and waste," thereby promoting environmental management.

To facilitate responsible corporate activities that address climate change, we have set the goal of reducing CO<sub>2</sub> emissions in FY2025, the final year of the 5-year business plan, by 25% compared to FY2015, in order to achieve our long-term CO2 emissions target of 37.5% reduction (a target well below 2°C<sup>+1</sup>) in FY2030 based on the approach of the Science Based Targets initiative (SBTi)<sup>+2</sup>, which aims to help accomplish the goal of the Paris Agreement<sup>\*3</sup> of keeping the average increase in global temperature below 2°C. This CO<sub>2</sub> emissions target is certified by SBTi, and the Company has participated in the Decarbonization Management Promotion Network established by the Japanese Ministry of the Environment and cooperated in the Ministry of the Environment's SBT promotional activities.

In FY2020, the Daiichi Sankyo Chemical Pharma Onahama Plant started to operate a solar power system (3.3 megawatts of power output) in December 2020, which is one of the largest self-consumption power systems in the pharmaceutical industry in Japan. The plant reduced CO<sub>2</sub> emissions by approximately 470 tons in FY2020 and is expected to reduce CO<sub>2</sub> emissions by approximately 1,800 tons per year. The Daiichi Sankyo Europe Pfaffenhofen Plant has also installed power and will start operation in FY2021. The plant is expected to reduce CO<sub>2</sub> emissions by approximately 350 tons per year. We are actively advancing the use of renewable energy overseas in other sites, including Europe and Brazil that have also expanded the use of renewable energy.

Our  $CO_2$  emissions for FY2020 were 182,865 tons (19.4% lower than in FY2015). We have worked on not only "actions to mitigate"  $CO_2$  emissions but also "actions to adapt" to influence

from climate change that is inevitable in the medium- to longterm, including weather-related disasters that have apparently become more and more serious in recent years and in particular, flood damage, etc. which is a serious risk.

If rivers near research facilities and plants of the Daiichi Sankyo Group overflow, the Group companies in Japan could also be forced to suspend operations due to flood damage. Therefore, we are preparing for emergencies through initiatives such as the development of flood control manuals, etc. while assessing potential flooding risk at our research facilities and plants and identifying measures to minimize the most significant damage to property such as transformation units and outdoor facilities and injury.

We will plan for weather-related disasters as part of our business continuity plan to ensure a stable supply of pharmaceutical products.

\*1 A target stricter than the target of 2°C set by SBTi in 2019.

\*2 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.

\*3 A legally binding international treaty on climate change. It was adopted by 196 Parties at COP 21 in Paris, on 12 December 2015.

### CO2 Emissions





Onahama Plant: the onsite solar power system

Promoting Environmental Management

ere. https://www.daiichisankyo.com/sustainability/the\_environment/policy-system/



TCFD TASK FORCE IN CLIMATE-RELATED FINANCIAL DISCLOSURES

We set up a cross-departmental task force in FY2019 and reviewed business risks and opportunities up to FY2030 in connection with the impact of various events arising from climate change on our business activities and "the degree of such risk" and "how much will such risk be mitigated by taking measures." We conducted a scenario analysis and publicized

Climate Change Risks Read more here. https://

### Measures for Environmental Risk

Because our member companies handle various chemical substances, the Daiichi Sankyo Group considers proper management of chemical substances as an important initiative and issue. To prevent air and water pollution, our plants in Japan have established voluntary control standards that are stricter than legal requirements and properly control the emissions at plants and research facilities in Group companies in Japan. Similar, Group company plants outside Japan also regularly monitor their emissions to ensure compliance with the laws and regulations of each country and region.

## Efficient Use of Resources

We have established waste reduction and more efficient use of resources as important issues. Consequently, we seek to save resources through efforts such as the streamlining of resources used in manufacturing processes, the comprehensive separation of unnecessary and waste materials, the reduction of the total volume of unnecessary and waste material, and resource recycling. Whenever possible, we choose waste disposal firms that recycle thoroughly. In response to the continued focus on the problem of plastic waste, we have actively promoted waste recycling and increased the recycling rate of plastic (the percentage of the amount recycled to the total amount of waste generated) from 38.6% in FY2019 to 52.0% in FY2020. Under the current 5-year business plan, we will address the waste plastic problem and promote waste recycling by setting the target of 70% or more of the waste plastic recycling rate as a Materiality KPI. With respect to the use of water, we consider the ability to utilize a sufficient amount of good quality freshwater in the value chain to be extremely important to continue business activities.



### Creation of Environmental Value through Energy Generation



In 2018, we conducted the largest scale construction work of a plant at Onahama Plant involving the construction of new buildings, demolition of existing buildings and renewal of power transformer units at the same time as the launch of the solar power system introduction project. In December 2020, such new solar power system in Onahama Plant started operation while we were advancing transformation to the fields of oncology and bio-pharmaceuticals. We believe that the construction of Onahama Plant contributed to the reinforcement of the Dalichi Sankyo Group's environmental management.

Junichi Takanashi General Administration Department (right) General Administration Department (right)

Yoshiaki Konrai we beli Onahama Plant (left) <sup>as the</sup> Daiichi Sankyo Chemical Pharma Co., Ltd.

the results in FY2020. Furthermore, our climate-related risks and opportunities based on the TCFD recommendations we carried out are reflected in the environmental targets and plans in the current 5-year business plan (FY2021–FY2025), including promotion of the use of renewable energy and measures for flood damage risk, etc. of weather-related disasters becoming more or more serious in recent years as set forth on the left.

We will further improve climate change-related risk analysis and disclose more information in line with the progress of the current 5-year business plan.

\* Task Force on Climate-Related Financial Disclosures

https://www.daiichisankyo.com/sustainability/the\_environment/climate\_strategy/#ancol

With the purpose of assessing the impact of water discharged from operation sites on the ecosystem, in FY2020, we continued to conduct WET testing\* at all plants and research facilities in Japan (seven operation sites). As a result, we confirmed that the discharged water has no serious impact on aquatic organisms in rivers, etc. In FY2021, we plan to conduct annual WET testing as usual and additional testing depending on changes in wastewater load at all of our plants and research facilities in Japan to promote appropriate wastewater management and improve the quality of discharged water.

\* Whole Effluent Toxicity Test. A testing method that utilizes the biological responses of fish, daphnia, and seaweed to determine the total toxicity of discharged water.

While promoting efficient use of water, the Daiichi Sankyo Group has identified, by using the WWF-DEG Water Risk Filter, three plants in total in China and Brazil as being located in high water risk areas. We are paying attention to regulatory trends and making an effort to further optimize water usage in these areas. Specific measures include using recycled water for sprinklers and using rainwater for sanitary water and other daily usages.



#### Waste Generated

Our conventional energy saving initiatives have been focused on reducing energy use. An action by generating energy using a renewable energy system was a new challenge for us, which involved cooperation and collaboration of many related parties.

Based on this experience, we will examine further actions to help achieve carbon neutrality by 2050 and we believe that we can expect to extend the example of Onahama Plant to other plants of Group companies as the model of environmentally advanced plants.

# Promoting the Success and Development of a Diverse Range of People Who Create Our **Competitive Advantages**

The Daiichi Sankyo Group positions its people as its most important asset. We respect diversity and work to realize the mutual long-term growth of the company and the employees who act based on our Core Values of Innovation, Integrity and Accountability. We realize this by encouraging them to have a high level of engagement and contribution.

#### Cultivate Employees with Highly Competitive Skills

We define our human resource management under the Daiichi Sankyo Group HR Management Philosophy, fairly treating employees covered by our Core Values wherever they may be in the world, developing their talent and helping them make maximum use of it. Furthermore, by providing our employees opportunities to work with colleagues globally as well as opportunities for rotational assignments among our locations in different countries and regions to experience different cultures as well as different ways of working and thinking. This will enhance an environment globally in which diversity is respected and in that way, we generate a competitive advantage that benefits our global business activities.

### Representation of a Diverse Range of People Who Create Our **Competitive Advantages**

For the companies comprising the Daiichi Sankyo Group to evolve into a"Global Pharma Innovator with Competitive Advantages in Oncology", the Group needs to keep delivering the values that only it can create, while adapting to environmental changes both inside and outside of the Group. We expect that our employees fulfill their potential, even in such changing environments, and also grow at work.

Based on the idea that our business is built on the growth of our employees, we have sought to provide them with more opportunities to take on challenges in multiple business areas through job rotation. For example, we launched the Create Our Future (COF) project in Japan in 2017 based on the principle of focusing on the success of our employees. In the COF project, we assigned a total of 803 employees to our priority areas, including oncology and bio-pharmaceuticals, over the three years up to April 2020.

On top of this project, we have implemented a Career Development Program (CDP) in Japan, a systematic framework to balance the growth of individuals and the development of the Group, to enhance our career development efforts.

For this CDP program, we have provided our employees in Japan with information they will need in making career choices. including job descriptions, and expected knowledge, work

## **Promote Global Talent Management**

Toward realizing our 2030 Vision, we have proactively recruited and employed qualified talents with broad experiences from both outside and inside of the Group. We have also developed a global talent management program to continue to develop leadership candidates. Specifically, we have identified the key positions required for realizing the management vision/mid-term business plan (a total of 20 positions identified as of April 2021) at the global level, ensuring the visibility of successor candidates and challenges surrounding the successor development. In addition, at other levels of the organization, we are also working to promote talent development measures tailored to employees' individual challenges, such as the provision of opportunities and positions that drive their growth, and the provision of training programs, to secure and retain talent. We have also actively provided international assignments and overseas study

experience and skills required within the various departments, and career path models that provide employees with a clear direction regarding how they can develop their careers and continue to grow into other areas. This is available to our employees in Japan on our internal portal site.

We have also implemented an Individual Development Plan, a self-fulfillment reporting system for Japan employees. The Plan allows employees to have a clear vision of their future career paths over mid-to-long-term, with various experiences gained through work as the driver for their change and growth. The Plan allows employees to identify their advantages and disadvantages through dialogue (interview) with their supervisors and thus align their envisioned career plans with those of their supervisors, and to help foster their awareness of the need to voluntarily forge their careers.

Further, to support individual employees who are voluntarily taking on challenges and are striving to improve themselves through autonomous actions, we have worked to enhance the measure for developing employees who are readily adaptable to changing business environments, including providing courses on specialized skills, training programs for career building for each generation, and the planning of DX related education programs (data literacy basics, data analysis applications) for all employees.

programs to allow future leaders to comprehend global business and expand their knowledge.

Cumulative Number of Employees Newly Seconded from Japan to Group Companies Outside of Japan





Optimizing and Developing Diversified Talents to Create Globally **Competitive Advantages** 

### People Strategy at Daiichi Sankyo, Inc.(DSI)

At DSI, we created the 5-year People Strategy in 2020 to enable and support Daiichi Sankyo's business growth after listening to many leaders and employees as well as external experts. We have been implementing various prioritized initiatives and programs in the 3 areas: JOIN, GROW, and THRIVE. In the area of GROW, our programs for DSI employees include leadership development, manager training, online learning, talent review and a mentoring program.

### Providing employees with growth and learning opportunities to develop global talents and leaders

In order to prepare for the future of our group, we are developing our future leaders who can effectively perform in globalizing business environments. For example, we started an audio program in Japanese called "DS15 (Discovery Station 15)", where employees share ideas and learn from each other, in December 2020. For 15 minutes a day, 4 days a week, dozens of participants in Japan and more-than 80 expatriates at DSI listen to topics on challenges and issues faced by Japanese employees in global and foreign environments including required skillsets, career development, communications issues, and cross-cultural issues.

We also have a voluntarily managed English conversation class 5 to 6 times on average per week for Japan-based employees and expatriates assigned to DSI. It has been named the "Speakers' Corner" where about 30 to 50 people think and discuss useful topics for global management in English, including leadership, communication, team management and mindset. When we started a new "Basic English Class" this year, the 15 Speakers' Corner participants volunteered as teaching facilitators to expand the English learning opportunities for an additional 50+ participants.

We hold a "Learning Forum" in English every month, inviting a DSI-based leader to discuss leadership and management challenges based on their experiences. It is attended by more than 100 employees in Japan and expatriates in the US. For DSI employees, we hold periodic "Bento Club" sessions to introduce Japanese business culture and customs to all DSI employees as well as a mentoring program for those who would like an individual opportunity to learn with a mentor. Finally, we started and plan to expand a "Global Learning Circle" where employees both in the US and Japan can learn from each other in a small group setting.

### Cross-cultural work experiences in globalizing organizations

Our employees who understand the ways of working in Japan and cultural uniqueness of Daiichi Sankyo can and will be very important influencers and cultural driver toward the future Daiichi Sankyo's organizational culture. Work experiences in cross-cultural and global environments, and in particular how each individual spends time during their overseas assignment, also have significant impacts on personal growth. To really globalize, it is important to expand our overseas assignment programs to include more diverse and multi-directional talent assignments across regions and countries.

### Diverse Workforce

At Daiichi Sankyo, our leaders develop their own expertise and strength, embrace curiosity to seek for new challenges, and can create an environment where openness and flexibility can generate new and innovative ideas. Even if you physically work in Japan, or no matter which country you live in, there will surely be an increase in opportunities to lead and work with your team members in different countries or regions. The growth of Daiichi Sankyo as well as our individual employee's growth can occur in parallel as we pursue to collectively optimize the organizational performance through the diverse Daiichi Sankyo workforce around the world.



Koji Ogawa

Corporate Officer Head of US Corporate Division. Daiichi Sankyo, Inc.

Promoting the Success and Development of a Diverse Range of People Who Create Our Competitive Advantages

#### "Be Inclusive & Embrace Diversity"

The Daiichi Sankyo Group companies take a broad definition of diversity, which includes not only nationality, race, gender, age and other protected categories but also varying specialties, approaches, values and lifestyles. The Group companies aim to further drive their growth by nurturing an environment where every one of their employees respects each other and by proactively accommodating a variety of perspectives at work.

### Initiatives to Promote the Active Role of Women in Japan

Based on the newly developed Action Plan for Empowering Women toward FY2025, the Group companies in Japan have worked on a broad range of initiatives for empowering women, including continuing to develop female candidates for managerial positions, supporting work-life balance, and fostering a positive workplace culture.

Since FY2019, we have held career design seminars (online webinars) for female employees in Japan whose careers may be easily impacted by life events, while since FY2020, we have broadened the scope of participants to include all employees in Japan to provide them with opportunities to think about their own career paths with life changes as their drivers.

We also held a meeting in Japan for exchanging opinions about the development of female candidates for management between the Group's management and SWAN, a network of women in managerial positions. From the perspective of fostering a positive workplace culture, through seminars targeted at newly appointed managerial employees, we have been striving to promote the understanding of how an organization can be managed in a manner to appreciate the variety in team members, view these differences as strengths, and thus improve the capability of the organization.

Going forward, in Japan, we will continue to push forward with initiatives based on our action plan to enhance our workplace environment in which female employees can develop their careers over the long term and work energetically.

> Detailed Initiatives and Timeline of the Action Plan for Further Empowering Women in Japan from FY2021 through FY2025

Initiative 1: Proac	tively develop female candidates for managerial positions (Japan)		
April 2021 -	Promote the development of female candidates for managerial positions and associated follow-up measures		
Initiative 2: Imple	ment activities to ensure new career development and provide growth opportunities for women		
April 2021 -	Understand and analyze the current status of career development and growth opportunities for women, consider implementing/implement programs, events, and networking activities that lead to new opportunities for career development and growth for women		
April 2022 -	Consider implementing/Implement measures to ensure career development and provide new growth opportunities for women in Japan		
Initiative 3: Enhar	nce and strengthen the system that facilitates more flexible workstyle and thus leads to continued retention of employees		
April 2021 -	Expand telework, newly establish a system of leave as part of the support for career development, incorporate productivity into personnel evaluation metrics, and implement measures to improve workstyle/the way of taking a leave from work		
April 2022 -	Enhance measures/systems to facilitate flexible workstyle and promote such measures/systems		
By March 2026	Foster a work environment in Japan in which employees feel it's easier to take a leave from work toward the goal that employees taking 18 paid holidays a year by FY2025		
Initiative 4: Opera	ate the personnel management system in Japan in a manner to support employees in balancing work and family		
April 2021 -	Consider implementing/implement measures in Japan to help balance work and family, and continue to encourage men to take parental leave		
October 2021 -	Implement measures in Japan to encourage male employees to share household chores and childcare		
Initiative 5: Foste	r awareness of inclusion & diversity (I&D) at workplace		
April 2021 -	Clearly define and publish I&D policies, and incorporate detailed I&D discussions in a variety of training programs in Japan		
October 2021 -	Hold seminars and e-learning opportunities on I&D		

### Creating a Workplace Environment that Empowers People with Disabilities (Japan)

We set a mid-term policy for the employment of people with disabilities in Japan, and promote such employment at Group companies such as Daiichi Sankyo Happiness (a special subsidiary company that meets the terms of the Act on the Promotion of the Employment of Disabled Persons). Daiichi Sankyo Happiness subdivides and simplifies workplace tasks to enable people with disabilities to be active participants, undertaking work from various other Group companies. In appreciation of these activities, Daiichi Sankyo Happiness was awarded the "Monisu Certification\*" on March 29, 2021, and as a result, is listed as one of the companies that excel in the

## Preparing LGBT-Friendly Environment

We have promoted the understanding of LGBT to employees in Japan and the introduction of a system to support LGBT with the aim of creating a LGBT-friendly work environment. Specifically, we have provided a heads-up about outing\* in the content of training programs, and have revised the internal system so that same-sex partners of Japan employees can be employment of people with physical and mental disabilities on the websites of Kanagawa Labor Bureau and

the Ministry of Health, Labour and Welfare. The employment rate of people with physical and mental disabilities for all the Group companies in Japan stood at 2.33% (vs. the legally required employment rate of 2.3%) as of July 2021.



eligible for support equivalent to those given to legal spouses since October 2020 in Japan. In appreciation of these efforts, we were awarded a bronze prize at "work with PRIDE 2020."

\* Act of revealing a person's sexual orientation or gender identity without the consent of the person.

#### Employee Health and Work Style Reforms

"To Contribute to the enrichment of quality of life around the world," the Daiichi Sankyo Group's purpose, it is essential that we first secure the physical and mental health and safety of our employees. To create a company in which each individual employee can work energetically in the best of physical and mental health and make maximum use of their capabilities, the Daiichi Sankyo Group has implemented a variety of employee health management and working environment related measures.

### Enhancing Health and Productivity Management

Priority measures taken to promote health globally include: 1) implementing measures against lifestyle-related diseases, 2) improving mental health, and 3) building an environment to encourage employees to receive medical checkups.

As for absenteeism (the number of employees who took non-work related accident/sick leave for 30 days or longer), we have worked on measures to improve the health of our employees around the world with the aim to reduce the rate by 20% from the level in FY2019 by FY2025.

### Evaluation Metrics/Targets for Maintaining/Improving Health (Group)

Evaluation metrics		Actual benchmark results	Numerical targets		
		(FY)	FY2021	FY2025	Comments
Number of employees who took non-work related sick leave for 30 days or longer		99 persons (2019)		80 persons	Down 20% from the standard value
Percentage of loss from presenteeism		18.3% (2020)		14%	Down 20% from the standard value
Percentage of individuals with anomalous findings	Blood lipids	40.6% (2019)	No numerical target*	30%	Improved to less than the general average in Japan
	Blood pressure	22.9% (2019)		16%	(based on data provided by KENPOREN, National
	Hepatic function	21.3% (2019)		15%	Federation of Health Insurance Societies, in 2019)
Incidence of accidental falls at work		24 cases (2018)		12 cases	50% lower than the standard value
Percentage of employees dealing with high-stress		4.0% (2020)		3.0%	
Rate of participation in health events		8.1% (2020)	15%	40%	Number of participants in event/all employees
Ratio of conducting specific health guidance		39.6% (2019)	50%	70%	Updated to the aggregated results after the end of the final fiscal year
Smoking rate		16.9% (2019)	13%	8%	0% in FY2030

\* No single-year target is set as improvement is difficult within a short period of time.

### Support for Diverse Work Styles and Work Hour Management in Japan

The Group has continued to make efforts to create an environment in which a diverse range of employees can work comfortably, through initiatives, such as appropriate work hour management, the introduction of flexible working arrangements, the implementation of a telework system for all employees, the introduction of systems for balancing work and childcare/ caregiving/medical treatment and related seminars and discussion meetings. Since FY2020, as the DS Smart Work initiative, we have worked to continuously create additional values and promote meaningful work with a view to improving productivity and engagement of each employee. Through innovating new ways of working, we have sought to create more time, aiming to enable employees to have more time away from work, thereby achieving the promotion of the work-life cycle.

#### A Diverse Range of Work Hour Adjustment Systems in Japan

Work hour adjustment system		Principal application	
1 Fixed time system		Production division	
2 Flex time system		Corporate staff division	
3 Discretionary work system	For planning work	Corporate staff division	
	For specialized work	R&D division	
4 System for work as off-site	orking hours treated	Sales division	
Solution Soluti Solution Solution Solution Solution Solution Solution So	work hour	Those in managerial positions	

To further drive initiatives to help employees maintain/ improve health in Japan, we have established the position of Chief Health Officer (Japan domestic), whereby the Company in Japan, its health insurance association and its labor union have collaborated in promoting health enhancement measures. Within the 5-year business plan, which started this year, we have set specific benchmarks and targets to strengthen a range of efforts toward achieving the plan.

p	Compar	nies	in	Japar	1)
<b>۳</b>	0011100			o ap a.	•,

To prevent employees from working excessive hours, since FY2019 we have put in place a working hours interval system, which requires employees to take at least an 11-hour break between finishing work and returning to work the next day. In addition, in Japan, the Company has set a standard upper limit on the number of work hours since FY2018. This limit applies to all employees, including those under the discretionary work system. The employee labor union and management collaborate together for other initiatives such as providing guidance and implementing work improvements for health management. In FY2020, the total annual working hours at the Daiichi Sankyo Group companies (in Japan) were 1,739 hours, 179 hours shorter than those in the overall industry.

Total An	nual Work	ing Hours			
(Hours)			ni Sankyo (non p companies ir	,	in Japan Overall industry
2,100	2,023	2,026	2,010	1.974	
2,000	•			1,974	1,918
1,900	1,823	1,822	1,804	1 700	
1,800	1.816	1.813		1,762	1,752
1,700	1,010	1,015	1,795	1,729	1,739
1,600 —	FY2016	FY2017	FY2018	FY2019	FY2020

# **Respect for Human Rights**

The Daiichi Sankyo Group established the Daiichi Sankyo Group Human Rights Policy in June 2020. Fundamental to the belief that respect for human rights is at the foundation of the corporate activities, we engage in line with our mission, and are strengthening various human rights initiatives.

#### Establishment of Human Rights Policy

The Daiichi Sankyo Group established the Daiichi Sankyo Group HR Management Philosophy in April 2012. Since then, we have worked to enhance our workplace environment, in which we respect employees' diversity and take their health and safety into consideration. We specify our respect for human rights in the Daiichi Sankyo Group Corporate Conduct Charter revised in April 2019, and the Daiichi Sankyo Group Employee Code of Conduct established in April 2020. In June 2020, the Daiichi Sankyo Group Human Rights Policy was established following the approval of the Company's Board of Directors.

In terms of the Human Rights Policy, as we engage in our corporate activities, we comply with all human rights related laws and regulations, respecting international codes of conduct and fundamental regulations on human rights, including the Universal Declaration of Human Rights. At the same time, the Group also identifies human rights related issues in connection with our business activities from the perspectives of "Responsibilities as a global pharmaceutical company," "Human rights in our supply chain," and "Responsibilities in the workplace."

In FY2020, we started to conduct human rights due diligence\* by setting up an internal team to address human rights

# Implementation of Human Rights Risk Assessment

In FY2019, the Company conducted human rights risk assessment to examine the status of the risk management in five areas (wages, discrimination/inhumane treatment, human rights in our supply chain, human rights of participants of clinical trials, and access to healthcare).

Subsequently in FY2020, a questionnaire survey was conducted for all group companies conducting business operations. In FY2021, we will promote human rights initiative based on the issues from the survey.

## Awareness Raising Activities on Human Rights

In FY2020, in order to raise the awareness of the Daiichi Sankyo Group Human Rights Policy and to create an opportunity for our personnel to think of our human rights initiatives more closely, we provided all the employees of group companies in Japan with e-learning programs for business and human rights under the theme of "Respect for human rights-Toward a sustainable society", and had an attendance of 96.9%.

In addition, in Japan, we held e-learning programs on work-place harassment, understanding of LGBT, and encouragement of men's participation in childcare.

issues. We will continue to make efforts to avoid a negative impact on human rights, which could occur resulting from our business activities.

And from FY2019, the Group has reported the initiatives to prevent modern slavery and human trafficking in our business activities including our supply chain in accordance with the United Kingdom Modern Slavery Act 2015.

\* A framework to assess, identify, prevent and mitigate any actual or potential human rights risks arising from our business activities



#### The Contents of the Questionnaire

Item	Contents			
Dissemination of human rights policies	Status of Human Rights Policy dissemination, Status of implementation of trainings related to human rights			
Address to human rights issues	Forced labor and human trafficking, Child labor, Discrimination, Freedom of association and collective bargaining rights, Working hours, Wage and employment contract, Inhumane treatment, Privacy, Negative impact on local communities, Health and safety, Considerations for human rights in research and development			
Management	Stakeholder engagement, Operation of reporting channels, Status of responsible procurement			

A general compliance training including certain aspects of human rights has been issued within the group companies in the United States, and a training on the German Equal Treatment Act for people managers for group companies in Europe (Germany)

We will continue to conduct awareness raising activities on human rights.

### Respect for Human Rights of Participants in Clinical Trials

The Company has established the Global Policy of Clinical Trials Standards and conducts clinical trials in accordance with global standards, in consideration of the human rights and safety of participants in clinical trials and based on high ethical and scientific standards.

Clinical trials are conducted in compliance with applicable regulations, the Declaration of Helsinki\*1, and ICH\*2-GCP\*3, upon obtaining individual's voluntary will after detailed explanation (informed consent).

The Company conducts all clinical trials after both ethical propriety and scientific validity are confirmed in accordance with the internal review processes. In particular, the Company ensures the first-in-human study is appropriate ethically and scientifically through clinical trial review meetings that include qualified physicians as review members. Furthermore, clinical

## Initiatives for Human Rights in Procurement

The Daiichi Sankyo Group stipulates in Article 2 of the Daiichi Sankyo Group Corporate Conduct Charter that "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," and represents "sustainable procurement" in the Daiichi Sankyo Group Procurement Policy . In the Business Partner Code of Conduct established pursuant to the Procurement Policy, the Group sets our expectations for business partners, that provide us with products and services, to comply with and respect

For Sustainable Procurement

### Promotion of Inclusion and Diversity

In the Group, the Human Resources Department of Daiichi Sankyo is in charge of matters related to the promotion of inclusion & diversity together with Human Resources Department of each group company. The Group takes a broad definition of diversity which includes not only protected categories such as, for example, nationality, gender, race, age and other personal attributes, but also the different specialties and approaches as well as values and lifestyle required for each job. We believe that if all employees of the Group actively accept each other's diversity, they will exhibit their abilities to the greatest extent possible, which, as a result, will contribute to the development of global business and the creation of innovation. Based on this idea, we engage in initiatives to foster a culture of mutual respect among employees.

trials are conducted after an external independent committee (Institutional Review Board / Independent Ethics Committee) also reviews the ethics (human rights of trial participants, etc.) and scientific validity, and approves the conduct of clinical trials.

The company ensures the training of the standard operation procedures aimed for ICH-GCP and clinical trial ethics to people who are engaged in clinical trials.

An independent department of the Company conducts the audit of clinical trial activities and drives remedial actions and preventive measures.

\*3: Abbreviation of "Good Clinical Practice" implementation standard of clinical trials of pharmaceuticals

various international norms, including human rights. Based on this Code, we conduct CSR Self-Assessment Questionnaire Surveys on a three-year cycle, aiming to increase communication with business partners. We conducted the second survey for FY2020–2022. The questionnaire for the survey includes items related to human rights.

Additionally, the Group is working on building a system to understand apparent risks of our business partners by using an external data source, enabling to act for improvement.

Through these activities, we will advance initiatives for human rights in procurement.

#### https://www.daiichisankyo.com/about\_us/responsibility/ethics-compliance/procurement/

As a global initiative, we promote "Creating ONE DS Culture Through Fostering Our Core Behaviors," which is included in the strategic pillars of the current 5-year business plan.

"Be Inclusive & Embrace Diversity" is one of the Three Core Behaviors, which will be embedded across the entire group companies, and means that the Group achieves larger goals through incorporating diverse perspectives into work while valuing each person. As an implementation of the Core Behaviors, we established the Global I&D project to promote inclusion & diversity by facilitating collaboration among representatives of the Group's global bases through regular information sharing.

For specific initiatives for Inclusion and Diversity (I&D), refer to page 77

<sup>\*1:</sup> Ethical principles for medical research involving human subjects.

<sup>\*2:</sup> Abbreviation of "International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

## Japan Business Unit



### Satoru Kimura

Head of Japan Business Unit

Satoru Kimura was engaged in work related to domestic sales of pharmaceuticals after entered the company in 1981. He assumed Representative Director, Senior Executive Officer in June 2021, after serving as Vice President of Kyoto branch, Sales & Marketing Division of Japan Company of the company.

#### Business environment projection and the unit's vision in 2030

Technologies of diagnosis, treatment, and drug discovery are continuously advancing. As digital transformation is accelerating, the environment will change in the next ten years faster than that in the previous ten years. Similarly, the healthcare environment may dramatically change.

However, no matter how much the healthcare environment changes, the basis of our activities is to "contribute to the enrichment of quality of life around the world," which is our purpose. We always aim to be an ethical, trusted, and respectful partner, and continue to contribute to healthcare.

We will strive to contribute to healthcare in Japan as the number one company in Japan by appropriately responding to all the customers' needs including treatment and prevention of diseases and medical cost reduction. For this, we pursue comprehensive business development. This includes the innovative pharmaceuticals business, vaccine business, and the generic business.

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

We believe that one of our strengths in the innovative pharmaceuticals business is trust from healthcare professionals.

We cover a wide range of therapeutic agents such as those for cardiovascular diseases including thromboembolism; lifestyle-related diseases; diseases related to the central nervous system including migraine headache and epilepsy; and diseases related to pain. With the aim of total care focusing on patients, we provide healthcare professionals with useful, thorough, and correct information quickly. As a result, we have continuously been ranked No.1 for MR evaluation conducted by an external organization for years.

In 2020, we launched Enhertu in Japan, and expanded our business to the oncology field. We endeavor to provide doctors with thorough information on not only cancer therapy but also any possible subject such as complication and comorbidity so that they can select the best therapy for each patient. This is the sales approach we are pursuing, and it is what we can do as we have a wide range of pharmaceuticals. Trust from healthcare professionals cannot be gained overnight. We will make efforts to further enhance our sales capabilities so that we can provide higherlevel information, in a timely manner and in a form required, to respond to a wide range of ever-changing needs based on experience in the primary care field we have built. With such efforts, we strive to be the most trusted healthcare partner also in the oncology field.

We aim to achieve a top level of sales in Japan and continue to grow. To achieve this, it is important that we strive to conduct activities to enhance the value of our products including maintaining drug prices to fit the product value as well as revisions of guidelines through evidence generation and dissemination and application of additional indications and dosage forms. In particular, we will collect, analyze, and evaluate unmet medical needs to strengthen the system of generating and disseminating evidence at an advanced level in the oncology field.

At the same time, facing the threat of infectious disease around the world, we recognize that our vaccine business has a large social responsibility. We strive to fulfill the responsibility of stably providing vaccines we produce. In addition, we will contribute to the society by promoting the development of vaccines that protect against emerging and re-emerging infections and developing a vaccine supply system to respond to future pandemic threats. Today, the generic business plays a role in the improvement of the medical insurance system in Japan. We continue to stably provide high quality generic medicines that not only reduce the economic burden of patients but also have features. These include authorized generics and medicines with formulation, labelling, and packaging innovations that are easy to swallow but hard to swallow accidentally. Furthermore, we will continue to provide pharmaceuticals considering patients and their families as well as healthcare professionals.

# **Oncology Business Unit**



Ken Keller Head of Oncology Business Unit

Ken Keller is President and CEO of Daiichi Sankyo, Inc. and head of the Global Oncology Business. Since joining Daiichi Sankyo, Inc. in 2014, he has shifted the structure of the U.S. business to focus on launching multiple oncology therapeutics in the coming years. Through his work with Daiichi Sankyo, and prior to that with Amgen Inc., Mr. Keller has more than 30 years of experience in the pharmaceutical industry. He is known for his inclusive leadership approach and his passion for bringing innovative drugs to patients in need

The Oncology Business Unit (OBU) is committed to achieving Daiichi Sankyo's 2030 Vision to become an "innovative global healthcare company contributing to the sustainable development of society." By aligning our U.S. and European oncology businesses and global oncology functions together under the new OBU in April 2021, we are now one unified team singularly devoted to people with cancer. As we look to become a top leader in oncology - we will do so by launching our three lead ADCs across a dozen indications in 30 countries potentially benefitting more than 50,000 people worldwide by 2025. The field of oncology moves fast; our OBU will allow Daiichi Sankyo to move at the speed in which the oncology field innovates; accelerating our decision making and increasing our agility to respond to the rapid changes we see in standards of care, treatment and diagnoses patterns, and payer dynamics, ultimately making us well positioned to realize the 2030 Vision. Together, and in collaboration with the rest of the organization, the OBU will bring an unprecedented focus to the delivery of our oncology medicines to patients around the world.

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

to their successful growth to date.

We are pleased with the overall adoption of *Enhertu*, as market share continues to grow quarter over quarter. Since our initial launch in December 2019, we have a more robust understanding of how *Enhertu* is being utilized in the real world with experience from approximately 5,000 patients receiving treatment. Our core strategy is to provide a strong support system enabling the appropriate use of Enhertu for adult patients with unresectable or metastatic HER2 positive breast cancer who received two or more prior anti-HER2-based regimens in the metastatic setting, and for adult patients with locally advanced or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen and educating healthcare professionals on the management of interstitial lung disease associated with Enhertu.

Since launching *Turalio* in 2019, both medical oncologists and orthopedic oncologists have been receptive to using it to treat appropriate patients with tenosynovial giant cell tumor (TGCT). Moving forward, we are concentrating our efforts on educating stakeholders about the disease, given it is a very rare disease and awareness has been very low, in addition to the risks and benefits of Turalio. We are also connecting physicians and patients to Sarcoma Centers of Excellence, helping to ensure that these providers are trained and REMS-certified to prescribe Turalio to appropriate patients.

It's important to keep in mind that people are at the heart of our business, whether it is the patients, customers or employees. It's our obligation and responsibility to deliver our medicines to patients and we have an incredible team of people within the OBU and across Daiichi Sankyo working collaboratively to make this happen. Together we will achieve our 2030 Vision.

### Business environment projection and the unit's vision in 2030

Achieving our long-term 2030 Vision and contributing to sustainable growth requires us to work collaboratively within the OBU as well across the organization to deliver on Daiichi Sankyo's global purpose to bring life-changing medicines to patients, customers and society overall. Our ADC pipeline has the potential to transform the current standard of care across multiple types of cancer including breast, lung, colorectal, gastric and more. We know the needs of the oncology community continue to rapidly change - from diagnosis patterns to standards of care. We must continue to evolve and adapt - operating with agility and simplicity - to deliver for our patients and customers. This is what we have done with *Enhertu*<sup>®</sup> and *Turalio*<sup>®</sup> – leading

# EU Specialty Business Unit



### Jan Van Ruymbeke

Head of EU Specialty Business Unit

Jan joined Daiichi Sankyo in 2012 as Managing director, CEO at Daiichi Sankyo Europe GmbH. A medical doctor by education, Jan joined the pharmaceutical industry at Cilag Benelux (a Johnson & Johnson Company) in 1989. After a short period in medical affairs, he moved to marketing and sales. From 1996 he was Janssen-Cilag Hungary's General Manager. At Novartis, from 2000, Jan was county president in South Africa. In 2005 he joined Grunenthal where he worked as General manager Spain and Iberia and as Head of Latin America till joining Daiichi Sankyo in 2012. Throughout his career Jan's focus has been on driving profitable growth by restlessly focusing on customer needs and creating customer centric organizations.

### Business environment projection and the unit's vision in 2030

Historically, Daiichi Sankyo in Europe focused on cardiovascular products which enabled us to become true experts in this area. Based on this wealth of experience, capabilities, and customer understanding, we defined our aspiration accordingly: "We want to be recognized as the benchmark for patient and customer centricity through delivering the best customer experience." Our ambitious goal is to exceed our customers' expectations. We want to achieve this by designing and delivering on customer experience collaboratively. Thus, we will be able to increase customer satisfaction, loyalty and advocacy which will be the driver for sustainable growth and contribute to our company's 2030 vision.

From a European perspective we also appreciate the 2030 vision's focus on our role in society. With environmental, social and access aspects becoming increasingly important, we are keen on contributing our part. Elements are the further reduction of our environmental impact, e.g. by using solar energy at our Pfaffenhofen site or by actively shaping a culture that fosters Inclusion & Diversity to make sure everybody can thrive at Daiichi Sankyo.

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

Becoming the benchmark for patient and customer centricity requires us to constantly learn and adapt. We must evolve together with our customers and always be aware of their needs and current and future challenges. This requires us to change our mindset and to constantly ask ourselves whether we are still on the right track. While not everything we do is and will be digital, digital capabilities will nevertheless help us to tackle these challenges.

Digital tools offer enormous opportunities, e.g., based on data analytics we can better tailor our offers. By gaining a deeper understanding of what our customers require to make the right decisions for their patients. we are better able to use the limited time we have with them. The pandemic served as a catalyst for this development. We established a Digital Excellence group in our Specialty business which focusses on exactly this: how can we use digital solutions to better understand and address customers' and patients' needs.

Part of this journey also includes changing to a bespoke omnichannel go-tomarket model for us to offer a unified customer experience.

Our cardiovascular portfolio is also an opportunity since it allows us to create synergies at customer level and be recognized as a partner of choice.

In addition, this portfolio approach helps us to be more efficient. While our anticoagulant Lixiana<sup>®</sup> (edoxaban) is advancing in its life cycle, we can put our capabilities and capacities to very good use with Nilemdo<sup>®</sup>/Nustendi<sup>®</sup> (bempedoic acid/ bempedoic acid with ezetimibe). Applying our resources across our cardiovascular portfolio, thus increasing return on investment, allows for reinvestments into other growth areas and future opportunities for further sustainable growth of the entire company.

All of this is only possible with the best people. Only people who are engaged, inspired, and dedicated will be able to deliver the best customer experience to fully realize the potential of our current product portfolio - people with the right mindset, values, and behaviors with an emphasis on commitment to customers and a collaborative and agile way of working, as well as empowerment and diversity. Attracting, retaining, and developing this talent is key for the success of our Specialty business in Europe.

# ASCA Business Unit



### Kiminori Nagao

Head of ASCA Business Unit

Kiminori Nagao assumed President of ASCA Company in April 2021. He has been engaged in work for development of new drugs since joining the company in 1988. As the Vice President of Development Division, his previous job, he promoted development of new drugs globally including Japan and Asia. For two years from 2014, he was in charge of clinical development and regulatory affairs of Asian countries except for Japan

patients as quickly as possible.

America.

\* VBP: Volume-Based Purchasing/Procurement. A policy of price reduction on drugs including generic drugs of which the government confirmed equivalence

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

Recently, however, as there is a large impact from countries' policies of drug price control, business transformation and continuous launches of new products are required. To respond to this, we have been working hard to establish the system and basis in each country for the oncology business which is expected to be our growth engine and expand our presence. We aim to launch new products in China within two years after their launch in the U.S. by accelerating the development in China. For this, we will reshape the development function in China and enhance our collaboration with related functions. We also aim to expand our footprints to deliver oncology drugs to more patients as guickly as we can.

We will maximumly expand business with a focus on appropriately capturing changes in each of the market; enhancing our strength, relationships between Daiichi Sankyo and stakeholders; and using digital and smart marketing. In addition, we will strengthen the business platform of each group company through measures such as licensing-in the products both in the primary care and oncology fields considering the portfolios as well as improving the efficiency of promotional activities. In China, as there is a significant impact from VBP, a certain degree of the decrease in sales and profits of the products selected for VBP might be unavoidable. We will try to enhance sales and secure profits by selecting appropriate sales channels and customer segments in light of the characteristics of our products and market needs.

During the period under the current 5-year business plan, we continuously focus on primary care business where the products like Lixiana are major contributor to the ASCA business. At the same time, we intend to make substantial investment in the oncology business so that it can expand the business in the ASCA regions in 2026 and beyond. Further, we make our best efforts to contribute to Daiichi Sankyo's 2030 vision by continuously uncover unmet needs in each country and responding to those needs.

### Business environment projection and the unit's vision in 2030

There are situations that the policies of drug price control are strengthened for products including long-listed products since the national health insurance finances is under pressure in the countries in Asia, South & Central America (ASCA). Such policies include VBP\* in China. On the other hand, the oncology market in the ASCA

countries is expected to grow significantly. Especially, there is a possibility that China becomes the largest market. We aim to "contribute to the enrichment of quality of life around the world," which is our purpose, by delivering our oncology products to more

We will strive to grow Daiichi Sankyo's presence globally by continuously launching the new products in the primary care and oncology fields, and by increasing the market share of *Lixiana*. We aim to double our sales and profits in the next ten years to strengthen the business of Daiichi Sankyo in Asia and South & Central

ASCA Business Unit is responsible for export business for our partners as well as our own business activities of seven group companies in China, Taiwan, South Korea, Thailand, Vietnam, Hong Kong, and Brazil. Every country has a different environment but each of the group companies has secured favorable sales and profits even after patent expiration of the products through their professional promotional activities with strong brand awareness in the primary care business. As a whole, the unit has steadily grown since its establishment in 2010.

## American Regent Unit



### Paul Diolosa

Head of American Regent Unit

Paul assumed the role of President and CEO of American Regent, Inc. in April 2021. Paul has spent the past 13 years committed to implementing significant investments in the company's facilities, equipment, people, and practices, including a state-of-the-art manufacturing expansion with a capacity to help millions of patients. His leadership in modernizing manufacturing operations led to promotions of increasing responsibility since he joined the company in 2008. Prior to joining American Regent, he served as Director of Engineering at Altana Pharmaceuticals for 10 years.

### Business environment projection and the unit's vision in 2030

American Regent, Inc. (ARI) employs over 1,150 people in New York, Ohio, Pennsylvania and Altkirch, France. We are a leading injectable medication specialty pharmaceutical company. The company has a long history of supplying a variety of drugs including branded IV iron, high quality injectable generics, and veterinary medicines, primarily to the U.S. marketplace. ARI will continue to strive for year-overyear revenue growth. Growth will be a multi-faceted approach, including continued focus on strong compliance, generic complex development, international expansion, portfolio optimization for CapEx utilization, Animal Health business growth and partnership through business development and M&A. Most importantly, success will be driven by strong compliance, cGMP focus, a culture of teamwork/collaboration, employee focus and care for patients.

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

ARI's product portfolio is comprised of an iron injection franchise with two leading products, Venofer<sup>®</sup> and Injectafer<sup>®</sup>, for the treatment of iron deficiency anemia, a generic injectable franchise with a portfolio of difficult-to-manufacture, sole-sourced, and competitively differentiated products, and a rapidly growing branded Animal Health injectable franchise. Our largest challenge is patent expiration of Injectafer in 2028 with a mitigation strategy of extending through the indication of Heart-FID clinical trials.

Taking advantage of our capabilities to develop difficult-to-manufacture and complex products, we continue to expand our portfolio of competitive products. Our broad portfolio of more than 30 marketed products is constantly evolving to meet our customers' needs and stay ahead of the dynamic generic marketplace.

The iron injection franchise focuses on two products: Venofer, which is used to treat iron deficiency anemia (IDA) resulting from chronic kidney disease, and Injectafer, which is indicated to treat IDA resulting from chronic kidney disease, as well as from various other causes, but cannot be used in patients undergoing dialvsis.

Due to its ability to treat a wide range of conditions and the convenience of being able to completely dose patients in only two administrations, Injectafer has enjoyed a rapid growth in market share since it was launched. To achieve further growth, Injectafer has increased its voice to meet GI and OB/GYN customer needs and continued awareness among dissatisfied oral iron patients.

These two products boast a combined share of the U.S. iron injection market of more than 70%, making ARI the undisputed leader in this market. With regard to life cycle management and expanded indications, Injectafer is currently enrolling a HEART-FID clinical study. This study will assess the efficacy and safety of iron therapy using Injectafer relative to placebo in treating patients with heart failure, iron deficiency, and a reduced election fraction.

ARI manufactures, markets, and supplies generic injectable products in vial and ampule presentations. The company has been launching new products continuously and successfully to achieve sustainable growth. ARI is focused on product development and successful submission of multiple supplemental and new drug applications in FY2021 and beyond, targeting a minimum of 5 filings and 5 product launches per year. The significant capital investment in plant manufacturing capacity to become one of the top suppliers in the U.S. generic injectable market for vials, and we will soon be introducing pre-filled syringes.

ARI's Animal Health franchise is anchored by Adequan<sup>®</sup>. Adequan<sup>®</sup>i.m. which is recommended to treat degenerative joint disease (DJD) in horses. Adeguan<sup>®</sup> Canine is recommended for the control of signs associated with DJD and is the only FDAapproved disease-modifying osteoarthritis drug (DMOAD). Future growth opportunities for this franchise have been secured with the internal acquisition of the Daiichi Sankyo Altkirch API manufacturing facility, currently undergoing investment to increase output. Studies are being planned to provide data to support subcutaneous injection for feline and canine. Successful generation of data will allow for ease of home injection by pet owners, increasing use and patient population. With 190 million cats and dogs in the United States and a 20-50% arthritis rate, there is enormous potential for growth. We will also plan on introducing a Chymase inhibitor injection for rash/itchy skin and Ephisol for improved circulation in horses.

American Regent is proud to be a Daiichi Sankyo company, providing innovative care for patients.

## Daiichi Sankyo Healthcare Unit

### Katsuhiko Yoshida

Head of Daiichi Sankyo Healthcare Unit

Katsuhiko Yoshida entered Fujisawa Pharmaceutical Co.,Ltd. in 1983. He assumed Representative Director, President of Daiichi Sankyo Healthcare Co., Ltd. in April 2019, after serving as a Director and head of Corporate Strategy Division of Zepharma, and as a Corporate Officer and Head of Corporate Strategy Division of Daiichi Sankyo Healthcare Co., Ltd..

The way we live and work will be changed within 10 years as population aging is advancing along with the declining birthrate as well as rapid progress of technology typified by AI and IoT. The relationships with other countries including Asian countries are getting closer and closer in business and culture. Today, at the same time, as natural disasters caused by global warming rage, response to the environmental crisis is the whole premise of every corporate activity. Even in the era of drastic changes, our mission-contribution to health and beauty-has never changed at all. We endeavor to help people of every generation increase their quality of life in the era of 100-year lifespan through our creative products and information. In addition, we will make efforts to protect the environment for future generations and contribute to achievement of a sustainable society where life is respected. As a consumer healthcare company based in Japan, we will continue to take on challenges.

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

strategies. 1. Domestic in-store sales: Aim to win the top share in our targeted OTC markets (excluding sales of tonic drinks) and enlarge our principal brands in the functional skincare and oral care markets.

2. In-house mail order: Expand skincare business and strengthen expansion into the life improver field. 3. Overseas business:

Accelerate the growth of our China business through enhancement of collaboration for cross-border e-commerce and products lines. For domestic in-store sales, we will foster following brands into a mega-brand: Lulu, cold remedy; Loxonin S, analgesic for internal and external use; and Minon, a series of body cleaning and skincare products for people with sensitive skin, as well as focusing salses development of drugs for skin. For in-house mail order, we plan to enhance the line-up of functional foods and OTC drugs as well as the line-up of Rice Force and Brightage, both skincare brands, and Regain, a tonic drug. For overseas business, we will further focus on the China market to build our brand equity and increase awareness of the brand there. In addition, we will make efforts not only to develop products but also to create new services through digital transformation so as to provide customers with more useful information.

The initiative for a sustainable society is one of important challenges in the 5-year business plan. For the initiative, we will implement own measures such as enhancement of environmentally-friendly plastic packages as a consumer company, not to mention that we will involve ourselves in the activities as a member of Daiichi Sankyo. At the same time, as a public organ, we will fulfill roles such as facilitating mutual growth between the company and employees through work, ensuring transparency, and respecting diversity.

### Business environment projection and the unit's vision in 2030

The strengths of Daiichi Sankyo Healthcare include: firstly, marketing capabilities as a consumer company to capture changes in society to stay ahead of consumers' needs, and secondly, research and development capabilities as a pharmaceutical company to generate creative and trusted products. Armed with these two advantages, we provide three categories of products, namely OTC drugs, products for skin and oral care, and life improver, via three channels comprising of in-store sales including drug stores, in-house mail order through our group company, Im Co. Ltd., and overseas markets including the Chinese market.

To ensure sustainable growth, we set a revenue target of 100.0 billion yen in the 5-year business plan toward 2025. Specifically, we are promoting the following

# **Research & Development Unit**



### Ken Takeshita

Head of Research & Development Unit

Ken Takeshita was engaged in research at the University of Tokyo and other universities after earning a bachelor's degree in molecular biology from Harvard University and his medical degree from Yale University. He then joined the pharmaceutical industry and led drug development programs including anti-cancer drugs at several global pharmaceutical companies. He served as Global Head of Development as well as interim Head of Research at Kite Pharma since 2019. He was appointed as Daiichi Sankvo's Global Head of R&D as of April 2021

#### Business environment projection and the unit's vision in 2030

The most important near-term mission of Global R&D unit is to further strengthen the global R&D organization for oncology and maximize the value of the oncology pipeline focusing on 3ADCs. Although the competition in oncology is fierce, there is a large market for oncology drugs in Japan, the U.S., Europe and Asia, and these markets are expected to grow steadily. By launching products that leverage our strengths in ADC technology with promising targets, such as HER2 and TROP2, we will realize our vision of "Global Top 10 in Oncology" by 2030.

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

To become one of the top 10 global companies, we will further refine our global development capabilities in oncology. First, we will systematically build global development footprints in order to efficiently conduct global clinical trials for 3ADCs, centered on Enhertu, which has been approved under the accelerated approval pathways in Japan, U.S. and EU. To date, we have achieved the first step in expanding our Europe development footprint. Furthermore, we will expand our development footprint in China and other countries for the global development of HER3-DXd. In the future, we will expand our development footprint in major regions around the world in a stepwise manner, anticipating the future pipeline following the 3ADCs, including DXd-ADC family, such as DS-7300. With the aim of becoming an unified global organization, we will further enhance our operational efficiency and contribute to the enrichment of quality of life around the world by promptly delivering our innovative pharmaceuticals.

In the oncology area, the standard of care is changing rapidly, and the competition in development is becoming even more intense. We will leverage our strategic partnership with external parties to accomplish global development and deliver our new drugs to patients worldwide. To maximize the value of our 3ADCs, we have been strengthening our internal development capabilities while leveraging our partnerships, including the development platform of our partner AstraZeneca for Enhertu and Dato-DXd, and our strategic CRO coalition with Syneos. We will continue to strengthen our agile global development organization that can flexibly respond to changes in the environment.

We recognize that R&D in non-oncology is also critical for our sustainable growth. It took us ten years to commercialize oncology drugs based on our DXd-ADC technology. As the mission of our research organization, we are actively investigating various modalities and advanced technologies that focus on areas beyond oncology to identify the next pillar for Daiichi Sankyo's growth following the DXd-ADC family. Toward 2030, we will create new pillars of growth by maximizing advantages of our oncology R&D, such as the DXd-ADC family and next-generation ADCs, while also engaging in R&D activities utilizing next-generation modality technologies, such as oligonucleotide therapeutics and gene therapy. We aim to generate innovative medicine that truly transforms standards of care in the rare disease, CNS and other areas where unmet medical needs are high, utilizing advances in translational science and precision medicine to enhance our ability to succeed.

The central nervous system area is a challenging disease area with high hurdles for drug discovery. However, our multimodality strategy, which is one of the strengths of our research, has a potential to create breakthrough new drugs in this area that can transform patients' lives by pursuing targets deemed unreachable in the past. We have an environment that allows us to pursue unique research activities based on out-of-box thinking and our unique medicinal chemistry capabilities, advanced technology platforms and unique applications of translational science and precision medicine. By maximizing 3ADCs and strengthening our global R&D organization, we strive to build a new pillar that will drive our sustainable growth.

## **Biologics Unit**



### Masayuki Yabuta

Head of Biologics Unit

Masayuki Yabuta joined Pharmaceutical Division in Suntory Co., Ltd., in 1985 and has been widely engaged in the production of biologics: developing culture process of biologics, designing a manufacturing plant at the Tatebayashi Plant facility, developing a production method of an enzyme used for HANP production, handling a R&D project with use of overseas Contract Manufacturing Organization (CMO), and so on. He joined the Biologics Technology Research Laboratories in the Pharmaceutical Technology Division of Daiichi Sankyo in 2010. He was appointed as Head of the Biologics Division in 2017 and has held his current position since 2020.

Biopharmaceuticals including antibody drugs have been growing due to their remarkable efficacy. In fact, biopharmaceuticals occupy more than half of the top 10 sales products in the global pharmaceutical market. Accordingly, we expect that antibody drugs including Enhertu will continue to lead the pharmaceutical market as an advanced medical treatment. Furthermore, in recent years, more and more innovative therapies are being developed for diseases that had no treatment yet, thanks to the advanced development of new modalities such as nucleic acid drugs, gene therapy, and cell therapy. Daiichi Sankyo also has been focusing on such fields. Over the next 10 years, it is critical for us not only to maximize the 3ADCs but also to develop next generation biopharmaceuticals that follow 3ADCs as new pillars, including DXd-ADCs, antibody related drugs, and new modalities. In addition, the global COVID-19 pandemic has reminded us of the importance of vaccine development. To respond to this, we will also focus on the development of vaccines by using our biotechnology platform. This will allow us to further promote our purpose, "To contribute to the enrichment of quality of life around the world."

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

The manufacture of biopharmaceuticals includes biological process, which produces complex molecules. This means that each phase of development until commercialization requires a high level of biotechnology. As the molecular structure of biopharmaceuticals greatly affects manufacturing efficiency, it is important to consider the productivity as a drug product at the discovery phase. We believe that creating modalities with excellent efficacy, and also conducting technology research on molecular design and manufacturing methods pursuing good productivity and reasonable cost will become more important.

The Biologics Unit intends to accelerate the product development of biopharmaceuticals by developing our own competitive biotechnology, with which, designing candidate biological products together with the Research & Development Unit, and constructing manufacturing methods in collaboration with the Pharmaceutical Technology and Supply Chain Units. Specifically, while further enhancing the already cultivated technology of antibody design, production cell development and mass production, we will support maximization of the 3ADCs and DXd-ADC from technology standpoint, and at the same time, apply the technology to the next generation antibody therapeutics, gene therapy, mRNA vaccines ,cell therapy and so on. We will take responsibility from molecular design through process development of biopharmaceuticals. Going forward, we aim to contribute to Daiichi Sankyo's sustainable growth from a biotechnology standpoint by creating a unique modality that is expected to be the next pillar following DXd-ADC.

In order to realize these goals, development of new technologies and human resources are essential. In doing so, it is especially important to develop technology with a broad perspective from molecule design to commercialization, and an organization structure is needed where the drug design and production design functions collaborate closely. In addition, it is important to increase the depth of biological researchers and technical experts throughout the entire Daiichi Sankyo Group. We strive to be the unit as well as corporation with world-class biotechnology by mutually connecting and collaborating biotech talents from the entire Group including other units and overseas companies through engaging common tasks and developing human resources while advancing our technology throughout the Group.

### Business environment projection and the unit's vision in 2030

88

# Pharmaceutical Technology Unit



### Hiroto Kashiwase

Head of Pharmaceutical Technology Unit

After joining Sankyo Co., Ltd. in 1989, Hiroto Kashiwase has engaged in research of antiviral agents for twelve years. He earned experience in Corporate strategy and managemen at the headquarters and contributed to the merging into Daiichi Sankyo. After the merger, he was involved in work related to pharmaceutical technology at CMC Planning Department, DAIICHI SANKYO, INC., Luitpold Pharmaceuticals, Inc. (currently, American Regent, Inc.). He assumed the Head of Pharmaceutical Technology Division in June 2019.

### Business environment projection and the unit's vision in 2030

Toward 2030, Daiichi Sankyo has an aim of having a solid position in the global oncology market and a new growth pillar of profits. To achieve this, we need to continuously develop products and modalities that are expected to be the next growth pillars following 3ADCs. The Pharmaceutical Technology Unit plays a role to establish pharmaceutical technologies for commercializing new drugs developed by Research & Development. We will strive to establish technologies for various candidate modalities including next generation antibodies following DXd-ADC, gene therapy, cell therapy, LNP<sup>\*1</sup>, and DTx<sup>\*2</sup>. We will make the most of our knowledge and experience to manufacture and supply investigational drugs in at timely manner, as well as developing stable manufacturing processes to achieve high-quality products. These manufacturing and analysis technologies are transferred to supply chain functions including overseas CMOs.

Another important role we play is to design formulations and packaging that are easy for patients and healthcare professionals to use, and develop relevant manufacturing methods. We have been promoting the development of products and technologies by using the information on healthcare professionals' needs collected by our marketing personnel. In particular, such information has helped develop orally disintegrating (OD) tablets and extended-release formulations of oral narcotic drugs with abuse deterrence. In 2030, also on the oncology and DXd-ADC fields, we will be contributing to our purpose, "The enrichment of quality of life," through craftspersonship based on the Patient Centric Mindset.

Daiichi Sankyo aims to promote ESG management to ensure sustainable operations and growth. From this perspective, pharmaceutical technology unit especially focuses on environmental matters and strives to promote technological approaches such as improvement of manufacturing processes and analytical methods, selection of materials, to reduce waste and energy.

\*1: Lipid Nano Particle, \*2: Digital Therapeutics

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

Pharmaceutical Technology Unit is required to respond to all of the modalities identified by the Research & Development Unit promptly and flexibly, as we are in charge of the development of manufacturing and evaluation methods for all of the items developed by the company. To achieve this, it is essential to make the most of our experience and intangible assets accumulated through the development of small molecules and ADCs in addition to obtaining new technologies and knowledge. The use of IT tools is a key to success. We will improve business efficiency by using IT tools with the aim of establishing a system where complex business operations can be performed promptly and stably. With IT tools, we will promote research with simulation and modeling, adjust manufacturing and supply of investigational drugs based on accurate and real-time demand information, accumulate and use the regulatory knowledge on various modalities and countries, and strengthening communications globally and locally. In addition to efficiency improvement, we will promote automation with robotics which will enable accumulation of a large volume of data, and use it for new research so that we can sophisticate and deepen new modalities by using our strengths: "Capabilities for deep understanding of the manufacturing processes" and "Capabilities for developing manufacturing process that can control drug quality."



Supply Chain Unit

## Junichi Fukute

Head of Supply Chain Unit

Joined the Company in 1981. Engaged in manufacturing of API (Active Pharmaceutical Ingredient) for 20 years at Odawara Plant and Onahama Plant. Took charge of the project to establish a plant for Loxonin API while working at Odawara Plant. Vice President, Supply Chain Strategy Department in 2005, Vice President, Procurement Department in 2007, Vice President, Supply Chain Technology Department in 2011, Vice President, Corporate **Business Management** Department in 2012, and Vice President, Supply Chain Planning Department in 2014. Corporate Officer in 2016, He assumed the Head of Supply Chain Division since April 2019.

### Business environment projection and the unit's vision in 2030

Sankyo.

typhoons, torrential rains).

Moreover, Supply Chain Unit will aim to achieve a decarbonized society, a circular economy and a society co-existing with nature to address social and environmental issues under the current 5-year business plan and contribute to the realization of a sustainable society by committing to various initiatives for logistics, packaging and facilities such as promotion of use of solar power systems, energy saving and energy generation, biomass plastics.

### Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

characteristics.

In order to maintain and reinforce our strength, represented by "a global manufacturing and supply system enabling launch and stable supply of products suitable for the market in each country," we are advancing transformation by investing our human resources and facilities in manufacturing biopharmaceuticals. In addition, we will promote to increase the mobility of human resources on a global level while advancing development and acquisition of professional talent.

For contribution to the principle of QCD and improvement of Resilience, Supply Chain Unit are emphasizing a mid-to-long term perspective taking global balance into consideration for the purpose of generating profit as well as working on the sophistication of our global supply chain management system that accurately forecasts demand that changes from day to day depending on the progress of development or sales. Particularly, for supply of DXd-ADCs, we have pursued diversification of risks by evaluating production bases based on the two levels - in Japan and overseas and within Daiichi Sankyo and CMOs. We will further reinforce the system "capable of providing a long-term stable supply of high-quality pharmaceutical products around the world in the event of an emergency such as a natural disaster." In addition, in order to achieve Data driven management through DX, we will steadily promote various measures (efficient, quality improved and predictive maintenance of ADC manufacturing) to achieve the smart factory that actively utilizes advanced digital technologies. Through these, we will improve Resilience.

In response to an increase in demand for 3ADCs, including Enhertu and the steady progress of the clinical studies of subsequent DXd-ADCs family, Supply Chain Unit will continue to pursue maximization of our supply capacity and stable supply of ADC products. At the same time, Supply Chain Unit will successfully establish a production and supply system in accordance with the identification and selection of the promising modalities that will become post-DXd-ADC growth drivers of Daiichi

However, in the process of innovation focused on ADC products and post DXd-ADC modalities, we remain consistent with QCD (Q: Quality, C: Cost, D: Delivery) as our base. In addition to QCD, we will position Resilience as an important factor and improve it to address COVID-19 and prepare for future pandemic of new infectious diseases and an increase of risk of large-scale natural disasters (large earthquakes,

For maximization of our supply capacity and stable supply of ADC products, Supply Chain Unit have consistently advanced streamlining of the production system to achieve a seamless system from production of investigational drugs to commercial production in order to ensure a stable supply of high quality products. We will continue to actively invest in production bases all over the world and to promote enhancement of our production capacity and securement of production lines of CMOs to establish a robust global production and supply structure.

Then, for establishment of a production and supply system for the post DXd-ADC modalities, Supply Chain Unit will advance development of a self-manufacturing policy and production system establishment scheme based on individual products'

# Quality Assurance & Regulatory Affairs Unit



### Miyuki Arai

Head of Quality Assurance & Regulatory Affairs Unit

After joining Daiichi Sankyo in 1985, Miyuki Arai was engaged in efficacy and pharmacological research of cancer immunotherapeutic agents for eight years at a research laboratory. Since 1993, she has been working for more than 20 years in regulatory affairs, including management of marketing authorization holders, development and post-approval regulatory affairs, safety and package insert matters and legality review of advertisement, etc. She was appointed as the Head of Pharmacovigilance Department in 2015, the Head of Safety and Risk Management Department in 2017, and the current position in April 2019.

### Business environment projection and the unit's vision in 2030

Quality assurance of product reliability and regulatory compliance are essential for the realization of the global top 10 in the oncology area and total healthcare services that provide optimal modalities to patients. In addition, given the prospects of environmental changes such as the aging society and entry into the healthcare business from other industries, it will be necessary to provide diversifying healthcare and therapeutic solutions to respond to various medical needs. We, QARA unit, aim to be an organization which contributes to business throughout the product lifecycle by securing reliability in an agile manner by the most efficient process, and by planning/executing seamless regulatory strategies with the relevant departments.

We also strongly desire to be an organization that leads a Quality First culture, in which every single employee recognizes the responsibility for quality, the executives proactively promote quality improvement activities through quality management review, and the entire company provides a stable supply of top-quality pharmaceutical products and highest quality medical information.

## Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

Until now, new products have been expanded to other regions after approved in Japan, the U.S. and Europe, and DS head office has taken the initiative in quality assurance for products and maintenance of approval in cooperation with DS group companies. Going forward, we need to handle more reliably, efficiently, and speedily so as to correspond to the acceleration of global expansion and numerous changes application plans toward maximizing the 3ADCs.

As for the quality assurance system, we will establish a globally unified quality management system for R&D, medical affairs, and pharmacovigilance areas, strategically manage quality issues and implement the PDCA cycle to ensure the reliability of medical information on a global basis. In the GMP area, the management of increasing overseas CMOs will be shared among three regions, Japan, the U.S. and Europe, and promote early detection and resolution of quality events/issues and technology transfer. As the same time, we will strengthen quality governance by comprehensively managing and horizontally deploying such information by DS head office. Furthermore, we will contribute to the stable supply of top-quality pharmaceutical products by introducing a global electronic system that enables real-time identification of process bottlenecks and continuous improvements, and expanding this system to include group companies in the future and making it a more robust quality management system.

As measures to enhance the regulatory affairs, we will visualize the regulatory status of products in each region, establish a process for collection and impact analysis of frequently updated regulatory information. In addition, for the purpose of efficient, effective and comprehensive plan and implementation of the regulatory submission strategy while taking into consideration each country's regulatory requirements, we will not only collaborate with the change management office, but also prepare to establish a seamless collaboration system that breaks down barriers between 3 regulatory affairs departments from development to post-marketing.

In providing optimal modalities to patients, we need to challenge in inexperienced areas, and find out how to leverage our knowledge. We will strive to develop and acquire specialists of our products and establish systems for quality assurance and regulatory affairs.

# Clinical Safety & Pharmacovigilance Unit



### Kento Wada

Head of Clinical Safety & Pharmacovigilance Unit

Kento Wada entered Suntory Limited in 1991 and was responsible for work including new drug development, project management in Japan and the U.S., the launch of subsidiaries in the U.S., and business planning. After transferring to Daiichi Sankyo in 2010, he was engaged in global safety management. In 2015, he planned and promoted the establishment of the Medical Affairs Division in Japan. He assumed the Head of Clinical Safety & Pharmacovigilance Division in April 2020 after serving as Vice President, Pharmacovigilance Department and Vice President, Post Marketing Study Department.

### Business environment projection and the unit's vision in 2030

A good drug must have a high-level quality combined with provision of appropriate information. Any drug carries a risk of adverse events, no matter how effective it is. Daiichi Sankyo strives to minimize patient safety risks by promoting appropriate usage of drugs. For this, we always objectively analyze safety information collected around the world and provide healthcare professionals with necessary information including that on prevention, suppression of aggravation, and measures for adverse events in a timely manner.

Toward 2030, we strive to provide patients with new modality products, which is our new business pillar, while working on the global expansion of oncology drugs including 3ADCs. This will enrich safety information, and at the same time, global risk management will become more diverse and complex. In addition, the speed of development, application, approval will be accelerated, and therefore, timely risk management in development will become more important. Similarly, increasing early approvals will raise the importance of risk management for post-marketing. As well as the above, it is important to maintain and manage safety also for non-oncology products including existing launched products. We need to have more sophisticated and efficient business operations as each country is tightening the required level of safety management.

The 2030 Vision of the Clinical Safety & Pharmacovigilance Unit is "Be a Global unit which contributes to ensuring patient safety by providing a high quality safety information in a timely manner for all products including expanding oncology products and new modality from development to post-marketing." We will strive to conduct proactive safety monitoring and risk management to ensure patient safety throughout the life cycle from development to post-marketing.

## Strengths to be leveraged/enhanced for sustainable growth Strategies/initiatives to address the challenges

We will implement four major strategies to achieve the 2030 Vision. First, we will endeavor to conduct a high level of safety management while responding to diverse and complex risk management. For this, we will identify the best analysis methods and tools and strengthen the function for safety analysis that helps us quickly perform proactive risk analysis and take safety measures in a timely manner. We will also use epidemiological methods to implement advanced safety measures. In particular, we will use data from actual clinical data to understand drug utilization in the real world and check the effectiveness of safety measures. Second, to respond to growing safety information, we will integrate the global process and management of case evaluation so as to increase operational efficiency. Third, we will strengthen the unit's global governance to make global decisions faster on various matters, as well as enhance collaboration with related departments in the development and postmarketing phases. This will help us establish a system with which we can understand challenges and timely and appropriate decision making from both global and local perspectives. Finally, to secure global human resources who can flexibly respond to changes and will be responsible for the next generation, we will facilitate personnel exchanges while enhancing internal human development and promoting personnel acquisition outside the company. We will strive to contribute to ensuring patient safety by achieving these four strategies and providing a high quality safety information in a timely manner.