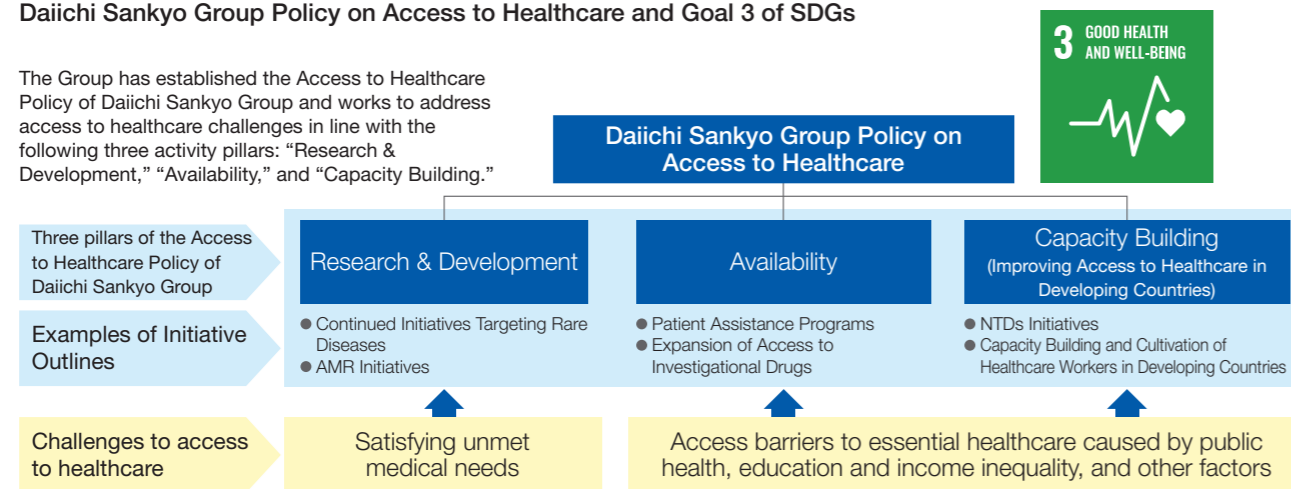


Improvement of Access to Healthcare

In addition to taking actions to address unmet medical needs, one of the important missions of pharmaceutical companies is addressing the problem of insufficient access to healthcare caused by various social factors, such as public health, education, and income inequality. The Daiichi Sankyo Group works on resolving the challenges to access to healthcare throughout its entire value chain in accordance with the Daiichi Sankyo Group Policy on Access to Healthcare. Through efforts to resolve these challenges, we contribute to achieving Goal 3: “Ensure healthy lives and promote well-being for all at all ages” of the Sustainable Development Goals (SDGs).

Daiichi Sankyo Group Policy on Access to Healthcare and Goal 3 of SDGs

The Group has established the Access to Healthcare Policy of Daiichi Sankyo Group and works to address access to healthcare challenges in line with the following three activity pillars: “Research & Development,” “Availability,” and “Capacity Building.”



Continued Initiatives Targeting Rare Diseases

The Daiichi Sankyo Group works actively on the development of pharmaceuticals for rare diseases with a small number of patients and with significant social needs for which no effective treatment is available.

DS-5141, a nucleic acid drug based on Daiichi Sankyo’s proprietary nucleic acid modification, 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 Ia (GSDIa) and is undergoing pre-clinical trials. The TNAP* inhibitor *DS-1211*, which targets pseudoxanthoma elasticum, has been evaluated in phase 1 clinical trials in the United States. The table below lists the orphan drugs currently available.

In the field of rare diseases, We will continue its quest to create innovative pharmaceuticals by using the Company’s strength in science and technology.

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

Orphan drugs

Disease	Drug name
Atypical hyperphenylalaninemia	<i>Biopten</i>
Severe spastic paralysis	<i>Gabalon intrathecal injection</i>
Toxic methemoglobinemia	<i>Methylene Blue</i>
Acute myeloid leukemia	<i>Quizartinib</i>
Tenosynovial giant cell tumor	<i>Pexidartinib</i>

Measures against Antimicrobial Resistance (AMR)

The emergence and spread of antimicrobial-resistant bacteria is now a major global public health issue. Unless appropriate measures are taken now, antimicrobial-resistant (AMR) bacteria-related infectious diseases are estimated to cause approximately 10 million deaths worldwide per year by 2050. The Daiichi Sankyo Group has taken measures against AMR by partnering with external organizations in utilizing its assets acquired through activities in the field of infectious diseases.

In 2019, the Company signed an agreement to participate in the AMR Screening Consortium led by the Global Antibiotic Research and Development Partnership (GARDP). Daiichi Sankyo is the third Japanese company to participate in the Consortium, which aims to acquire novel compounds with antibacterial activity by using the chemical libraries of the respective companies. Last year, we transferred 110,000 strains of clinical isolates in Japan to the National Institute of Infectious Diseases, free of charge. The isolates were pooled in a drug-susceptibility study of *levofloxacin*, a synthetic antibiotic created by Daiichi Sankyo. These isolates are expected to be used widely for research at the Antimicrobial Resistance Research Center of National Institute of Infectious Diseases.

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.

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 the Sustainable Development Goals (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 originating in Japan and aims to achieve drug discovery for combating infectious diseases in developing countries.

The Group is 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.

Capacity Building

Barriers to healthcare access in developing countries are attributable to a wide range of factors, including insufficient healthcare insurance system and medical infrastructure, and shortage of healthcare professionals.

To address these healthcare access-related issues, Daiichi Sankyo has worked since 2011 on vaccination, prenatal and postnatal health checkups and other mobile healthcare field clinic services, cultivation of healthcare

workers, and awareness-raising activities for local residents, among other initiatives, in Cameroon, Tanzania, India, and other regions where medical infrastructure is insufficient. In China, we have undertaken activities for 5 years since 2015 to improve the health and nutritional status of children under 5 years of age through cultivation of healthcare workers and strengthening of the abilities of local residents in impoverished areas where ethnic minorities reside.

In Myanmar, we have worked since 2019 on mobile medical services with vehicles, as well as capacity building and awareness-raising activities for healthcare workers, community health volunteers, and local residents. Due to the impact of COVID-19, scheduled activities such as mobile medical services have been restricted. Nevertheless, community health volunteers trained in the project are undertaking awareness-raising activities for disease prevention and follow-up of malnourished children for local residents while receiving support from remote healthcare workers with communication devices.



A child undergoing health checkup

VOICE For healthy lives for all



Sustainability Promotion Department
Environmental Management & Global Health Group
Osamu Watanabe

Since 2011, in collaboration with the international NGO Plan International, we have carried out mobile healthcare field clinics in Tanzania and a training of healthcare workers and a raising awareness among guardians in China. In Myanmar, we are currently implementing a mobile clinic project with vehicles. The ultimate goal of our activities is to enable local people to take over and develop the activities on their own after the completion of the project. The goal has been achieved in the three countries where the projects were completed. In Tanzania, local residents have built a health center by themselves. In China, awareness-raising activities on maternal and child health and nutrition management, among other activities, have spread even outside the targeted areas.

In order to reduce health disparities in the world, we will remain committed to improving access to healthcare and creating an environment where local residents play a central role in solving their problems on their own.

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 the highest level of ethics and social consciousness appropriate for a life science-oriented company.

Implementation of the Daiichi Sankyo Group Employee Code of Conduct

In recent years, global companies are expected to establish broad-ranging global policies regarding the requirements for the behavior of individuals across their respective organizations. Moreover, global policies must be adhered to and disclosed appropriately outside of a company to show that its global business activities are being conducted with integrity. Replacing the Daiichi Sankyo Group Individual Conduct Principles, we have newly established the Daiichi Sankyo Group Employee Code of Conduct ("ECC") to provide broader, uniform standards of individual behavior expected of the executives and employees of all Daiichi Sankyo Group companies must comply with in April 2020.

We are conducting training programs regularly to increase awareness of the ECC.



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 strong corporate ethics, 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 Japan Daiichi Sankyo Group companies since fiscal 2016. 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 Japan Daiichi Sankyo Group companies, such as presidents and compliance officers. We also conduct compliance trainings annually for new employees of the Company and Japan Daiichi Sankyo Group companies and newly-appointed managers for each respective position. Employees at overseas Daiichi Sankyo Group companies 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 Daiichi Sankyo Group, as part of educational activities in Daiichi Sankyo Group. For example, we periodically send messages of the Company's CEO regarding the importance of compliance globally in order to further raise awareness of compliance.



Using a Compliance Reporting System

We have established and operated a compliance reporting system according to the circumstances in each region. We also implement measures to ensure its effectiveness. It is clearly stated in the internal rules that a person who has reported an actual or potential compliance issues, or who has asked for advice, is protected from retaliation.

The Company has compliance reporting systems in place that can be used to report and consult about legal and regulatory violations, harassment, policy violations, or other internal issues at the Company or Japan Daiichi Sankyo Group companies to the applicable internal Legal Affairs Department, Compliance Department, or to an external law firm in certain special cases. We respond promptly and appropriately to prevent damage from occurring or spreading. 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.

Furthermore, each Japan Daiichi Sankyo Group company provides reporting channels such as a hotline or e-mail system.

In addition, the Company also receives reports or consultation from the outside of the Company through the Company's website. In fiscal 2019, the Company and Japan Daiichi Sankyo Group companies conducted group discussion-type, interactive trainings or online trainings for compliance reporting targeted toward all employees.

Each Daiichi Sankyo Group company outside of Japan also provides reporting channels. For example, Daiichi Sankyo, Inc. (DSI) provides a hotline and web-based channels, managed by an outside vendor, for accepting reports of compliance-related matters 24-hours a day, 7-days a week and consultation about such reports. In

addition, Daiichi Sankyo Europe GmbH ("DSE") provides external channels for accepting reports and consultation from European subsidiaries in each language. DSI and DSE also receive reports and consultation from the outside of the companies on their websites.

Measures to Combat Counterfeit Medicines

In response to the growing threat of counterfeit pharmaceuticals, Daiichi Sankyo is reviewing the sealing materials used in the products manufactured and marketed by us, and working on changing their package specifications. We are also working to evaluate and introduce technologies to prevent counterfeit pharmaceuticals from being marketed. In order to enhance the traceability of pharmaceutical products, the labelling of GS1 codes will become obligatory by 2021, and pharmaceutical companies in Japan will be required to display the codes incorporating data on expiration dates and manufacturing numbers on the sales package unit and the tertiary package unit. Daiichi Sankyo is responding to this obligation, and GS1 codes are now being used for more than 90% of our products. They will be used on all products by 2021.

In European countries, the United States, and other countries where serialization^{*1} is becoming a requirement, we are taking steps to reliably address this in each individual country. Within the United States in particular, we are already responding to serialization requirements based on the Drug Supply Chain Security Act (DSCSA), and we have also completed serialization at sales unit and packaging level.

In addition, we are actively promoting compliance with the GDP^{*2} to increase the assurance of reliability during the storage and transportation of pharmaceuticals. Moreover, Daiichi Sankyo is a member of Rx-360, a consortium of global pharmaceutical companies and suppliers. The

purpose of the consortium is to introduce a global quality assurance system and audit program to prevent counterfeiting. We are also striving to precisely respond in accordance with the regulations and risks in all countries and regions where we operate, in order to combat the global issue of counterfeit pharmaceuticals and are engaging in diligent study to ensure we can safely deliver pharmaceuticals to patients.

^{*1} The assigning of a unique serial number to each sales packing unit for product logistics management (tracking and tracing).

^{*2} Good Distribution Practice.

Enhancing Anti-Bribery & Anti-Corruption System

The laws and regulations against bribery and other forms of corruption in countries around the world are growing stricter with each coming year. Thus, it is becoming increasingly important for companies developing their operations on a global scale to implement initiatives for preventing bribery and other forms of corruption.

We clearly state the expectation that executives and employees may not engage in any bribery and corruption practices in the ECC. Along with the ECC, the Daiichi Sankyo Group Anti-Bribery & Anti-Corruption Policy, which was established in October 2017, specifically prohibits cash payment to government officials and healthcare professionals.

We also continue to conduct trainings for anti-bribery and anti-corruption regularly and bolster our anti-bribery and anti-corruption structure. We take measures against bribery and other unwanted activities in business in high-risk countries in particular. The measures include regular visits to our Group companies in such countries by compliance function in the Legal Affairs Department of the Company.

VOICE Establishment of Ethics & Compliance Group



Senior Director, Ethics & Compliance Group,
Legal Affairs Department,
Daiichi Sankyo Co., Ltd.

Kasumi Fujii

Established in April 2020, the Ethics & Compliance Group of the Company's Legal Affairs Department plays a central role in the compliance promotional activities of the entire Daiichi Sankyo Group. Specifically, the Ethics & Compliance Group serves as the administrative office for the Corporate Ethics Committee and the Global Compliance Advisory Committee in the Company, examines global policies on compliance, conducts Compliance Awareness Surveys, provides compliance training, and responds to hotline reports (and other reporting channels), among other activities. In recent years, it is becoming increasingly important for companies not only to comply with laws, regulations, and other requirements but also to act ethically. In addition to thorough compliance with applicable laws, regulations and other requirements, our Group companies implement a range of compliance promotional activities to encourage all executives and employees to make ethical decisions based on "Integrity." New compliance-related challenges are also emerging as our Group companies' business changes. The Ethics & Compliance Group will work closely with relevant departments across the Company to resolve these challenges and minimize compliance risks.

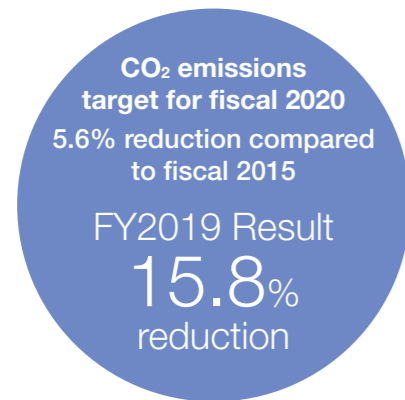
Promoting Environmental Management

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

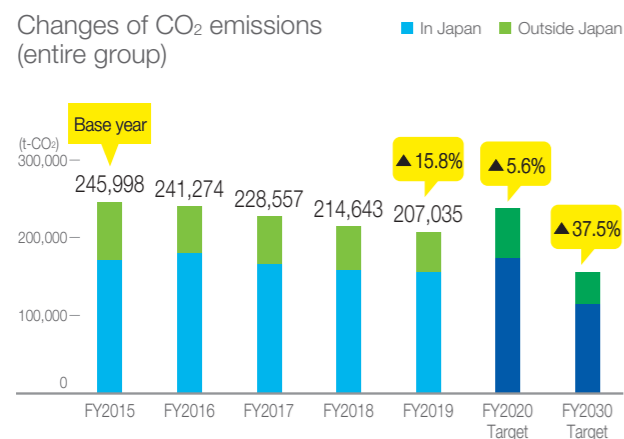
Setting a Target to Reduce CO₂ with Consideration for Long-Term Goals (Reducing CO₂ by 37.5% by Fiscal 2030 Compared to Fiscal 2015)

As a target to reduce greenhouse gases, the Daiichi Sankyo Group has set a long-term target of reducing CO₂ emissions by 37.5% by fiscal 2030 (Well Below 2°C target). This target has been approved by the Science Based Targets initiative (SBTi),* which is consistent with the Paris Agreement. Our target to reduce greenhouse gases emitted through business activities at the Group falls in line with the necessary degree of reduction for keeping the average increase in global temperature below 2°C. In fiscal 2019, we achieved a 15.8% reduction of CO₂ emissions from fiscal 2015, meaning that we have gone beyond our target for fiscal 2020 of 5.6% reduction. We will continue to engage in initiatives for CO₂ reduction in consideration of long-term goals in 2030.

*Science Based Targets initiative (SBTi): An international initiative that encourages companies to set CO₂ 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.



Changes of CO₂ emissions (entire group)



Utilization of Renewable Energy

The Daiichi Sankyo Chemical Pharma Onahama Plant has decided to install a self-consumption solar power system, which is to be completed and put into operation by the end of fiscal 2020. This will be one of the largest self-consumption solar power systems in the pharmaceutical industry in Japan. The system is expected to supply 3.3 megawatts of power for use in the Plant (estimated annual energy production of approx. 4,155 MWh). The use of renewable energy from sunlight is expected to reduce CO₂ emissions by approximately 1,800 tons per year, which is equivalent to approximately 20% of the Plant's total annual CO₂ emissions.

Moreover, operating sites in Europe and Brazil have significantly reduced CO₂ emissions by expanding the use of renewable energy. For example, the Daiichi Sankyo Europe Pfaffenhofen Plant will install a 0.65 megawatts solar power system. We are continuously endeavoring to incorporate renewable energy for overseas operating sites.



Daiichi Sankyo Chemical Pharma Onahama Plant: concept drawing of the onsite solar power system following completion

CDP Supplier Engagement Rating

In recognition of corporate supply chain engagement on climate change issues to reduce greenhouse gas emissions, Daiichi Sankyo has been awarded a position on the Supplier Engagement Leaderboard by CDP,* an international NGO working in the field of the environment.

In fiscal 2019, more than 4,800 companies were evaluated for their efforts to reduce greenhouse gas emissions and lower risks throughout supply chains, and 159 companies were listed on the Supplier Engagement

Leaderboard. Of the 159 companies, 28 were Japanese companies, which included Daiichi Sankyo. We will continue to deepen our understanding of risks and opportunities related to climate change together with our suppliers as business partners. In addition, we will implement initiatives with environmental and social considerations.



*CDP is an international nongovernmental organization (NGO) based in the United Kingdom that addresses environmental issues such as climate change. CDP requests major companies and cities around the world to disclose information on how they are tackling climate change, water management, and other issues, and conducts surveys and ratings. CDP conducts surveys with the support of institutional investors. CDP is one of the most trusted assessment agencies.

ISO14001 Certification

The Group promotes the acquisition of the international standard for the environmental management system (EMS), ISO14001 certification, in particular, at operating sites that use large amount of energy for manufacturing.

We have acquired ISO14001 certification in a multi-site registration that integrates all production sites of Group companies in Japan in one certification scope. Furthermore, of our overseas Group companies, the Beijing and Shanghai Plants in China, the Altkirch Plant in France, and the Alphaville Plant in Brazil have acquired ISO14001 certification. In fiscal 2019, we acquired ISO14001 certification for the Pfaffenhofen Plant in Germany, bringing the acquisition rate of the certification at production sites to 87.0% (on a CO₂ emissions basis). Other plants, which have not yet acquired ISO14001 certification at this moment, are also working hard to get the acquisition.

VOICE Environmental Protection at Our Pfaffenhofen Plant

Pfaffenhofen Plant is the important production site outside of Japan and significantly contributes to our company's global production capacity.

Managing our environmental impact is a key priority for colleagues in Pfaffenhofen. With their support, we have implemented several measures to transform our vision of sustainability into a reality, such as using hydropower, sourcing heating energy through biomass cogeneration and banning the use of plastic in our canteen.

Additionally, the establishment of a formal environmental management system (EMS) according to DIN EN ISO 14001 was a major sustainability milestone. The project, implemented by a cross-functional core team, led by our EHS Manager Martin Schroeder, enables us to systematically monitor our environmental performance using strategies aimed at reducing our environmental impact. Within a year, we met the requirements defined by DIN EN ISO 14001 and received certification by SGS Group in December 2019.

This achievement would have been impossible without the dedication of our colleagues. We are determined to create a green business, set a positive example for society and to inspire colleagues to adopt sustainable lifestyles themselves.



ISO14001 Project Core Team

Daiichi Sankyo Europe GmbH
Pfaffenhofen Plant (Germany)

Promoting Environmental Management

Information Disclosure Based on Recommendations of the TCFD

In May 2019, Daiichi Sankyo expressed support for the Recommendations of the TCFD, which are intended to support companies in the assessment, management, and disclosure of climate-related risks and opportunities.

We analyze, address, and disclose climate-related risks and opportunities in accordance with the Recommendations of the TCFD.



Governance

The Group has established the EHS Management Committee formed of members including group companies in an effort to protect the environment and ensure the health and safety of employees and contribute to the development of a sustainable society while achieving the uniform management and promotion of environment, health, and safety management for which there is a high likelihood of risks occurring. We hold discussions on policies, target setting, and activities related to global EHS management at this committee twice a year.

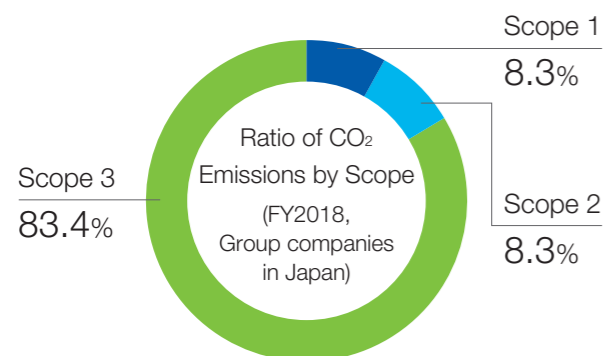
In fiscal 2019, the committee met in July and February to discuss measures for combating climate change, optimizing the environmental management system, and disclosing information in response to the recommendations of the TCFD, among other agenda items.

[Read more here](#)

Corporate Governance
https://www.daiichisankyo.com/about_us/governance/
Environmental Management Promotion System
https://www.daiichisankyo.com/sustainability/the_environment/policy-system/

Strategy

As the impact of various environmental factors increases, we will need to realize a sustainable society if we are to continue our corporate activities. Particularly for



pharmaceuticals, which are life-related products, disruption of the supply chain due to worsening meteorological disasters and a decline in the supply capacity of pharmaceuticals are major risks, both from business and social perspectives. On the other hand, CO₂ emissions are characterized by low direct emissions from business activities (Scope 1 and Scope 2) and high indirect emissions from the supply chain (Scope 3). Thus, we consider transition risks are relatively low. Based on this understanding of the environment, the Daiichi Sankyo Group conducted a scenario analysis and risk assessment in accordance with the Recommendations of the TCFD in order to clarify the resilience of our businesses towards climate change.

Risk Management

As regards climate change risks, a cross-departmental task team was established in fiscal 2019, and workshops on the outline of scenario analysis and the IEA^{*1}/IPCC^{*2} were held for employees from relevant departments. In this way, we enhanced our understanding of what happens to the world when transition risks increase (1.5°C scenario, 2°C scenario, etc.) or when physical risks increase (4.0°C scenario, etc.). In addition, business risks and opportunities through to fiscal 2030 were examined.

^{*1} International Energy Agency
^{*2} Intergovernmental Panel on Climate Change

Risk	
2°C Scenario	Introduction of carbon taxes, increased costs for introducing renewable energy facilities, and reputational risk attributable to insufficient disclosure
4°C Scenario	Supply chain disruption, temporary suspension of operations at company sites, increased air conditioning costs due to rising temperatures, and difficulty in operation due to water withdrawal risk, and reduced productivity of products derived from natural compounds
Opportunity	
2°C Scenario	Measures to achieve Science Based Targets (SBTs)
4°C Scenario	Contribution to diseases that will increase with climate change

Source: 2°C Scenario, IEA WEO 2018 SDS; 4°C Scenario, IPCC RCP8.5

Results of scenario analysis

For each business, the potential impact and resilience (toughness) were clarified, and a comprehensive evaluation was performed, taking into account financial impacts as well as investor perspectives.

Scenario	Key Risk	Event	Potential Impact on Daiichi Sankyo	Degree of Impact	Daiichi Sankyo's Resilience	Business Risk
2°C Scenario (world with advanced transition)	Strengthening policies and regulations related to decarbonization	Introduction of carbon taxes	<ul style="list-style-type: none"> A carbon tax 100 \$/ t-CO₂ in 2030 will result in approx. 2.0 billion yen Increased costs associated with supplier transition risk responses 	Minor	<ul style="list-style-type: none"> Adapt to a decarbonized society and turn the risk into an opportunity by continuing to take a range of measures to achieve SBTs, although the financial impact is not significant in terms of amount 	Minor/ Opportunity
		Increased costs for introducing renewable energy facilities	<ul style="list-style-type: none"> Energy sources are mainly electricity and gas. Renewable electricity is already being purchased in some areas Replacing all electricity used within the Group with renewable energy will cost 0.3 to 0.6 billion yen, but the impact will be minor 	Minor	<ul style="list-style-type: none"> Consider all options for de-fossilization (for all fossil fuels, including gas) 	Minor/ Opportunity
4°C Scenario (world with increasing physical impacts)	Increased frequency and scale of meteorological disasters (such as heavy rains, floods, and typhoons)	Supply chain disruption	<ul style="list-style-type: none"> Increased concerns over the stable supply 	Major	<ul style="list-style-type: none"> Strengthen inventory control to ensure the stable supply in the event of a disaster Purchase from multiple suppliers. Raw materials that cannot be purchased from multiple suppliers are to be examined 	Minor
		Temporary suspension of operations at company sites	<ul style="list-style-type: none"> Key research centers may be flooded Manufacturing bases are unlikely to be flooded even if located close to a river. However, traffic disruption may lead to temporary suspension of operations 	Major	<ul style="list-style-type: none"> Continue to examine ways to strengthen our operating bases and optimize our global bases in light of our business continuity plan Include more training for flood responses/ countermeasures in our emergency drills to enhance resilience 	Minor
	Temperature rise	Increased prevalence of diseases associated with climate change	<ul style="list-style-type: none"> Increased demand for products for malignant melanoma, cardiovascular, respiratory, and tropical diseases 	Major	<ul style="list-style-type: none"> Expand research and development of pharmaceuticals for the diseases Ensure production lines and strengthen inventory control 	Opportunity
		Increased air conditioning costs	<ul style="list-style-type: none"> At our head office, research and development bases, and manufacturing bases, most operations are performed basically indoors, and air conditioning costs increase as the temperature rises 	Minor	<ul style="list-style-type: none"> Continue to improve energy efficiency, although the costs are within an absorbable range and their impact is small 	Minor
	Water shortages	Risk of operations being infeasible	<ul style="list-style-type: none"> Plants in China and Brazil are at greatest water withdrawal risk and are likely to be shut down because of flooding 	Major	<ul style="list-style-type: none"> In the event of plants in China being shut down for a long period of time, consider emergency supply measures, such as using other manufacturing sites and outsourcing manufacturing, in line with trends in pharmaceutical regulations 	Minor
	Biodiversity loss	Reduced productivity of products derived from natural compounds	<ul style="list-style-type: none"> No product has been subject to major impacts to date 	Minor	<ul style="list-style-type: none"> Continue to monitor risks and opportunities for products derived from natural compounds 	Minor

Indicators and Targets

As indicators and targets for assessing and managing climate-related risks and opportunities, the numerical targets specified in the Medium-Term Environmental Management Policy are used. Progress has been made as

planned. Based on the results of this scenario analysis, we will include more aggressive indicators and targets in the next Medium-Term Environmental Management Policy.

Fourth Medium-Term Environmental Management Policy (FY2016–FY2020)

Fourth Medium-Term Environmental Management Policy
Lower the environmental impact of all operations by conserving energy and resources, or reducing greenhouse gas emissions and waste.
Lower environmental risks by continuously improving our environmental management systems in such areas as environmental compliance, pollution prevention, and chemical substances management.
Manage the external risks that have the potential to generate a change in business operations, such as climate change and water risks.
Ensure that operations reflect the need to preserve biodiversity and use ecosystem services sustainably.
Enhance environmental disclosure, improve the reliability of information, and engage in environmental communications with stakeholders.

[Read more here](#)

Promoting Environmental Management
https://www.daiichisankyo.com/sustainability/the_environment/policy-system/

Mutual Growth of Employees and the Company

The Daiichi Sankyo Group positions its people as the 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 who share our Core Values wherever they may be in the world, developing their talent and helping them make maximum use of it. Furthermore, by providing rotational opportunities for our employees among our locations in different countries and regions to experience different cultures and ways of thinking and creating an environment in which diversity is respected, we generate a competitive advantage that benefits our global business activities.

Proactive Employment of Talents from Around the World

In the belief that diversity is the source of organizational learning and competitive advantage, we actively welcome talented person out from around the world for all positions and business fields. When making recruitment decisions, in addition to each individual's career experience, we also evaluate individuals based on the elements required to drive our global organization forward, namely "Intercultural Competency, Respecting People and Values, and Embrace Change." Decisions are made following a review by a team of related parties made up of individuals from different regions and cultures.

Promoting Group Talent Management

In order to continually produce quality leaders responsible for the Group's future, we are promoting Group talent management that focuses principally on the development of next-generation leaders. We identify the key positions required for the realization of management vision/mid-term business plan (a total of 22 positions as of April 2020) at

the global level, ensuring the visibility of successor candidates and challenges surrounding the successor development. In addition, we are also working to promote leadership development measures tailored to employees' individual challenges, such as the provision of opportunities and positions that facilitate further growth, and the provision of training programs, allowing us to secure and retain optimal talents. We have also been actively providing international assignment and overseas study programs to allow future leaders to comprehend global business and expand their knowledge. As of April 2020, 105 individuals are engaged in work outside of Japan.

Promoting Active Participation of Internal Human Resources to Realize Our 2025 Vision: the COF Project

To achieve our 2025 vision of becoming a Global Pharma Innovator with competitive advantage in oncology, and the transformation of Daiichi Sankyo from a company with a business focused principally on the area of cardiovascular to a global company offering innovative pharmaceuticals in

specialty area centered on oncology, we need to continue further allocating our business resources to the areas where we are building our capacity.

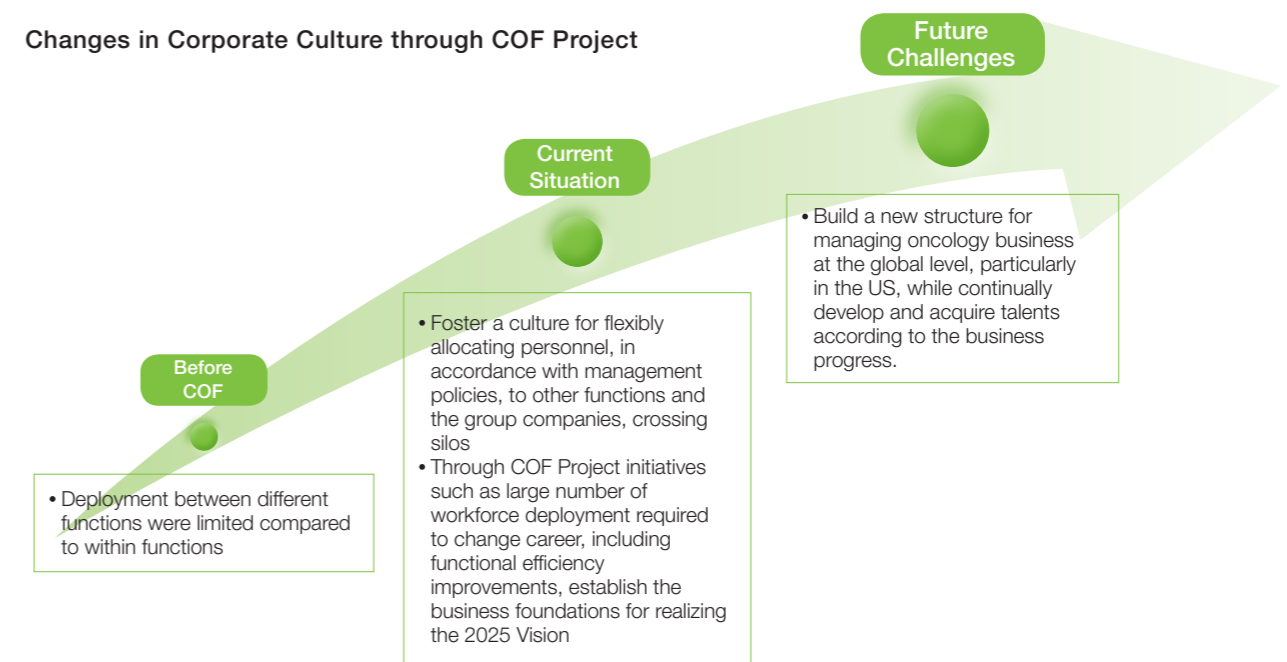
In accordance with the principle of "proactively invest in internal talents," we started in 2017 the Create Our Future (COF) project in Japan, under which we deploy, in a timely fashion, adequate workforce as required, particularly in the areas of oncology and bio-pharmaceuticals, which we are positioning at the core of our future business. We aim through this project to achieve the group's sustainable growth.

Through this project, in order to support employees who will be taking on challenges in new areas, we launched the Career Development Program (CDP) in Japan which, specifically, included support for diverse career development such as dialogue between supervisors and their subordinates to confirm future career over the

medium-to long-term through "Individual Development Plan". CDP also provides information about job description as well as expected work experience, knowledge and skills at each organization, and future career path model via the company's intranet site. In addition, we provide training on the special skills required to demonstrate a performance after moving to a new post as well as comprehensive education systems.

Through the COF project, 803 employees in Japan were allocated to new areas in which the Company is strengthening its capacity over the three years up until and including April 2020. These efforts not only allow us to flexibly deploy workforce in accordance with our management policies, going beyond the silos between functional organizations/group companies, but they also help foster a corporate culture in which employees positively take on new career challenges.

Changes in Corporate Culture through COF Project



COF Project Overview

	FY2017	FY2018	FY2019
Overview	Identify focus areas, formulate workforce plan, and develop deployment policy		Promote actual deployment and develop the CDP*
Project activities	<p>Project launch</p> <ul style="list-style-type: none"> • Share management policies • Top-down deployment of workforce • Middle-up functional efficiency improvements 	<p>Identify focus areas and set numerical deployment targets for each area</p> <ul style="list-style-type: none"> • Formulate detailed three-year workforce expense plans 	<p>Set deployment / education policy</p> <ul style="list-style-type: none"> • Develop deployment policy • Develop education policy
Principal timeline for oncology business	<p>August: Received Breakthrough Therapy Designation from FDA for breast cancer treatment using DS-8201</p> <p>August: Started Phase 2 clinical trials of DS-8201 for treatment of breast cancer</p> <p>March: Received SAKIGAKE Designation from Japanese Ministry of Health, Labour and Welfare for stomach cancer treatment using DS-8201</p>	<p>May: Started Phase 2 clinical trials of DS-8201 for treatment of non-small cell lung cancer</p> <p>September: Started Phase 3 clinical trials of DS-8201 for treatment of breast cancer</p> <p>March: Started global partnership with AstraZeneca for pharmaceutical development and commercialization</p>	<p>September: Application for approval of manufacturing and commercialization of DS-8201 in Japan</p> <p>December: DS-8201 approved for sales in the US</p> <p>January: Launch of ENHERTU in the US</p>

* Career Development Program

VOICE Taking a step forward allowed me to find a new version of myself



Clinical Safety & Pharmacovigilance Division
Pharmacovigilance Department
Safety Planning Group III
Kengo Noguchi

As someone who worked as a researcher for more than 18 years after joining this company, I was not at all expecting to start working in a division for safety management. At first, I was confused and thought "why me?" but I soon started taking it positively, realizing it could be an opportunity for a new career development. In my new position, I am responsible for the safety measures required for post-launch pharmaceuticals in fields such as oncology and infectious diseases. Even in my new role, there are many situations that allow me to leverage the knowledge and experience I built up as a researcher, and this has allowed me to feel how all of our jobs are tied together through science, even across different divisions.

As I was unaware of any work outside my previous department, I first felt a strong resistance to suddenly taking up something new, but after the transfer I realize that, although the approach is different, all of the different divisions are working towards the same objectives and the same goals. In future, I hope that I make use of my knowledge and experience that I have fostered so far, so that I can improve my strengths.

Mutual Growth of Employees and the Company

Promoting Diversity and Inclusion (D&I)

The Daiichi Sankyo Group takes a broad definition of diversity which includes not only nationality, gender, age and other personal attributes, but also the different specialties and approaches required for each job as well as differences in values and lifestyle. We understand that crucial aspect for developing global businesses and creating innovation is that all employees actively accept each other's diversity and exhibit their abilities to the greatest extent possible. As such, we engage in initiatives to foster a culture of mutual respect among employees.

Initiatives to Promote the Active Role of Women

In accordance with the "Action Plan for Empowering Women" produced by Japan Daiichi Sankyo in 2016, we seek to address following objectives; (1) encouraging the professional development of female employees, (2) supporting work-life balance, and (3) fostering a positive workplace culture. We are implementing a wide range of initiatives to address these objectives including providing various types of training and comprehensive systems for supporting work-life balance.

In FY2019, we held a career design seminar in Japan for female employees, whose careers may be easily impacted by life events. More than 200 employees across Japan were provided with an opportunity to discuss their career and life plan, with a view to continuing to make a vibrant contribution in the workplace, as well as in their own goals. We also held discussion meetings in Japan for employees who are working while raising children. In this forum, employees discussed concerns and worries on balancing career and family, and shared ideas for how to overcome these issues. This initiative created a network for easily accessible consultations among the employees.

From the perspective of fostering a positive workplace culture, we have striven to promote understanding in the management of the organization among newly appointed managerial employees so as to appreciate the variety in team members, and to view these differences as strengths, thus improving the capability of the organization.

Going forward, in Japan, we will continue to take initiatives based on our action plan to create a workplace environment in which female employees can develop their career over the long term and contribute in managerial positions or in roles as line managers.

Creating a Workplace Environment that Empowers People with Disabilities

We set a medium-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). We subdivide and simplify workplace tasks to enable people with disabilities to make active participant, taking on work from various other Group companies. In FY2019, the Daiichi Sankyo Group companies in Japan employed individuals with disabilities at a ratio of 2.3% (the legally required employment ratio is 2.2%).

Preparing LGBT-Friendly Environment

We are proactively improving our workplace to become more LGBT-friendly in two ways, firstly through the education required to create an accepting corporate culture and secondly through the provision of appropriate employment conditions. In FY2019, we invited experts from outside company to speak at a seminar for our human resources personnel and provided a poster session on LGBT issues in RD Forum in Japan. In FY2020, we implemented e-learning programs for all of our employees. In addition, for same-sex partners who meet the designated conditions, we plan to apply the same employment conditions, including welfare benefits and various allowances, as those granted to legally married couples.

Employee Health and Work Style Reforms

In order 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, we are implementing various measures relating to employee health management and working environment.

Enhancing Health and Productivity Management

In order to further strengthen our initiatives for the maintenance and improvement of employee health, the Daiichi Sankyo Group is working to enhance health and productivity management under our internal system led by the chief executive officer of EHS management. In order to

provide an environment that allows employees to accurately understand their personal health status and take action to maintain and improve their own health, we are also strengthening initiatives including setting evaluation indices and goals, based on the health guidance and education which help them achieve the goals.

Evaluation Indices and Goals for Health Maintenance and Improvement in Japan

Evaluation Index	FY2018 Results	FY2019 Results	FY 2020 Target
Smoking rate	17.9%	16.9%	15%
Ratio of implementing health-related events at each workplace	74.3%	79.4%	100%
Self-care initiative rate ^{*1}	73.7%	79.5%	80%
Ratio of medical examination	62.4%	63.1%	80%
Ratio of conducting specific health guidance	39.6%	—	50%
Ratio of individuals with abnormal findings receiving checkups at a medical institution ^{*2}	89.0%	85.2%	100%

*1 The rate of self-care initiatives taken by people designated as having high levels of stress as a result of stress checks

*2 The ratio of employees that have received checkups at a medical institution after being instructed to do so in regular checkups

Support for Diverse Work Styles and Work Hour Management in Japan

Through initiatives such as appropriate work hour management and the introduction of flexible working arrangements, and also through events such as seminars and discussion meetings on balancing a career with child rearing/caregiving, the Group is continually working to create an environment which is comfortable for a diverse range of employees to work. From FY2019, we have provided even more flexible working arrangements by abolishing core time in our flex time system. Through innovating new ways of working, we seek to create more time, aiming to enable employees to have more time away from work, whereby achieving "productivity improvement"

and "promotion of the work-life cycle."

To prevent employees from working excessive hours, in FY 2019 we introduced a working hours interval system, which requires employees to take at least an 11-hour break between finishing work and starting their next shift. In addition, the Company has set a standard limit on the number of work hours since FY2018. This limit applies to all employees, including those under the discretionary work system. Labor and management collaborate together for other initiatives such as providing guidance and implementing work improvements for health management. In FY 2019, the total annual working hours in the Daiichi Sankyo Group (in Japan) were 1,729 hours, 245 hours shorter than those in the general industry.

COLUMN

Aiming to create a workplace where every individual employee can play an active role

Thinking about female empowerment in the workplace: Current situation and perspectives for the future

We brought together employees from various different organizations and divisions in Japan to discuss and exchange opinions on empowerment of women in the workplace. We heard views on various topics including each attendee's past personal experience, the changing workplace environment for women, and the workplace environment that the Daiichi Sankyo Group aims to achieve for the future.

Below are some of the attendees' comments:

- It's important to focus on respecting the individuality, not just on visible elements such as gender.
- Rather than insist on adhering to previous ways of working, I want to create an environment in which each individual can play an active role.
- We should get beyond the phrase "female empowerment," to create a society in which all employees can work with energy and passion.
- We should strive to build systems which enhance mutual support available at any time.

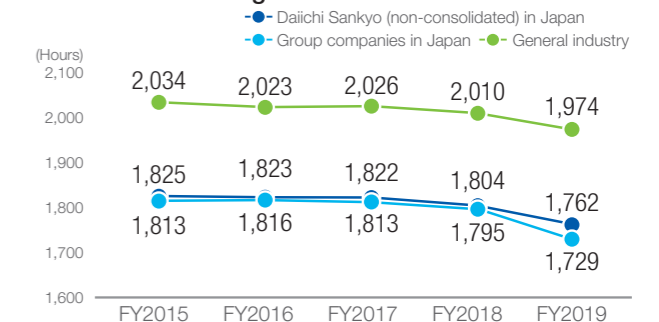


Participants in the meeting to exchange views

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 working hours treated as off-site	Sales division	
⑤ Not subject to work hour management	Those in managerial positions	

Total annual working hours



Evaluation for personnel-related corporate activities

- 2020 Certified Health and Productivity Management Organization Recognition Program (Large Enterprise Category)—White 500
- Kurumin / Platinum Kurumin certification
- Eruboshi Certification
- Award for Outstanding Offices for the Employment of Persons with Disabilities (Minister of Health, Labour and Welfare Award, JEED president's Award)
- 20th Telework Promotion Awards, honorable mention (Implementing Telework category)



Respect for Human Rights

The Daiichi Sankyo Group established the Daiichi Sankyo Group HR Management Philosophy in 2012. Since then, we have worked to improve our workplace environment, in which we respect employees' diversity and takes their health and safety into consideration. In 2019, we revised Daiichi Sankyo Group Corporate Conduct Charter and declared "Respect for Human Rights" in Article 4, clarifying our Group's position. We have also included "respect for the rights of all people and compliance with labor standards" in the Daiichi Sankyo Group Employee Code of Conduct.

Under the belief that respect for human rights is at the foundation of the corporate activities we engage in line with our mission, the Daiichi Sankyo Group is strengthening various human rights initiatives.

Establishment of Human Rights Policy

The Daiichi Sankyo Group Human Rights Policy was established in June, 2020 following the approval of the Company's Board of Directors.

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, we also identify human rights related issues in connection with our business activities from perspectives such as "Responsibilities as a global pharmaceutical company," "Human rights in our supply chain," and "Responsibilities in the workplace."

Going forward, we will continue to build a system for human rights due diligence* based on this policy, keeping up-to-date with human rights issues globally, and will strive to avoid a negative impact on human rights which may occur through our business activities.

*A framework to understand, evaluate, prevent and reduce existent and potential human rights risks in corporate activities

Respect for Human Rights in Procurement

The Daiichi Sankyo Group requests its major business partners to conduct a CSR Self-Assessment Survey every

	Number of companies receiving the questionnaire	Number of respondents (Response rate)	Number of companies we communicated with
Total	381	355 (93%)	20
Sub-total of (1) to (3)	248	230 (93%)	17
(1) Raw Materials*1	119	113 (95%)	11
(2) Licensed Products and Consigned Manufacturing Products*2	99	92 (93%)	2
(3) Manufacturer/ Non-tier 1 Supplier*3	30	25 (83%)	4
Indirect materials*4	133	125 (94%)	3

*1 Raw materials for the pharmaceutical products manufactured by the Daiichi Sankyo Group

*2 Outsourcing to contract manufacturing organization

*3 Manufacturers of raw materials for our products that have no direct contract with the Daiichi Sankyo Group

*4 Purchased goods (facilities, equipment, services) other than those described in (1) to (3)

three years based on the Business Partner Code of Conduct, in order to deepen their understanding of our Group's view and strengthen communication with them. Approximately 350 major domestic and global business partners responded to the first survey. We confirm the initiatives business partners are implementing to protect human rights through this survey, which includes questions related to "labor and respect for human rights."

We also conducted a follow-up survey. In fiscal 2019, we had face-to-face communication with 20 partners to help them gain an in-depth understanding of our Group's sustainable procurement policy and to exchange views for generating ideas and sharing issues. These efforts aimed to promote sustainable procurement based on mutual cooperation.

Respect for the Human Rights of Participants in Clinical Trials

Daiichi Sankyo conducts clinical trials in accordance with the Declaration of Helsinki that defines the standards for ethical medical research involving human subjects, while also adhering to ICH*1-GCP*2 and complying with the applicable regulations of relevant countries. This means that clinical trials are only conducted after obtaining voluntary informed consent from participants. All clinical trials sponsored by Daiichi Sankyo are evaluated in terms of ethical standards and scientific validity based on internal review processes. In particular, we ensure that our first in human study is an appropriate through clinical trial review meetings that include employees who are qualified physicians as review members. Furthermore, clinical trials are conducted after an external independent committee (Institutional Review Board / Independent Ethics Committee) also reviews the same content (human rights of trial subjects, etc.) and approves the conduct of clinical trials. Daiichi Sankyo provides training programs on GCP and Ethics related to clinical trials to people who are engaged in clinical trials. R&D & PV Quality Assurance Department conducts audits of the Company's clinical trial activities to promote appropriate correction and preventive measures.

*1 Abbreviation of "International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use."

*2 Abbreviation of "Good Clinical Practice," implementation standard of clinical trials of pharmaceuticals.

Sales & Marketing

Japan Four Businesses Responding to Diverse Medical Needs

In Japan, with the birth rate declining and the population aging, not only the treatment of diseases, but also medical cost reduction, prevention, self-medication, and other diverse medical needs are being highlighted in line with changes in society.

The Daiichi Sankyo Group engages in 4 businesses focused around one of its strengths, the innovative pharmaceutical business,* the other 3 are the generic business, vaccine business, and OTC-related business. As the No.1 company in Japan, Daiichi Sankyo addresses a wide range of medical needs of society, making comprehensive contributions to medicine in the country.

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

Innovative Pharmaceuticals Business: Sales & Marketing Unit

Japan is an important market for the Daiichi Sankyo Group in terms of its revenue generated on a regional basis. The Sales & Marketing Unit delivers a wide range of innovative pharmaceuticals to patients in Japan, ranging from the anticoagulant LIXIANA and other products in the primary care area*1 to oncology products, among others, in the specialty care area.*2 Taking the perspective of total care centered on patients, we aim to meet the needs of each customer and to contribute to healthcare in Japan by providing relevant information correctly, quickly, and carefully to all healthcare professionals who treat patients with diverse symptoms and conditions.

*1 Drugs mainly prescribed by general practitioners

*2 Drugs mainly prescribed by hospitals/specialists

Strength and Challenge

Based on the BRIDGE's*1 concept of serving as a bridge between patients, their families, and healthcare professionals by emphasizing the connection between people, and providing proper information and products, we develop medical representatives (MRs) activities with the aim of being recognized as a reliable medical partner by everyone involved in healthcare. These activities have been highly evaluated by healthcare professionals. In a survey conducted by an external organization, we have been ranked No.1 for MR evaluation for 8 consecutive years.*2

In order to maintain our sales capabilities, we have developed and improved internal training programs and worked to foster a corporate culture of self-improvement. As a result, all MRs have passed the certificate test for 10 consecutive years. Going forward, we will place a new focus on developing MRs with oncological expertise, considering the increasing importance of oncology products. We intend to encourage MRs to enhance their sales capabilities so that they can respond to a wide range of ever-changing information needs at the right time, in the right way, and in a manner tailored to each and every healthcare provider.

*1 Bright Days Together

*2 Based on survey conducted by INTAGE Healthcare Inc.

Progress of Major Initiatives

Growth of LIXIANA

LIXIANA (edoxaban tosilate hydrate) is an oral anticoagulant developed by Daiichi Sankyo.

With its excellent usefulness and high convenience of once-daily dosing, we work to make a medical contribution and promote the proper use of LIXIANA, with the hope of helping the prevention of thromboembolism in many patients who need anticoagulant therapy.

In fiscal 2020, LIXIANA will overcome the impact of special expansion re-pricing and maintain the No.1 market share as the Group's mainstay product. We will promote and support the growth of OD tablets (orally disintegrating tablets) by leveraging its strength, which is highly regarded for its ease of use particularly in elderly patients.

Growth of Tarlige

Tarlige (mirogabalin besilate) is a domestic peripheral neuropathic pain*1 treatment developed by Daiichi Sankyo. The drug binds strongly and continuously to the calcium channel $\alpha 2\delta$ -1 subunit*2 and exerts analgesic effects.

*1 Pain resulted from damage or dysfunction of peripheral nerves arising from a variety of causes. Typical examples include diabetic peripheral neuropathic pain and postherpetic neuralgia.

*2 The subunit is involved in the development and maintenance of peripheral neuropathic pain



We make a contribution to patients and healthcare professionals by offering the new treatment option in the field of peripheral neuropathic pain. In addition, we promote the proper use of *Tarlige*.

In fiscal 2019, which was the first year of *Tarlige* being distributed, the drug was prescribed to patients who have concerns about peripheral neuropathic pain in everyday life. As a result, we expanded our market share. In March 2020, the limitation on the duration of treatment with the drug was lifted. We will continue to promote the proper use and work to further grow *Tarlige*.

Generic Business: Daiichi Sankyo Espha Co., Ltd.

The Government of Japan is promoting the use of generic drugs to reduce the burden on patients and improve the national health insurance finances.

With the increasing need for generic drugs and high expectations from society, Daiichi Sankyo Espha takes pride in being as an innovator in the domestic generic pharmaceutical industry and to contribute to increasing medication adherence*¹, provides authorized generics (AG)*², or a new standard for generics featuring formulation, labelling, and packaging innovations that are easy to swallow but hard to swallow accidentally. In this way, Daiichi Sankyo Espha works to meet diverse needs of patients, their families, and healthcare professionals.

*¹ The extent to which patients actively follow a medication regimen as prescribed by their health care providers

*² Generic drugs that are the same as their original drugs in drug substances, additives, manufacturing method, and other aspects, and are marketed with permission from brand-name pharmaceutical companies

Strength and challenge

Daiichi Sankyo Espha's AGs are generic drugs that take over the asset of trust accumulated by original drugs in clinical practice and contribute to patients and healthcare professionals. With these AGs, Daiichi Sankyo Espha offers trust and confidence that it has fostered as a manufacturer of new drugs.

With a steady increase in the use of generic drugs in Japan, the role of generic drug companies that serve as an infrastructure supporting healthcare is becoming increasingly important. In addition to ensuring the quality of a large number of products, a long-term stable supply of them is demanded by society.

Daiichi Sankyo Espha operates with the goal of offering generic drugs that are reliable in terms of quality assurance, stable supply, information provision, and economy, which are the most important factors for pharmaceuticals.

Launch of ENHERTU

In May 2020, Daiichi Sankyo launched the treatment for malignant tumors, *ENHERTU* (*fam-trastuzumab deruxtecan-nxki*). *ENHERTU* is a promising new product in the field of oncology.

We make a contribution to patients and healthcare professionals by offering the new treatment option to patients with HER2 positive unresectable or recurrent breast cancer who have been previously treated with chemotherapy (limited to the use to patients who are refractory or intolerant to standard treatments). In addition, we promote the proper use of *ENHERTU*.

Progress of key initiatives

Expand the lineup of oncology drugs

A number of huge seller AGs launched to date (i.e., *telmisartan* family, *olmesartan*, *rosuvastatin*, *silodosin*), as well as subsequent educational activities for physicians and pharmacists, among others, have built up trust of Daiichi Sankyo Espha of AG.

However, the company never remains the same and is currently enhancing its product portfolio to evolve from Daiichi Sankyo Espha of AG to Daiichi Sankyo Espha of AG with competitive advantage in oncology. In accordance with its policy to ensure information sharing with physicians in medical institutions, medical representatives dedicated to medical institutions are assigned to promote the 4 ingredients of *gefitinib*, *bicalutamide*, *anastrozole*, and *tamoxifen*.

Packaging that reduces the risk of accidental ingestion

There are cases where the family members of patients, especially small children, take relatively high risk medicines such as anticancer drugs by mistake. Daiichi Sankyo Espha developed outer packaging for PTP sheets (C-Guard/Child Guard) for the purpose of preventing people from accidentally touching drugs and drugs from falling out, with the added feature that it prevents accidental ingestion by small children.



Vaccine Business

The global 2009 H1N1 influenza pandemic triggered a surge in interest in vaccines to prevent infectious diseases in all countries around the world, including Japan. The recent outbreak of COVID-19 has had a significant impact on the economy and people's daily lives and further intensified the need for vaccines to unprecedented levels.

The Daiichi Sankyo Group is fully aware of its social responsibility as a domestic pharmaceutical company running a vaccine business. With the aim of enhancing the environment surrounding preventive care in Japan and improving health and hygiene as an integral part of the national security, the Group promotes the vaccine business.

Strength and challenge

Some of the vaccines produced by Daiichi Sankyo are used for routine vaccination. Therefore, the Company is responsible for providing society with a stable supply of the required amount of vaccines. Daiichi Sankyo introduces state-of-the-art equipment and improves its production technology and efficiency on a constant basis to maintain a system for stable supply to society. To prepare a pandemic influenza outbreak, we works to build a system to supply necessary vaccines to the public with our proprietary cell culture technology. This is part of our efforts to achieve a sustainable society.

Progress of major initiatives

Stable supply of vaccines

Seasonal influenza vaccines are used for vaccination before an epidemic period in winter. Thus, we need to ship the required amount of vaccines targeting the strains of a virus becoming prevalent on a timely manner. In order to prepare for a "twindemic" of influenza and COVID-19, Daiichi Sankyo works to improve production efficiency through an effort to reduce lead time by utilizing a flexible shift production structure in order to achieve faster shipping and more increased production before an influenza pandemic.



Production system for a possible pandemic

Daiichi Sankyo is working to maintain and manage a system whereby the Company can supply novel influenza vaccines reliably in the event of a pandemic. We have put into place a system capable of supplying vaccines for approximately 23 million people. In addition, we are working on action plans and training in the event of a pandemic.

Promote new vaccine development

Daiichi Sankyo is pursuing research and development of vaccines that will transform the standard of care (SOC) based on its strength in Science & Technology. The vaccines under development include a 3-valent combination vaccine containing three live attenuated viruses of measles, mumps, and rubella (MMR vaccine).

In response to COVID-19, Daiichi Sankyo is actively engaged in research and development of new vaccines by utilizing its new modalities and through collaboration between industries, governments, and academic institutions.*

For details of actions against COVID-19, refer to page 43



Cell and virus culture with large tanks

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

In Japan, although the average life expectancy has been one of the highest in the world, not only the length of life but also its quality matters in this day and age. Taking care of your health on a daily basis to prevent disease, or self-care, leads to increasing your healthy life expectancy. In addition, the concept of self-medication has gained acceptance. Self-medication is a practice of using over-the-counter (OTC) drugs to relieve symptoms of mild cold, fever, headache, menstrual pain, and other similar conditions. This trend is becoming more and more pronounced, and the needs are diversifying.

In addition to OTC drugs^{*1}, Daiichi Sankyo Healthcare handles a wide range of products including skin care cosmetics and oral care products. Among the Daiichi Sankyo groups, Daiichi Sankyo Healthcare is a unit that is closer to customers more broadly. Through the contact and communication with customers, we will continue to create products and services with a high level of customer satisfaction and contribute to improving the quality of life (QOL) of people who wish to be healthier and more attractive.

^{*} Over-the-counter drugs available in pharmacies, drug stores, etc.

Strength and challenge

By leveraging its R&D and marketing capabilities originated from a pharmaceutical company, Daiichi Sankyo Healthcare aims to become a “total healthcare” company beyond the boundaries of the traditional OTC business. To this end, we intend to develop new growth areas and sales channels and expand our business overseas, rather than to remain within the current scope of our business.



Progress of major initiatives

Sustainable growth of OTC business

Daiichi Sankyo Healthcare pursues sustainable growth of OTC-related business by strengthening its mainstay brands including the cold remedy *Lulu*, which has been familiar to many families for many years since its launch in 1951, and antipyretic analgesic *Loxonin*, an OTC drug using *loxoprofen* sodium hydrate developed by Daiichi Sankyo.

Accelerate growth of skin care and oral care business

Skin care and oral care are promising areas for future growth. Daiichi Sankyo Healthcare is working to accelerate the growth of its skin and oral care products. The skin care products include *MINON*, a series of body cleaning products developed based on dermatology for people with sensitive/dry skin, and *Transino*, which contains tranexamic acid developed by Daiichi Sankyo and is the only OTC drug approved for the indication of melasma, a type of discoloration. The oral care products include the medicinal toothpaste *Clean Dental* and the new brand *Breath Labo*.

Expand direct marketing business

The direct marketing business is an important sales channel for delivering our products to more customers. Through the marketing business company Im Co. Ltd., Daiichi Sankyo Healthcare operates its mainstay brand *RICE FORCE* and new aging care brand *BRIGHTAGE* developed by the company.

Overseas business development

With a focus on *MINON Amino Moist series*, Daiichi Sankyo Healthcare is also strengthening its overseas business operations in China, Hong Kong, and Taiwan. In China, Daiichi Sankyo Healthcare performs sales and marketing activities through Daiichi Sankyo China (DSCN), a member of the Daiichi Sankyo Group.

Overseas Overseas Businesses with “Global Products” and “Regional Value Products”

Daiichi Sankyo Group currently does overseas businesses through Daiichi Sankyo Inc. and American Regent, Inc., in the U.S., Daiichi Sankyo Europe in European countries and ASCA^{*} company in Asia, South & Central America regions. We aspire to grow our overseas businesses not only through the delivery of “Global Products” such as *LIXIANA* and *ENHERTU*, but also through “Regional Value Products” matched to the specific needs of patients and healthcare providers in our various regions and countries

^{*}Asia, South & Central America

Daiichi Sankyo, Inc.

Given that Daiichi Sankyo Group aspires to be a global enterprise, growth in the U.S. market, the world’s largest market for pharmaceuticals, is of critical importance. Daiichi Sankyo, Inc. has a history of success having grown *Benicar* (antihypertensive agent) into a blockbuster medicine in the U.S.

Strengths and challenges

The core business of Daiichi Sankyo Group has begun to shift from the primary care field to the specialty field, which centers on hospital/specialty healthcare providers. We have taken great strides toward achieving our goal of becoming a leader in oncology in the U.S. by attracting new, talented, creative and experienced colleagues to join us in our mission. The U.S. commercial teams, including sales, managed markets, marketing and more, have deep and broad cancer expertise and work collaboratively to bring value and patient-focused information to those providers who treat cancer.

Progress of major initiatives

Launch of TURALIO

TURALIO (*pexidartinib*) is the first and only approved therapy for adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery, and is now available by prescription in the U.S.

TGCT is typically a non-malignant tumor that can be locally aggressive. There were no approved systemic treatment options other than surgery before the approval of *TURALIO*.

TURALIO is prescribed through a Risk Evaluation and Mitigation Strategy (REMS) Program in order to mitigate

the risk of serious liver injury seen with *TURALIO* in our clinical trials.



Launch of ENHERTU

ENHERTU (*fam-trastuzumab deruxtecan-nxki*), a HER2 directed antibody drug conjugate, became available by prescription in the U.S. in January 2020.

ENHERTU is a new treatment option for adult patients with unresectable or metastatic HER2 positive breast cancer who have received two more prior anti-HER2-based regimens in the metastatic setting.

In 2019, Daiichi Sankyo entered into a global development and commercialization agreement (excluding Japan) concerning *ENHERTU* with AstraZeneca. Together, Daiichi Sankyo and AstraZeneca are able to accelerate the growth of *ENHERTU* by leveraging the strengths of both companies.



American Regent, Inc.

American Regent, Inc. (ARI) is 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 US marketplace. The company employs over 1,000 people in New York, Ohio and Pennsylvania.

Strength and challenge

ARI's product portfolio is comprised of an iron injection franchise with two leading products, *Venofer* and *Injectafer*, for the treatment of iron deficiency anemia, a generic injectable franchise with a portfolio of difficult-to-manufacture, sole-sourced, and competitively differentiated products.

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.

Progress of major initiatives

Iron injection franchise

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 dialysis.

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 share of 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 regards 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 ejection fraction.



Generic injectable franchise

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 FY2020 and beyond.

ARI is also in the process of executing a significant capital investment in plant manufacturing capacity to become one of the top suppliers in the U.S. generic injectable market.



New Albany factory in the U.S

Daiichi Sankyo Europe

Daiichi Sankyo Europe (DSE) currently has affiliates in 13 European countries. Through licensing and sales agreements, our products are available in almost every European country. Our European headquarters is in Munich, Germany, and close by, in Pfaffenhofen, is one of our global production plants.

Strengths and challenges

Europe is an important market for the Daiichi Sankyo Group, following Japan and the United States.

The current mainstay of DSE is the anticoagulant *Lixiana*. Focusing on maximizing the product potential of *Lixiana* by growing market share, we will expand our business by adding further cardiovascular products to our portfolio as well as oncology products such as *ENHERTU*.

Progress of major initiatives

Growth of *Lixiana*

Since we launched *Lixiana* in 2015, most countries in Europe have introduced it in their local markets.

DSE is marketing *Lixiana* in more than 10 European countries. In countries where DSE does not have its own affiliates, e.g. Northern or Eastern European countries, *Lixiana* is commercialized via partners such as Servier or MSD.

The market share has been growing to almost 16% in the European countries where DSE has its own affiliates (excl. France and Turkey). The sales revenue in Germany is the second highest after Japan.

To achieve further growth we have defined a single-minded proposition for *Lixiana*: "Your choice for the elderly NVAf patient" which is rolled-out across all European markets.



Approvals for NILEMDO and NUSTENDI

NILEMDO (*Bempedoic acid*) and *NUSTENDI* (Fixed dose combination tablet of *bempedoic acid* and *ezetimibe*) in-licensed from Esperion, have been approved by the European Commission in March and April 2020 respectively for cholesterol-lowering treatment. The new products are an ideal fit to the capabilities we have developed over the last years. They can build on and use synergies with *LIXIANA* and thus enhance our value as a business in Europe.



Preparing for oncology

Besides getting ready for new products in the cardiovascular space, Daiichi Sankyo in Europe is also diligently preparing for the future oncology business.

We have hired talented professionals for medical, market access, marketing, field force and other functions. The European commercial organization is set up well to successfully launch our oncology products.

ASCA Company

The ASCA*1 Company is responsible for operations in Asia, South & Central America, and other regions. In addition to performing sales and promotional activities through its 7 subsidiaries (in China, Korea, Taiwan, Thailand, Hong Kong, Brazil, and Vietnam*2), the ASCA Company also exports its bulks and products to licensees. The ASCA Company owns its formulating plants in China and Brazil and performs production operations there. The ASCA Company employs approximately 2,100 people at its business bases. The company has rolled out its business optimized to market and customer needs in each country and region (regional value), contributing to healthcare in each place.

*1 Asia, South & Central America
*2 Currently representative office

Strength and challenge

China is an important market for the ASCA Company because revenue from its China business accounts for the largest share of its total revenue. With its mainstay products, including the antihypertensive agent *olmesartan*, synthetic antibacterial agent *Cravit*, and hypercholesterolemia treatment *Mevalotin*, the ASCA Company operates in the market. While the China market is large, regulations are complex, and the ASCA Company is focusing on building and expanding its sales structure to maximize its potential.

The anticoagulant *LIXIANA*, one of the Group's global products, is also an important product for the ASCA Company. Since its launch in Korea in 2015, *LIXIANA* has been marketed in Taiwan, Hong Kong, Thailand, Brazil, and China via the ASCA Company's own sales organization. The ASCA Company takes full advantage of the customer base it has built for *Mevalotin* and *olmesartan*, which are also cardiovascular products, to further expand the market share of *LIXIANA* in each country. In countries where the ASCA Company does not have subsidiaries, such as Indonesia and the Middle East countries, the company will work to maximize product value by selling products through its partners.



Progress of major initiatives

Strengthen the operating structure in China

In the past, the ASCA Company has sought to expand sales through active sales alliance with local companies. Currently, the company is working to expand its own marketing territories while improving profitability, taking into account regulatory changes such as health insurance and bidding system reforms, as well as changes in the market environment.

Expand LIXIANA

The market share of *LIXIANA* is steadily increasing as a result of product strategies tailored to the market environment and other conditions in each country. In Korea, *LIXIANA* has maintained the largest DOAC* monthly share. In Taiwan, various marketing promotion activities have resulted in increased market share. In China, the ASCA Company is working to have *LIXIANA* listed on the National Reimbursement Drug List (NRDL) and making other efforts for sales growth in the future.

* Direct oral anti coagulant

Build an operating structure to launch oncology products

In the ASCA regions, the ASCA Company also works on building an operating structure and preparing for market launch, among other activities, in order to deliver *ENHERTU* and other oncology products to patients as soon as possible.

A new operating structure is being built with focus on designing functions and organizations as well as promoting talent acquisition required for oncology business.



Shanghai factory in China

Research & Development (R&D)

The mission and role of Research and Development (R&D) is to continue to contribute to establishing global standard of treatment and prevention methods to improve human health. This can be achieved by creating high-value-added novel therapies continuously by leveraging our accumulated knowledge and experience of high-quality and innovative drug discovery and development.

Our inquiring mind and desire to contribute humanity drive our R&D. We are supported by our passionate desire to create new medicines that contribute to the health and enriched lives of people around the world and deliver them to patients as soon as possible. We will continue to take on the challenge of creating innovative medicines.

Strength and challenge

- Strength** Cutting-edge science & technology cultivated over years of operation as a drug discovery-oriented company
- Challenge** On-track delivery of large-scale clinical trials in oncology, as well as research, development, and regulatory submissions for regenerative medicines. Further evolution of research and development using new technologies such as ICT, AI, and RWD*

* RWD (Real World Data): Data collected in the daily clinical environment (Real World), not in the experimental environment (Ideal World) like clinical trials.

Revised R&D strategy

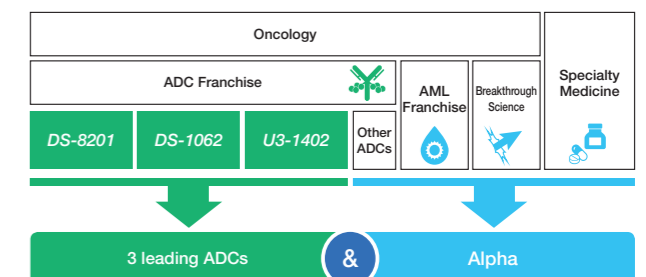
For R&D 2025 Vision, three pillars were established in the oncology field: Antibody Drug Conjugate (ADC) Franchise, Acute Myeloid Leukemia (AML) Franchise, and Breakthrough Science. Of the three, ADC Franchise, in particular, saw steady progress in clinical development of three ADCs, starting with *DS-8201*, and the potential of each ADC has increased to the point where it can be called a major pillar. Since these ADCs products use the same platform technology, with a view to going forward to "post-ADC," new drug discovery platform technologies that will drive Daiichi Sankyo's sustainable growth and creation of novel products that will transform the standard of care have become important themes to tackle.

Thus, we decided to adopt our new R&D strategy as "3 and Alpha."

The number "3" refers to the three ADCs, for which we will continue to focus on our spending in R&D expenses and human resources to maximize their product values. The word "Alpha" signifies the driving force that gives birth to leading edge science bringing true innovation that can transform the SOC*. With Alpha, we intend to contribute to supporting Daiichi Sankyo's sustainable growth, with the goal of new innovation ahead of the world not only in the oncology field, but also in rare diseases, CNS diseases, and other disease areas with high unmet medical needs.

Going forward, we will pursue for more agile and flexible resource allocation and to facilitate collaboration between organizations. We hope that this revised strategy will lead to an improvement in efficiency under resource constraints, as well as to a cascade of further innovation.

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



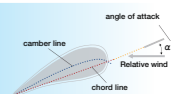
3 leading ADCs

- DS-8201:** Maximizing value through alliance with AstraZeneca
- DS-1062:** Maximizing value through alliance with AstraZeneca
- U3-1402:** Potential for early market entry

Science-based precision medicine:

Three ADCs and vectors/receptors based on the unique biology of DXd technology

Alpha= "Angle of attack" on airplane wings



Alpha= A benchmark for investment efficiency in the financial economy



Alpha= Driving force that gives birth to leading edge science bringing true innovation that can transform the standard of care (SOC)



Progress of major initiatives

3 ADCs

Characteristics of Daiichi Sankyo's ADC

In order to examine the benefits and issues of the preceding antibody drug conjugates (ADCs) and solve these issues, our researchers screened and optimized combinations of antibodies, linkers, and payloads to ultimately produce the Daiichi Sankyo's ADC technology. Daiichi Sankyo's ADC has been established as a platform technology where the payload-linker can be combined with a variety of antibodies, and we are currently developing seven DXd-ADCs loaded with a payload, a new derivative of the DNA topoisomerase I inhibitor *DX-8951* (DXd). The main characteristics of this technology are summarized in the figure below.

Characteristics 1	New payload	Characteristics of Payload
Characteristics 2	High potency of payload	
Characteristics 3	Bystander antitumor effect	
Characteristics 4	Payload with a short half-life in the blood	Characteristics of Linker
Characteristics 5	Stable linker	
Characteristics 6	Selectively cleaved linker in cancer cells	
Characteristics 7	High drug-antibody ratio	

Characteristics 1 New payload

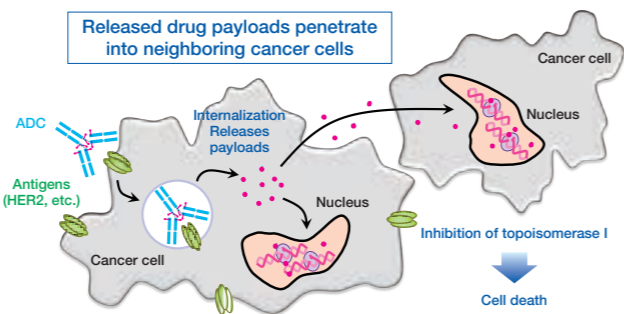
The payload of Daiichi Sankyo's ADCs is DXd, a novel derivative of the DNA topoisomerase I inhibitor *DX-8951*, which was created by former Daiichi Pharmaceutical.

Characteristics 2 High potency of payload

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

Characteristics 3 Bystander antitumor effect

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



Characteristics 4 Payload with a short half-life in the blood

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

Characteristics 5 Stable linker

For ADC technology to exhibit cancer cell-specific efficacy, the payloads must be reliably delivered to cancer cells, and here the linker plays an important role. If the linker is unstable, the ADC may degrade after administration and the payloads will be released in the blood. This can reduce efficacy before the payloads are carried to the cancer cells, and can potentially cause side effects if the payloads affect normal cells. Pharmacokinetic analysis of the phase 1 study has confirmed the stability in human blood of Daiichi Sankyo's ADC construct.

Characteristics 6 Selectively cleaved linker in cancer cells

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

Characteristics 7 High drug-antibody ratio

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

Below is an overview of our pipeline. For detailed data (safety, efficacy, etc.) presented at scientific conferences, please see "IR Library" for investors on our website.

[Read more here](https://www.daiichisankyo.com/investors/library/) **IR Library for investors**
https://www.daiichisankyo.com/investors/library/

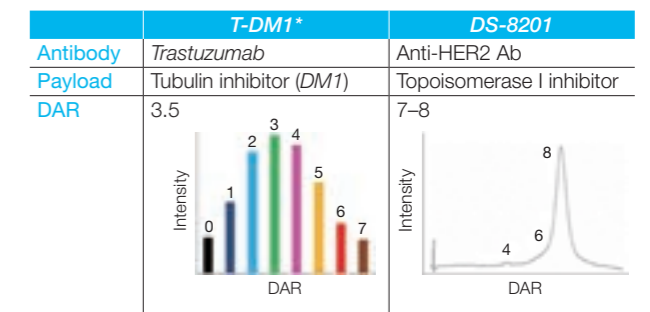
Trastuzumab deruxtecan / DS-8201 (anti-HER2-ADC)

DS-8201 is an anti-HER2 antibody drug conjugate (ADC) comprising Daiichi Sankyo's proprietary linker and payload (DXd) covalently combined with an anti-HER2 antibody.

Strategic Collaboration with AstraZeneca

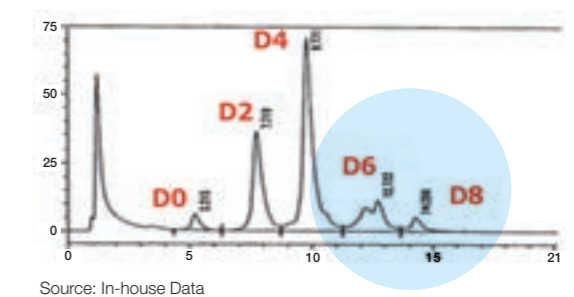
In order to maximize the value of *DS-8201*, we entered into a global joint development and commercialization agreement in March 2019 with AstraZeneca, a company with a wealth of experience and resources in oncology. Under the agreement, the two companies are jointly developing monotherapy/combotherapy for HER2-expressing cancers, and the development costs will be shared between the two companies. As for commercialization, the two companies will undertake co-promotion in regions other than Japan and share profits and losses. In Japan, Daiichi Sankyo will be the sole marketer and will pay royalties to AstraZeneca.

Distribution of binding payload



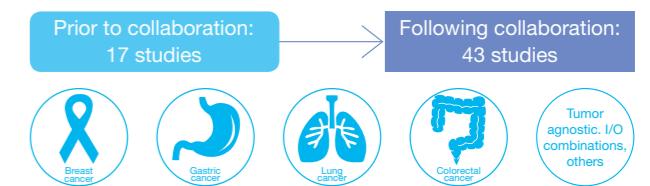
* *Kadcyla* BLA
Source: Ogitani-Y et al., Clin. Cancer Res. 2016; 22:5097-5108, Marcoux-J et al., Protein Science 2015; 24:1210-1223

DS-1062: Distribution of the number of payload



Source: In-house Data

Our collaboration with AstraZeneca is progressing well. Before the agreement was signed, we were planning 17 clinical studies, but the number has increased to 43 after the agreement. These studies will start in sequence from fiscal 2020.



Research & Development (R&D)

► The list of *DS-8201* studies (as of August 2020)

	Cancer type	Phase	Study name	Description	Status
1		Phase 1	N/A	First-in-human study HER2-positive breast cancer, HER2-low breast cancer, HER2-positive gastric cancer, and other cancers	Has results
2	Breast cancer	Phase 2	DESTINY-Breast01	HER2-positive breast cancer post <i>T-DM1</i>	Has results
3		Phase 3	DESTINY-Breast02	HER2-positive breast cancer 3L, vs. phys choice of SOC	Data expected in FY2021 H2
4		Phase 3	DESTINY-Breast03	HER2-positive breast cancer 2L, vs. <i>T-DM1</i>	Data anticipated in FY2021 H1
5		Phase 3	DESTINY-Breast04	HER2-low breast cancer, 2L/3L vs. phys choice of SOC	Data anticipated in FY2021 H2
6		Phase 3	DESTINY-Breast05	HER2-positive breast cancer, post-neoadjuvant	In preparation
7		Phase 3	DESTINY-Breast06	HER2-low hormone therapy refractory breast cancer, vs. phys choice of SOC	In progress
8		Phase 1b/2	BEGONIA	TNBC, combination with <i>durvalumab</i>	In progress
9		Gastric cancer	Phase 2	DESTINY-Gastric01	HER2-positive gastric cancer 3L~ vs. phys choice of SOC (HER2-low gastric cancer in exploratory cohort)
10	Phase 2		DESTINY-Gastric02	HER2-positive gastric cancer 2L	In progress
11	Phase 1b/2		DESTINY-Gastric03	HER2-positive gastric cancer, 2L~/1L	In progress
12	Lung cancer	Phase 2	DESTINY-Lung01	HER2m NSCLC, HER2-positive NSCLC	Data anticipated in FY2021 H1
13		Phase 2	HUDSON	NSCLC, combination with <i>durvalumab</i>	In progress
14	Colorectal cancer	Phase 2	DESTINY-CRC01	HER2-positive colorectal cancer 3L (HER2-low colorectal cancer in exploratory cohort)	Has results
15	Other	Phase 1	N/A	Breast cancer, bladder cancer, combination with <i>nivolumab</i>	In progress
16		Phase 1	N/A	NSCLC, breast cancer, combination with <i>pembrolizumab</i>	In progress
17		Phase 2	DESTINY-PanTumor02	HER2-expressing cancer (bladder, biliary tract, cervical, endometrial, ovarian, pancreatic, and other rare cancers)	In preparation

1 First-in-human Phase 1 Study

Phase 1 study, started in September 2015, has been conducted mainly on patients with breast, gastric, lung, or colorectal cancer. Interim results of the study were presented at the past conferences of the American Society of Clinical Oncology (ASCO), the European Society for Medical Oncology (ESMO), the San Antonio Breast Cancer Symposium (SABCS), the World Conference on Lung Cancer (WCLC), and other academic conferences.

In fiscal 2019, data was published in prominent scientific journals; the primary analysis results of the study were published in *the Lancet Oncology* for HER2-positive breast cancer and gastric cancer, *the Journal of Clinical Oncology* for HER2-low breast cancer, and *CANCER DISCOVERY* for other HER2-expressing or -mutated cancers.

Breast cancer

2 DESTINY-Breast01 study

The primary analysis results of this study were presented orally at the SABCS in December 2019. The results were also published in *the New England Journal of Medicine*. Based on the results, we submitted BLA in the U.S. in August 2019, obtained approval in December 2019 and launched in January 2020. In Japan, we submitted NDA in September 2019, obtained approval in March 2020 and launched in May 2020. In Europe, approval application was accepted in June 2020 and is being review under accelerated assessment.

6 DESTINY-Breast05 study

This is a head-to-head comparative study of *DS-8201* versus *T-DM1* in patients with residual invasive HER2-positive breast cancer following preoperative chemotherapy who are at high risk for recurrence. Preparations are underway to initiate the study in the second half of fiscal 2020.

Gastric cancer

9 DESTINY-Gastric01 study

The primary analysis results of this study were presented at the ASCO in May 2020. The result was also published in *the New England Journal of Medicine*. In Japan, sNDA was filed in April 2020. Since the SAKIGAKE designation has been granted to this indication, the review duration is expected to be 6 months or less. In May 2020, the drug received the Breakthrough Therapy and Orphan Drug Designations from the U.S. Food and Drug Administration (FDA), despite the study having been conducted only in Japan and South Korea. Going forward, we plan to proceed with discussions with the FDA so that we can submit sBLA in the U.S. as soon as possible.

Lung cancer

12 DESTINY-Lung01 study

Interim data from the HER2-mutated cohort were presented at the ASCO in May 2020. In May 2020, *DS-8201* received the Breakthrough Therapy Designation from the U.S. FDA based on the interim data.

Colorectal cancer

14 DESTINY-CRC01 study

The primary analysis results from the HER2-positive cohort were presented at the ASCO in May 2020.

DS-1062 (Anti-TROP2-ADC)

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

Strategic Collaboration with AstraZeneca

In order to maximize the value of *DS-1062* through accelerated development, and to allocate resources to the subsequent DXd-ADC and Alpha projects, in July 2020 Daiichi Sankyo entered into a global joint development and

commercialization agreement for *DS-1062* with AstraZeneca, a company with a wealth of experience in lung cancer. The form of the agreement is almost the same as that for *DS-8201*.

► The list of *DS-1062* studies (as of August 2020)

	Cancer type	Phase	Study name	Description	Status
1		Phase 1/2	N/A	First-in-human study NSCLC, TNBC	In progress
2	Lung cancer	Phase 2	N/A	NSCLC (with mutation)	In preparation
3		Phase 1	N/A	NSCLC, combination with <i>pembrolizumab</i>	In preparation

1 First-in-human phase 1 study (NSCLC, TNBC)

The phase 1 study, begun in February 2018 included patients with non-small cell lung cancer (NSCLC). Last year, interim data on NSCLC were presented at the WCLC in September 2019 and at the ASCO in May 2020. In June 2020, a triple-negative breast cancer (TNBC) cohort was added to this study.

3 Phase 1 study (NSCLC, combination with pembrolizumab)

In May 2020, Daiichi Sankyo entered into an agreement with Merck for clinical study to evaluate the combination of *DS-1062* and *pembrolizumab*. Preparations are underway to initiate the study in the second half of fiscal 2020. In addition, we are planning to test *DS-1062* in combination with other immune checkpoint inhibitors (I/O agents). We are considering developing *DS-1062* in combination with I/O agents for the 1st-line treatment of NSCLC.

Patritumab deruxtecan / U3-1402 (Anti HER3-ADC)

U3-1402 is an anti-HER3 ADC comprising our proprietary linker and payload conjugated to the anti-HER3 antibody patritumab.

► The list of *U3-1402* studies (as of August 2020)

	Cancer type	Phase	Study name	Description	Status
1	Breast cancer	Phase 1/2	N/A	First-in-human study HER3-positive breast cancer	In progress
2	Lung cancer	Phase 1	N/A	NSCLC	In progress
3		Phase 1	N/A	EGFR-mutated NSCLC, combination with <i>osimertinib</i>	In preparation
4	CRC	Phase 2	N/A	Colorectal cancer	In preparation

1 First-in-human phase 1 study (HER3-positive breast cancer)

This study has been underway since December 2016 and shown that HER3 expression detected in some patients prior to the first dose of *U3-1402* decreases following the initiation of treatment. In HER3-positive breast cancer, patient selection is key to determining the efficacy and safety of *U3-1402*. Therefore, we will focus on the development of biomarkers and review our future development plans.

2 Phase 1 study (NSCLC)

At the WCLC in September 2019, interim data on the efficacy and safety of *U3-1402* were presented for the dose-escalation part.

3 Phase 1 study (EGFR-mutated NSCLC, combination with osimertinib)

In August 2020, Daiichi Sankyo entered into an agreement with AstraZeneca for clinical study to evaluate the combination of *U3-1402* and *osimertinib*. With the aim of developing *U3-1402* as a 2nd-line treatment of EGFR-mutated NSCLC, preparations are underway to initiate the phase 1 study in the second half of fiscal 2020.

Alpha

Oncology

Quizartinib (FLT3 inhibitor)

Quizartinib is an FLT3 inhibitor with a potent inhibitory activity against mutated gene called FLT3-ITD, which is present in around 30% of acute myeloid leukemia (AML) patients.

In Japan, the Ministry of Health, Labour and Welfare approved *quizartinib* for the indication of relapsed/refractory FLT3-ITD AML in June 2019. The drug was launched in October 2019 under the brand name of *Vanflyta*.

In the U.S., we received a Complete Response Letter in June 2019. In Europe, we received a negative view on approval from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in October 2019.

Phase 3 study of 1st-line treatment (QuANTUM-First study) is currently underway globally.

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

Pexidartinib is a receptor tyrosine kinase inhibitor showing specific inhibitory activity against CSF-1R/KIT/ and FLT3.

Pexidartinib was approved by the FDA for the indication of tenosynovial giant cell tumor (TGCT) in August 2019, and was launched under the brand name of *Turalio*. In Europe, we received a negative view on approval from the EMA's CHMP in June 2020.

We are also discussing a development in the Asian region, including Japan.

Axicabtagene ciloleucel (anti-CD19 CAR-T cell)

Axicabtagene ciloleucel is a cell therapy (chimeric antigen receptor T cell: CAR-T cell) product licensed-in from Kite Pharma, Inc., a subsidiary of Gilead Sciences, Inc. in the U.S. The product targets the CD19 antigen expressed on the surface of B-cell lymphoma.

Daiichi Sankyo submitted NDA in Japan in March 2020 based on the results from a global phase 1/2 clinical study (ZUMA-1 study) conducted by Kite Pharma and a phase 2 study in Japan conducted by Daiichi Sankyo. The agent has been designated as an Orphan Regenerative Medicine Product by the Ministry of Health, Labour and Welfare.

DS-1647/G47Δ (oncolytic HSV-1)

DS-1647(G47Δ) is a cutting-edge (third-generation) oncolytic virus created by Professor Tomoki Todo of the Institute of Medical Science of the University of Tokyo, by using genetic modification technologies to modify herpes simplex virus type 1 so that it only multiplies inside cancer cells.

We plan to submit NDA in Japan based on the results from the investigator-initiated clinical study undertaken by Professor Todo. The SAKIGAKE designation has been granted to *DS-1647* by the Ministry of Health, Labour and Welfare.

Valemetostat/DS-3201/EZH1/2 inhibitor

DS-3201 is an inhibitor of the histone methyltransferases *EZH1* and *EZH2*. Some cancer cells show *EZH1/2*-dependent proliferation.

The following studies are currently underway: phase 2 study in patients with adult T-cell leukemia-lymphoma in Japan; global phase 1 study in patients with non-Hodgkin's lymphoma, including relapsed/refractory peripheral T-cell lymphoma (PTCL); and phase 1 study in patients with acute myeloid leukemia/lymphoma in the U.S.

In April 2019, the SAKIGAKE designation was granted to *DS-3201* by the Ministry of Health, Labour and Welfare for the treatment of PTCL.

DXd-ADC

Of the seven DXd-ADCs are currently under development at the Company, four are being developed as part of "Alpha". For DS-7300 and DS-6157, phase 1 studies are underway. DS-6000 (target not disclosed) and DS-3939 (anti-TA-MUC1-ADC) are in preclinical phase.

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

DS-7300 is an anti-B7-H3-ADC using DXd-ADC platform. B7-H3 is a type I transmembrane protein belonging to the B7 family.

Since October 2019, phase 1/2 study have been performed in patients with solid tumors (head and neck, esophageal, non-small cell lung, and other cancers) in Japan and the U.S.

DS-6157 (anti-GPR20-ADC)

DS-6157 is an anti-GPR20-ADC using DXd-ADC platform. GPR20 is an orphan G protein-coupled receptor (GPCR) that is expressed specifically in gastrointestinal stromal tumors (GISTs).

Since May 2020, phase 1 study have been performed in patients with GIST in Japan and the U.S.

In a phase 1/2 study that has been performed in Japan since October 2015, results of a 12-week treatment with DS-5141 have shown that Exon 45 skipping during splicing was confirmed in all 7 patients, and the dystrophin protein was observed in one patient. Following the results, a subsequent 48-week study has been in progress, the results of which will become available at the end of 2020.

DMD projects using ENA[®] nucleic acid modification include those for DS-5144 (exon 44 skipping), DS-5150 (exon 50 skipping), DS-5151 (exon 51 skipping), and DS-5153 (exon 53 skipping) and these projects are in pre-clinical phase.

DS-4108

DS-4108, a nucleic acid drug, which uses ENA[®] technology similar to that for DS-5141 to control splicing, has been created from a joint research with Kobe Gakuin University, the National Center for Child Health and Development, and Hiroshima University. DS-4108 is being developed as a treatment for glycogen storage disease type Ia (GSDIa) caused by specific gene mutation. GSDIa is a rare disease with the incidence of 1 in 100,000 that causes fasting hypoglycemia, hepatomegaly, and other conditions due to a congenital deficiency of sugar-producing enzyme (glucose-6-phosphatase, G6Pase). No drug therapy has been approved for GSDIa and the disease is managed with strict diet therapy.

ENA[®] has thus expanded beyond the DMD projects and is expected to become a new platform technology following the DXd-ADC platform technology.

DS-1211

The TNAP inhibitor DS-1211 has been developed as a treatment for pseudoxanthoma elasticum. In this disease calcification of blood vessels and connective tissues occur gradually and causes skin lesions, decreased visual acuity, and cardiovascular complications, among others, due to genetic mutations in ABCC6. For pseudoxanthoma elasticum, no drug therapy has been approved, and the estimated number of patients is 18,000 in Japan, the U.S., and five European countries. Currently, phase 1 study have been completed, and phase 2 study are in preparation.

DS-6016

The anti-ALK2 antibody DS-6016 has been under a collaborative research effort with Saitama Medical University, which was selected for AMED's CiCLE program in August 2017. DS-6016 targets fibrodysplasia ossificans progressiva (FOP), a disease characterized primarily by heterotopic ossification in which bone is formed in tissues that are not normally formed due to genetic mutations in ALK2, a key receptor in the transmission of osteogenic signals. It has been reported that area of heterotopic ossification expands with age, and total assistance becomes necessary for almost all patients who are aged 40 years and older. Currently, no approved drug therapy is available. FOP is very rare, and the number of patients is estimated to be little less than 80 in Japan and little less than 300 in the U.S. Preparations are underway to initiate a phase 1 study.

Specialty Medicine

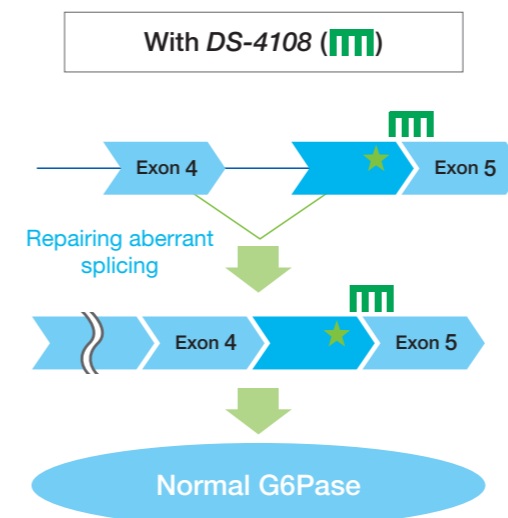
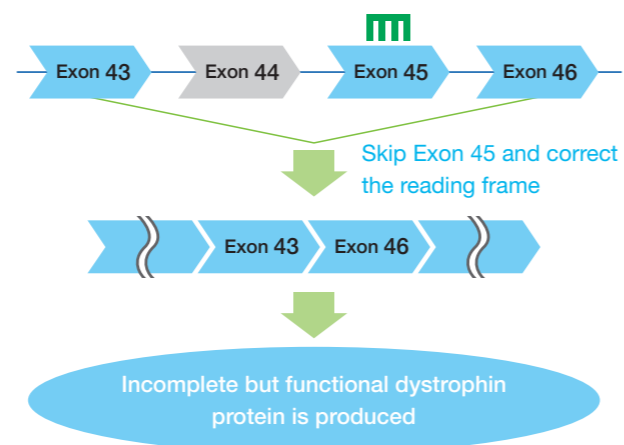
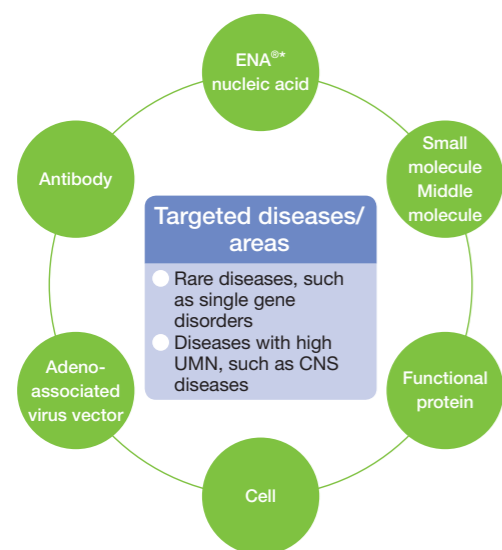
In the Specialty Medicine area, Daiichi Sankyo has set forth a medium-to-long-term vision of delivering innovative pharmaceuticals to patients suffering from diseases for which no effective treatment is available or for which existing treatments are insufficient. Daiichi Sankyo's immediate goal is to become a world-class innovator with competitive advantage in rare diseases by taking advantage of our strengths in science and technology and pursuing innovation. Our ultimate goal is to become a world-class innovator in the Specialty Medicine.

We will make the maximum use of a wide range of our modalities to develop drugs for rare diseases, such as single gene disorders, or other diseases with high unmet medical needs (UMN), such as diseases of the central nervous system (CNS).

DS-5141 (nucleic acid drug)

DS-5141 is a nucleic acid drug using our proprietary nucleic acid modification (ENA[®]). ENA[®] is an ethylene-bridged nucleic acid in which ethylene is bridged at the furanose sugar ring at 2'-O and 4'-C ends. ENA[®] demonstrates high binding force with DNA and RNA as well as superior thermal and nuclease resistance.

Duchenne muscular dystrophy (DMD) is an X-linked recessive muscular disorder that is caused by a dystrophin gene abnormality that results in the production of no dystrophin protein. DS-5141 is expected to improve the symptoms of DMD by skipping exon 45 and producing an incomplete but functional dystrophin protein in the splicing process where messenger RNA is produced from the dystrophin gene in patient's myocytes.



Correct the aberrant splicing by ENA[®] oligonucleotide and induce production of normal G6Pase

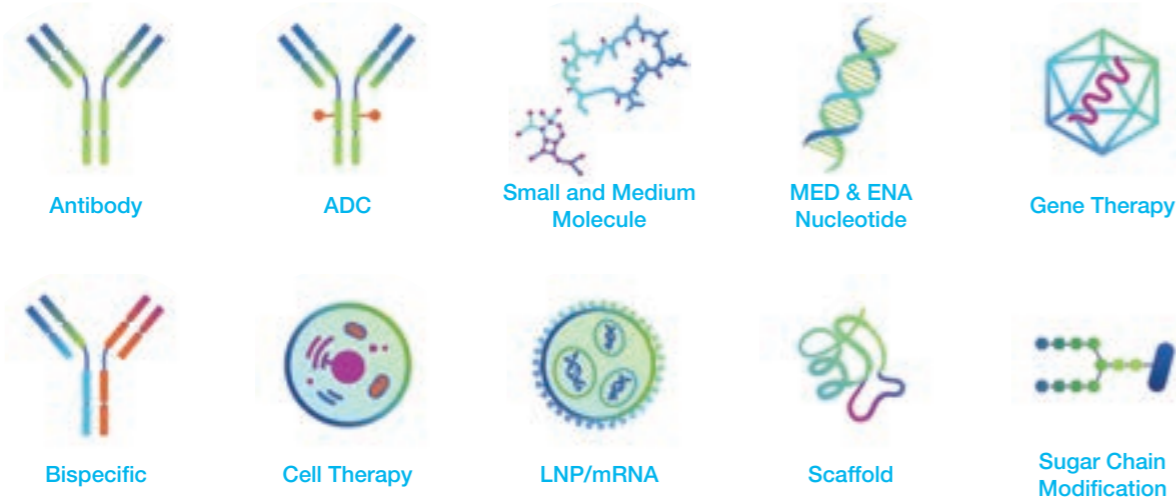
* 2'-O,4'-C-Ethylene-bridged Nucleic Acids. A modified nucleic acid made using proprietary technology owned by Daiichi Sankyo. ENA[®] is a registered trademark of Daiichi Sankyo.

Research

Create new modalities

Daiichi Sankyo has been advancing drug discovery research by use of a wide variety of modalities, including next generation ADCs, bispecific antibodies, nucleic acid drugs, cell therapy (including iPS cells), gene therapy, and LNP-mRNA, in addition to small molecules, *DS-8201*, and

other DXd-ADCs. We have been promoting multi-modality strategy to create the optimal modality for the disease by an appropriate modality for the drug target and the disease, and by simultaneously developing a new modality.



Efforts in gene therapies

Daiichi Sankyo focuses on gene therapy using the adeno-associated virus (AAV) vector, which is considered to be the most feasible vector among gene therapies. We will initiate gene therapy research for monogenic rare diseases first and plan to start clinical studies for several projects in fiscal 2024 and beyond. In parallel, mass production technology we will be established in order to apply the gene therapy to serious common diseases for which existing treatments are insufficient.

Since we considered building in-house manufacturing capability as a major hurdle for the development of gene therapy drugs, we decided to introduce manufacturing technology from Ultragenyx Pharmaceutical Inc. Ultragenyx Pharmaceutical Inc. has developed its own AAV production system using HeLa and HEK293 cells, and has already achieved actual performances of clinical studies, ensured stable quality of products, and attained know-how on mass production and analytical techniques for quality control. Through the introduction of this technology, we will soon establish in-house manufacturing capability for gene

therapy programs, and begin manufacturing investigational drugs by the mid-2020s. Daiichi Sankyo has several gene therapy drug candidates undergoing nonclinical studies. One of the focused project is for retinitis pigmentosa, for which we have undertaken a collaborative research with Nagoya Institute of Technology. Retinitis pigmentosa is a genetic disorder characterized by the loss of photoreceptors, which exist in the retinal cells of healthy people and causes severe deterioration of visual acuity as the disease progresses. In this collaborative research program, we have identified the highly active, novel photo-responsive protein. Improvement of visual acuity is expected if the protein could be expressed in retina through gene therapy. In addition to establishing manufacturing technology for gene therapy drugs, we will accelerate the research and aim to realize early practical use of innovative pharmaceuticals for patients.

Pharmaceutical Technology

The Pharmaceutical Technology works to establish technologies for the commercialization and production of new medicines created through research and development.

Through research and regulatory application activities related to drug substances, drug products, and quality evaluation, we develop commercial production processes to achieve high-quality and stable production, in addition to processes to manufacture and supply investigational drugs, whereby transferring manufacturing and analysis technologies to supply chain functions. After the launch of products, we continue to work on establishing and improving manufacturing processes in alignment with the life cycles of products, including improving usability and taking measures against counterfeit drugs, in order to increase the added value of our medicines.

Strength and challenge

Strength	Capabilities to establish robust commercial production processes and quality evaluation methods for drug substances and drug products, to implement application processes steadily, and to develop products that meet the unmet needs of patients and healthcare professionals
Challenge	Continued efforts to establish research and development capability for production processes adapted to a wide range of modalities following ADCs

Progress of major initiatives

Increasing production of *DS-8201* following the collaboration with AstraZeneca

With a significant increase in demand for *DS-8201* following the strategic collaboration with AstraZeneca at the end of March 2019, as well as the steady progress in the clinical studies of subsequent DXd-ADCs, we are facing an urgent need to expand our production capacity for ADCs, which is a key task. In response to the increase in demand, we have built new production bases inside and outside our Group, worked on regulatory filing of new manufacturing bases, and established a structure to support more clinical studies with a limited number of investigational drugs, thereby contributing to maximizing the value of *DS-8201*.

Going through the filing process for *ENHERTU* in the U.S. and Japan at an unprecedented speed in our history

With the mission of delivering *ENHERTU*, Daiichi Sankyo's first global oncology product, to patients as soon as possible, we worked on the filing process. To attain simultaneous filing in the U.S. and Japan, a process was established and implemented to streamline the preparation of application data on the design of drug substances, drug products, and quality. In the U.S., all data related to manufacturing process validation were submitted to the U.S. Food and Drug Administration (FDA) following the filing of application, ahead of the deadline agreed with the FDA. This contributed to the accelerated approval of *ENHERTU*. In addition, we were able to respond to inquiries from authorities in the U.S. and Japan in an on-time manner by sharing information promptly and forming timely agreements on the responses to queries with AstraZeneca. As a result of these measures, approval was obtained in an unprecedented short period of time in the Company's history.

Increasing added value through pharmaceutical technology

One of the important roles of the Pharmaceutical Technology Unit is to design formulations and packaging that are easy for patients and healthcare professionals to use and suitable for patients in terms of their diseases, as well as to develop relevant manufacturing methods. We make an effective use of our researchers' findings obtained during their visits to healthcare settings and information collected by our marketing personnel concerning the needs of healthcare professionals to promote the development of products and technologies. Examples of our past efforts include the development of *LIXIANA* orally disintegrating (OD) tablets, *Olmetec* OD tablets, and extended-release formulations of oral narcotic drugs. To provide a new treatment option for patients with COVID-19 as soon as possible, Daiichi Sankyo utilizes technology acquired through the development of anti-influenza agent *Inavir* to promote research and development of *nafamostat* inhalation formulation.

Developing highly productive expression systems in novel CHO cell* line

In the strategic collaboration with AstraZeneca for *DS-8201* and *DS-1062* and the early development of subsequent DXd-ADCs and other antibody drug pipelines, important issues for the Company have been improving antibody productivity and reducing manufacturing lead time. In the manufacturing of antibody drugs, long period of time for cell culture has been one of the reasons for the prolonged manufacturing lead time and high cost. The Company has participated in the Manufacturing Technology Association of Biologics (MAB) supported by the Ministry of Economy, Trade and Industry (METI) and the Japan Agency for Medical Research and Development (AMED), and successfully obtained novel CHO cell line with high proliferative ability. In addition, a new CHO cell expression system developed by combination with an in-house developed vector showed about three to four times higher antibody productivity than the previous system. In the future, we will be able to shorten manufacturing lead time, supply investigational drugs in a timely manner, and achieve low-cost commercial production by applying this technology to the manufacturing of subsequent DXd-ADCs and other antibody drugs.

* Chinese hamster ovary cells. Widely used in the manufacture of antibody drugs.

Pharmaceutical Technology

Future efforts

Increasing production of DXd-ADCs and future modalities

As a result of the strategic collaboration with AstraZeneca for *DS-8201* and following *DS-1062* and the steady progress in the clinical studies of subsequent DXd-ADCs, an ever-more-extensive expansion of the production capacity is required for manufacturing investigational drugs and commercial products. We facilitate on-time technology transfer to commercial production facilities, considering an option of further utilizing contract manufacturing organization (CMOs). For research on the drug

substances, drug products, and quality evaluation of new modalities, such as next generation ADCs, nucleic acid, cell therapy, and gene therapy, we are working hard to develop and utilize advanced technologies, including ones derived from strategic use of specialized contract development and manufacturing organizations (CDMOs). In addition, we will work on enhancing our development/quality research structure for vaccines such as *DS-5670* (COVID-19 vaccine).

Activity Report

Supply Chain

A supply chain is a series of processes from the procurement of raw materials to the production, inventory control, and delivery of products. Our supply chain is shifting rapidly to oncology/biological products. In particular, in response to the rapid expansion of antibody-drug conjugate (ADC) products, we are strengthening our production and supply system by making large capital expenditures for manufacture of biological products and adding contract manufacturers worldwide, among other efforts.

Strength and challenge

Strength Launch and stable supply of products suitable for the market in each country through a global manufacturing and supply 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

Challenge To establish a stable supply system, taking into account development and launch schedules for the subsequent ADCs
To establish storage and transportation/delivery systems for regenerative medical products such as *DS-1647 (G47Δ)* and *axicabtagene ciloleucel* (anti-CD19 CAR-T cell)

Progress of major initiatives

Formulate and steadily promote supply strategies in response to the increased demand for 3 ADCs

Considering a significant increase in demand for *ENHERTU* following the announcement of a strategic collaboration with AstraZeneca at the end of March 2019, demand

forecast for *DS-1062*, and modification to the 5-year business plan, which was made at the end of October 2019 to clarify that the Company would place a top priority on maximizing the value of 3 ADCs, Daiichi Sankyo has strengthened its production system to maximize the capacity to supply 3 ADCs. In order to ensure stable supply in the future, the Company has increased its in-house production capacity and acquired production lines at overseas contract manufacturing organizations (CMOs).

As for *ENHERTU*, we swiftly began supplying products in the U.S. and Japan.

Contribute to generating group profits by reducing costs

The supply chain of a company plays an important role in pursuing cost reductions to generate profits. For *edoxaban*, which sustains our current revenue, we improve manufacturing methods in our plants, explore new sources of raw materials, and make other ongoing efforts to reduce costs. We have also achieved a significant cost reduction in equipment procurement by examining specifications carefully and making inquiries to competitive suppliers, under a situation where engineering operations that require a large capital expenditure are on the rise.

Global supply chain management

As the Daiichi Sankyo Group is a global supplier of products, global supply chain management is critical to ensuring a stable supply of products. We have established and worked to strengthen a tripartite global supply chain management system for the global procurement of raw materials, control of production volumes, inventory control, delivery, and resolution of supply and demand management issues in Japan, U.S., and Europe.

Future efforts

Steadily promote the establishment of a stable supply system in response to increased demand for 3 ADCs

To maximize the value of 3 ADCs, Daiichi Sankyo plans to make investments of more than ¥100.0 billion in manufacturing facilities by fiscal 2022. In addition to further strengthening its production system to maximize the capacity to supply 3 ADCs, we will build a supply system to ensure stable supply in the future. We also continue to train manufacturing personnel for biological products.

Activity Report

Medical Affairs

The Medical Affairs Unit collects, analyzes, and evaluates medical information related to the Company's products; and generates and disseminates evidence, whereby contributing to treatment and maximizing the medical value of the Company's products. We identify clinical questions existing in the real clinical setting through collecting, analyzing and evaluating information on unmet medical needs and develop medical strategies to solve them. We perform clinical research activities based on the medical strategies and disseminate new evidence. Repeating this cycle of information collection, analysis and evaluation; and evidence generation and dissemination leads to improved medical value of the products. In addition, we are evolving product information functions and enhancing the quality of responses to our stakeholders.

Strength and challenge

Strength Know-how on information collection, analysis, and evaluation, and evidence generation and dissemination obtained from numerous clinical studies that we have performed mainly in the cardiovascular area
Our high capability in Japan for responding to inquiries from physicians and paramedical staff, which we were ranked No. 1 in a call center satisfaction ranking of pharmaceutical companies.

Challenge To strengthen organization/function for more sophisticated evidence generation and dissemination in the oncology area as a pharmaceutical company with competitive advantage in oncology

Promote reliable and stable supply during the COVID-19 pandemic

Daiichi Sankyo establishes a task force in its supply chain to achieve stable supply by continuing the operation of plants through thorough infection prevention measures and securing routes for importing raw materials for drug substances and intermediates.

Steadily promote the use and management of advanced technology

The Daiichi Sankyo Group has accelerated research and development of new modality products, such as CAR-T cell therapy, nucleic acid drug, gene therapy, and siRNA*. For its supply chain, we examine transportation/delivery methods that fit the characteristics of each new modality. Currently, we are developing a commercial logistics scheme for regenerative medical products that require transportation and delivery in the ultra-low temperature range, such as *DS-1647 (G47Δ)*, an oncolytic virus, and *axicabtagene ciloleucel*, a CAR-T cell product.

* small interfering RNA

Progress of major initiatives

Generate and disseminate scientific evidence on *edoxaban*

Edoxaban is becoming one of the best anticoagulant therapy options for patients with cardiovascular disease worldwide, particularly in Japan and Europe. In fiscal 2019, evidence obtained through several clinical researches including ENTRUST-AF PCI study was presented in major academic conferences and journals, and the evidence was cited in 3 global and 3 Japanese clinical guidelines. Currently, we are conducting a large observational study aimed at revealing the real clinical setting data of anticoagulant therapy and prognosis in elderly patients

Medical Affairs

aged 75 years or older with non-valvular atrial fibrillation, and the study results are becoming available. We will remain committed to generating and disseminating more evidence so that *edoxaban* contributes to more patients.

Generate and disseminate scientific evidence in the oncology field on a global scale

In order to enhance the capabilities to generate and disseminate evidence for *ENHERTU* and other oncology products on a global scale, we strengthen our functions globally and in Japan and engage in a range of medical activities.

In collaboration with AstraZeneca, we have promoted the activities in line with a global medical strategy to generate and disseminate evidence on breast and other cancers after the launch of *ENHERTU*. The Medical Affairs is also responsible for the Company's publication strategy as part of evidence disseminating activities. In fiscal 2019, we made an oral presentation of the results from DESTINY-Breast01 study, which were the first pivotal study results of DXd-ADC pipelines at the San Antonio Breast Cancer Symposium (SABCS). The results were also simultaneously published in the *New England Journal of Medicine*. Through these events, we were able to disseminate the evidence effectively. As the oncology medical practice continues to advance at a fast-moving pace, it is essential to collect information on treatments and competitive products. We are conducting several activities to contribute to maximizing the medical value of products from an early stage of research and development by enhancing these functions to collect, analyze, and evaluate information, as well as by strengthening cooperation with related functions.



Future efforts

Further strengthening of evidence generation and dissemination in the oncology field

To contribute to maximizing the value of DXd-ADC pipelines and other products as a pharmaceutical company with competitive advantage in oncology, we promote developing cancer type-based medical strategies in addition to product-based medical strategies, and carry out relevant activities. In addition, we enhance the functions of medical science liaison (MSL), real world evidence (RWE), and companion diagnostics/biomarkers. Cooperating with related functions, we complement "Fast to Market strategies (meaning strategies to obtain approval and launch a product in the shortest period of time)" from a scientific and medical perspective. Through patient advocacy activities (such as support for patient groups) mainly outside Japan and the publication of patient-friendly manuscripts, we will also strengthen patient-centric information collection and evidence dissemination.

Take advantage of digital health tools/care

With the aim of improving patient's drug adherence, promoting the proper use of drugs, monitoring the efficacy and side effects that are reported from patients, supporting the diagnosis of diseases, and understanding potential medical needs, we have initiated the development of electronic patient reported outcome (ePRO)/personal health record (PHR) applications and evaluation of applying them to clinical researches for various products.

We will use ePRO/PHR as a platform to gain experiences and know-how in digital health tools/care.

Quality & Safety

Quality & Safety unit undertakes the following activities from research and development through to post-marketing phases in order to assure the quality of medicines and the reliability of information and to ensure the safety of pharmaceutical products, the: 1) ensuring the reliability of processes and data related to the manufacturing and analysis of products; 2) ensuring the reliability of data on efficacy and safety, as well as the quality of products, in terms of Good Practice (GxP) compliance; 3) promoting compliance through comprehensive management of regulatory affairs functions; 4) performing pharmacovigilance activities in an accurate manner, including collecting, assessing, and analyzing product safety information; 5) promoting the proper use of products in a timely manner to minimize risks; and 6) ensuring regulatory compliance concerning safety information.

Strength and challenge

Strength Experience and know-how in quality assurance and safety management that we have gained through the roll-out of various global products while responding appropriately to the requirements of each country, with standards for the quality and safety of pharmaceutical products becoming increasingly stringent at a rapid pace in many countries around the world

Challenge To acquire resources needed to enhance timely quality assurance and safety management systems in response to a significant increase and acceleration of clinical studies following the strategic collaboration for *DS-8201* and *DS-1062*, as well as progress in research and development and business evolution for other products including new modalities

inspections and other activities, and underwent inspections by the authorities. As a result, we were able to acquire compliance with the requirements by the FDA and the Ministry of Health, Labour and Welfare.

With regard to the safety of *DS-8201*, interstitial lung diseases (ILDs) have been defined as an "important identified risk," and a global ILD risk management system has been established. We work to swiftly obtain information on the cases of ILDs reported in various countries, and assess and analyze it in cooperation with AstraZeneca.

In Japan, in addition to formulating a drug risk management plan, we manage distribution by identifying medical institutions and physicians capable of managing ILDs. To ensure that medical representatives can provide medical institutions with information promptly in response to their inquiries regarding safety, we have set up a safety communicator system and worked on other efforts to strengthen our support system.

We will build a similar system for *DS-1062*.

Progress of major initiatives

Restructuring of organizations

Although the Daiichi Sankyo Group's past product portfolio focused on cardiovascular products, oncology pipelines have expanded in recent years, and development is also accelerating. In fiscal 2019, we launched *Tarlige*, *ENHERTU*, and many other products and performed many clinical studies of oncology products. As the oncology business is expanding, the Company has established independent safety management functions to ensure prompt and accurate decision-making concerning safety measures for oncology products for which safety management becomes increasingly complex.

Global initiatives concerning quality assurance and safety measures for oncology products

Pharmaceutical companies are required to comply with GxPs and must comply with inspections by regulatory authorities in each country in order to obtain approval. *ENHERTU* is Daiichi Sankyo's first oncology product for which approval application was filed based on global clinical studies and it was approved in December 2019 in the U.S. and March 2020 in Japan. *ENHERTU* was also the Company's first biologics product that had undergone an inspection by the Food and Drug Administration (FDA). For this reason, we formed a response team at an early stage, made sufficient preparations through mock

Future efforts

In addition to the global roll-out of *DS-8201*, we will accelerate and expand the development of *DS-1062* in alliance with AstraZeneca. This will result in more complex operations in quality assurance and safety management and a significant increase in information. In order to provide a stable supply and information to ensure that the product is used without uneasiness, we will promote quality assurance and safety management in light of the characteristics of anticancer drugs and ADCs.

In Japan, we will also develop the business of regenerative medical products such as *axicabtagene ciloleuce* and *DS-1647(G47Δ)*. These new modality products require measures not needed for conventional small molecule drugs and antibody products. Therefore, we will perform proper and accurate quality assurance and safety management depending on the characteristics of regenerative medical products (handling of biological samples, custom-made, etc.).