History of Daiichi Sankyo

Daiichi Sankyo was born out of the merger of Sankyo Co., Ltd., and Daiichi Pharmaceutical Co., Ltd., two drug discovery-oriented companies with histories spanning roughly a century. From the 1980s onward, both companies proceeded to expand their operations globally while developing and launching new products. Pravastatin, levofloxacin and olmesartan became blockbuster drugs* on the global market.

Meanwhile, these companies maintained a strong presence for a long time in the Japanese market through their honest and trustworthy sales activities. The two companies’ histories of placing focus on science, expanding global business from early phases and progressing as Japan’s leading companies have led to creating the current Daiichi Sankyo.

Value Creation Story

History of Daiichi Sankyo—Path to the Merger

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

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

* Blockbuster drugs whose annual peak sales exceed ¥100 billion (or $1 billion).
History of Daiichi Sankyo—Road After the Merger

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

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

Notes:
1. Excluding Ranbaxy subsidiaries Ltd.
2. Figures for fiscal 2011 and 2012 are based on financial results as of fiscal year ending March 2012.
3. *2 Index compiled by S&P Dow Jones Indices LLC and RobecoSAM AG recognizing companies that exhibit sustainability.
4. * Abbreviation of Antibody Drug Conjugate

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

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

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

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

Promoting Environmental Management

Promoting Compliance Management

Creating Innovative Pharmaceuticals

Improving Access to Healthcare

Providing the Highest Quality Medical Information

Providing a Stable Supply of Top-Quality Pharmaceutical Products

Promoting Environmental Management

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

Introduction of Our Initiatives

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

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

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

Basic Policy

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

Setting a Target to Reduce CO₂ (by 27% Compared to 2015) with Consideration for Long-Term Goals

We have set a target at Daiichi Sankyo Group to reduce greenhouse gases, and this target has been approved by the Science Based Targets Initiative (SBTi). Our target to reduce greenhouse gases emitted through business activities at the Group falls in line with the necessary degree of reduction for keeping the average increase in global temperature below 2°C. In fiscal 2018, we achieved a 12.7% reduction of CO₂ emissions from fiscal 2015, meaning that we have gone beyond our target for fiscal 2020. We will continue to engage in initiatives for CO₂ reduction in consideration of long-term goals in 2030.

Building a System to Secure the Reliability of Environmental Performance Data

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

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

Other Initiatives: Structure for promoting environmental management; response to water risks; effective use of resources; control of chemical substances; initiatives for biodiversity conservation. The Company updates its corporate website with information regularly. https://www.daiichisankyo.com/aboutлаesponsibility/ourbusiness/environment/index.html

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

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

Corporate Governance Aimed at Fulfilling Our Mission

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

Creating Innovative Pharmaceuticals

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

Improving Access to Healthcare

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

Providing the Highest Quality Medical Information

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

Promoting Compliance Management

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

Introduction of Our Initiatives

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

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

Preparing for Environmental Changes

Establishing the Daiichi Sankyo Group Global AntiBribery & Anti-Corruption Policy
The laws and regulations that pertain to bribery and other forms of corruption in countries around the world are growing stricter with each coming year. Thus, it is becoming increasingly important for companies with global operations to implement initiatives for the prevention of bribery and other forms of corruption.

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

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

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

Other initiatives: Compliance system; sustainable procurement; information security; R&D ethics. The Company updates its corporate website with information regularly.

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

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

Introduction of Our Initiatives

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

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

Other initiatives: Promotion of occupational health and safety, signing of a Statement of Support for the Women’s Empowerment Principles (WEPs). The Company updates its corporate website with information regularly.

COF Project Overview

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

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

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

Introduction of Initiatives

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

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

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

New Modalities

Daiichi Sankyo has been advancing research on modalities in which, in addition to small molecules and DS-8201 in the ADC franchise, we conduct research of next generation ADC, bispecific antibodies, nucleic acid drugs, oncolytic viruses, cell therapies, and other medicines in the ADC franchise. We conduct research of next generation ADC, bispecific antibodies, nucleic acid drugs, oncolytic viruses, cell therapies, and other medicines in the ADC franchise. We continue creating innovative pharmaceuticals through such experience.

Maximizing Created Value

With the aim of obtaining approval and launching new drug candidates as quickly as possible, we have been evolving our R&D process. To strengthen the creation of cancer treatment medicines, in particular, we have combined oncology field research and development into one sub unit. Also, in collaboration and coordination with Medical Affairs and Global Marketing, we make decisions swiftly and optimize resource allocation.

Furthermore, in an attempt to strengthen our translational research**, we have built and started the operation of a platform that enables us to make the most of our clinical data. Going forward, we will store and utilize data from other institutions working in our joint research. Using knowledge obtained from this database, we will develop companion diagnostics and conduct small-scale clinical trials with high success rates. Storing data through this platform also enables us to react immediately and appropriately upon obtaining new scientific knowledge.

In clinical development, we develop clinical trial plans, taking into account the specialty of the doctor and medical institution based on the characteristics of the project as well as from a global viewpoint. Thus, we conducted the phase 1 study for DS-8201 in Japan ahead of other countries.

Meanwhile, we collaborate with major laboratories in the U.S. that have a wealth of experience and expertise in the field of oncology and authentic academia with a track record of success to introduce different types of know-how on the development of pharmaceuticals for cancers.

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

Improving Access to Healthcare

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

Introduction of Our Initiatives

Establishing the Access to Healthcare Policy of Daiichi Sankyo Group

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

Access to Healthcare policy of Daiichi Sankyo Group

Challenges to access to healthcare

Unmet medical needs
Access barriers to essential healthcare managed by social factors such as public health, education and income inequality

Solutions in healthcare fields with low treatment satisfaction
Improvements of availability of pharmaceuticals
Reliability of hospital healthcare infrastructure

Research & Development
Availability
Capacity Building

Initiatives Targeting Rare Diseases

(Restrictive & Development)

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

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<thead>
<tr>
<th>Disease</th>
<th>Drug Name</th>
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<tbody>
<tr>
<td>Atypical hyperphenylalaninemia</td>
<td>Ripretinib</td>
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<tr>
<td>Acute myeloid leukemia</td>
<td>Quizartinib</td>
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<tr>
<td>Neuroendocrine cancer</td>
<td>Pemigatinib</td>
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<tr>
<td>Duchenne muscular dystrophy</td>
<td>DM1-Amylase/DS-1647</td>
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<td>Severe spastic paralysis</td>
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</tbody>
</table>

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

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

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

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

Other initiatives: Participating in Access Accelerated, vaccine production technology transfer for Vietnam.

The Company updates its corporate website with information regularly.

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

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

Managing Safety Information and Promoting Proper Use

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

Introduction of Our Initiatives

Developing Pharmaceuticals Based on Statistical Evidence

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

Generate Information (Evidence) Through Clinical Research and Other Activities

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

Value Creation Story

Medium-to-Long-Term Initiatives and Challenges

Providing the Highest Quality Medical Information

Basic Policy

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

Introduction of Our Initiatives

Developing Manufacturing Processes

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

Manufacturing and Supply Systems (Supply Chain Management)

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

Quality Assurance at a Global Standard

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

Systems for Achieving Stable Supply During Emergencies

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

**Daiichi Sankyo’s Strengths**

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

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

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**Science & Technology**

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

**Daiichi Sankyo’s Proprietary Antibody Drug Conjugate (ADC) Technologies**

DS-8201 was created through Daiichi Sankyo’s proprietary science and technology. The antibody portion of this drug was created by applying the antibody research and protein engineering capability of the former Sankyo, while the drug payload and linker were born out of the research capabilities of the former Daiichi Pharmaceutical. Our ADC project started in 2016 by examining the merits and issues regarding the preceding ADC. In order to solve these issues regarding the preceding ADC, our researchers screened and optimized over several hundred combinations of antibodies, linkers, and payloads to ultimately produce the technology we have now. Daiichi Sankyo’s ADC has been established as a platform technology where a payload and linker can be combined with many different antibodies, and we are currently developing seven ADC projects.

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**Global Management System Uniting Intellectuals from Around the World**

**Global Management Committee and Global Matrix Management**

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

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

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

* Global Executive Meeting for Research and Development

**Robust, Global Pool of Talent**

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

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

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

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

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

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

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**Preparedness to Diverse Medical Needs**

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

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

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**Comprehensive Training Programs**

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

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**Diverse Modality Technologies**

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

**Powerful Research Engines**

Many Nobel laureates have come from Japan to date, and Japan has shown the world its high standard of research. At Daiichi Sankyo, we hire many talented researchers from excellent universities in Japan every year from a wide range of fields, including pharmacology, medicinal chemistry, pharmaco-kinetics, toxicology and pharmaceutical technology. Additionally we strive to improve the scientific level of research employees after joining the company, sending many of them to study at overseas universities and prestigious research institutions. These researchers take part in cross-functional project teams together with the development division, the pharmaceutical technology division, the marketing division, conducting research every day in order to create new drugs.

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

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

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**Four Businesses Responding to Diverse Medical Needs**

**Continuous launch & sales growth of own products**

- Launching and achieving sales growth in ERBITUX and LOKANSA
- Newly launched Tarlige and MINNESIO in fiscal 2019

**Growth of Japanese business**

- Top class sales capabilities in variety and quality
- Fine-tuned sales capabilities

**Sales growth of acquired products**

- Acquiring and achieving sales growth in NEXUM, Memry, RAMMARK/FIRA/AL, TENELIA/CANALIA, and VINMAT

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For details, refer to page 26.
Daiichi Sankyo set out our 2025 Vision of becoming a “Global Pharma Innovator with Competitive Advantage in Oncology.” The vision for Daiichi Sankyo in 2025 entails the Company having a specialty area centered on oncology as the core business, having enriched regional value products aligned with the regional market, and having innovative products and pipelines changing SOC in each market. At the same time, the Company aims to realize shareholders’ value through highly efficient management.

**Why Oncology?**

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

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

**Six Strategic Targets for Accomplishing Our Performance Targets**

- **Expand global revenue**
  - (fiscal 2018 revenue: ¥117.7 billion)
- **Ranked No.1 in market share of domestic ethical drugs for three consecutive years**
- **Continually launching new products** (Targile and MINVEGO)
- **Expand American Regent business**
  - (fiscal 2018 revenue: ¥44.2 billion)
- **Re-examined strategy for the pain franchise of Daiichi Sankyo, Inc.**
- **Established Oncology Business**
  - Accumulated promising clinical data on DS-8201 and working ahead of schedule for the target data to submit an application for approval
  - Presented positive clinical data on U3-1402 and DS-1062
  - Submitted an NDA for Quizartinib and Pemitrex
- **Optimized global manufacturing structure**
  - (four locations closed)
- **Optimized global manufacturing structure**
  - (two locations closed and decided to sell one location)
- **Growth Investments and Shareholder Returns**
  - Issued super-long-term unsecured corporate bonds (¥100.0 billion)
  - Acquired own shares (¥100.0 billion over three-year period)
  - Maintained a total return ratio of 100% or more (114.8% over three-year period)
I would like to begin by thanking all of our stakeholders for the ongoing support to Daiichi Sankyo.

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

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

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

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

Since the development of 5-year business plan (fiscal 2016 to 2020) in March 2016, we are committed to establish a foundation for sustainable growth mainly consisting of the achievement of six strategic targets to transform ourselves toward our 2025 Vision of becoming a “Global Pharma Innovator with competitive advantage in oncology.”

Daiichi Sankyo has set revenue of ¥1,100.0 billion, operating profit of ¥165.0 billion, and return on equity (ROE) of more than 8% for fiscal 2020 as key numerical targets. In addition, for fiscal 2020, we aim to have three to five late-stage pipeline products that can be launched within the next five years with the potential to generate annual revenue exceeding ¥100.0 billion each at peak.

Establish Foundation for Sustainable Growth (Six Strategic Targets)

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

* Broadly applied best treatment practice in today’s medical science

2. Revision of Targets (Presented in October 2018)

In October 2018, we revised the 5-year business plan. Although edoxaban, an oral anticoagulant that is one of our global mainstay products, strongly increased its market share in Japan and Europe, achievement of the targets initially set for fiscal 2020 has become challenging. This is due to the sense of uncertainty over future growth of Japan business as result of a radical reform of the NHI drug price system in the country, the unsuccessful development of new drugs in the U.S. pain business, and so on.

On the other hand, we decided to expand our investments to maximize the potential for our ADC franchise with DS-8201 listed first, and based on several strong data for the ADC franchise. Accordingly, we decided to delay our initial fiscal 2020 target (revenue of ¥1,100.0 billion, operating profit of ¥165.0 billion, and return on equity (ROE) of more than 8%) for two years to fiscal 2022.

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

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

3. Revision Based on Impact of Strategic Alliance with AstraZeneca

After the revision of numerical targets for the current 5-year business plan in October 2018, Daiichi Sankyo decided to form strategic alliance with AstraZeneca for DS-8201 in March 2019. Currently, we are having discussion with AstraZeneca on the details of the development and commercialization plan. Once we reach agreement, we will present Daiichi Sankyo’s updated numerical targets including revised resource allocation for the other development projects such as U3-1402.

Examples of Initiatives for Improving Corporate Value

Here, I will explain our specific ROE improvement and capital cost reduction initiatives as part of our initiatives for improving corporate value, following (1) to (6) in the figure below.

To Improve Corporate Value

- Improve ROE
  - Operating Profit Ratio to Revenue
  - Total Asset Turnover Ratio
  - Financial Leverage
- Reduce Capital Cost
  - Streamline Non-core Assets
  - Realize Optimal Ratio of Capital to Liability, Enhance Shareholder Returns
- Extensive Risk Management, Initiatives for Sustainability
  - Realize Engagement through Reinforcing IR Activities
- Other initiatives
Concerning the optimization of operating structures, for manufacturing, marketing & sales, and R&D.

In terms of investment, our focus is to optimize business portfolio by reinforcing financial investment decisions with capital cost in mind and taking synergies into consideration.

When making investment decisions for the business or capital expenditure, which has significant impact on future profit, we will support such decision through reading the future business environment, vision, and strategy, and by setting the hurdle rate, discount rate and other factors in response to market and business risks.

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

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

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

Daiichi Sankyo Group aims to realize its 2025 Vision of striving to become a “Global Pharma Innovator with competitive advantage in oncology.” In light of the strong progress in oncology development with focus on ADC, we formed a strategic alliance with AstraZeneca for DS-8201, which is our first ADC project. In March 2019 and have been making steady progress in development.

From a mid-term perspective, prior investment in preparation for the launch of oncology products is anticipated in each region. With respect to business development, demand for funds is expected to increase further to obtain pipelines, products, and businesses that meet the strategy. In addition, strategic investment from a long-term perspective is also essential. As such, I understand the role of CFO is extremely significant.

Going forward, I will continue to improve corporate value by enhancing shareholder returns while paying attention to the balance between investment and profitability.

In Closing
5-Year Business Plan Overview and Progress: Grow Edoxaban

Strategic Target

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

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

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

1 5-Year business plan

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

2 Progress to date

(1) Growth in Japan

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

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

(2) Growth in each country

Since it's marketed, steadily increasing the number of countries in which edoxaban has been marketed, it has been on the market in more than 30 countries and regions globally. In addition to steady growth in Asian region like South Korea and Taiwan, as well as in European region like Belgium and Germany, it was marketed in Brazil in August 2018 and was approved in China in December 2018. Going forward, we aim to achieve further growth by successfully marketing it in China.

3 Life-cycle management initiatives

Currently, we are engaged in many clinical studies and lifecycle management activities, collectively referred to as EDOSURE® that create data on how edoxaban is used in clinical settings.

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

What are direct oral anticoagulants?

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

Warfarin has long been the standard treatment to prevent blood clots. However, there are many restrictions to which attention needs to be paid when using warfarin such as periodic monitoring with blood tests, a variety of drug interactions, and dietary restrictions. Direct oral anticoagulants including edoxaban have been developed to significantly improve the inconvenience of warfarin as mentioned above.
5-Year Business Plan Overview and Progress: Grow as the No.1 Company in Japan

Strategic Target

Grow as the No.1 Company in Japan

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

1 5-Year business plan

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

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

* No.1 in the bone resorption inhibitor market

Total revenue from the six major products has steadily expanded, from ¥197.3 billion in fiscal 2016 to ¥212.8 billion in fiscal 2017. However, in fiscal 2018, revenue remained almost unchanged at ¥211.5 billion, due to factors such as significant reduction in the drug price of NEXIUM, which are more severe than expected at the time of the 4th mid-term business plan announcement. In fiscal 2019, revenue is expected to increase y-y to ¥217.0 billion, despite the impact of the drug price revision. Although the market environment is becoming increasingly challenging, we will leverage our extensive product portfolio and excellent sales capabilities to achieve our fiscal 2020 target of ¥243 billion in revenue.

2 Progress to date

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

During the 5-year business plan, we have successfully achieved many feats seen below, including Vimpat, an epileptic agent, and CANALIA combination tablet, a treatment for type 2 diabetes mellitus, growing with a sales revenue target of ¥10 billion or more for fiscal 2019. Furthermore Daiichi Sankyo has ranked No.1 both in MR evaluation*, which is an important foundation for sustainable growth, for seven consecutive years, and in revenue from pharmaceutical products in Japan for three consecutive years.

* Based on survey conducted by ANTERIO Inc.

Pharmaceutical Market in Japan

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

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

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

Structure of Japanese Pharmaceutical Market

Approx. 90%*

Prescription pharmaceuticals

- Requires prescriptions from physicians
- Has official set prices (NHI drug prices)
- Includes vaccine

Approx. 10%

OTC and Others

- Includes general pharmaceuticals and fresh menthol products
- Includes vitamin and mineral supplements
- Purchasable at pharmacies and drug stores
- Can be advertised as individual brands

Approx. 81%*

New drugs

- Innovative pharmaceuticals

Approx. 9%*

Generic pharmaceuticals
Establish Oncology Business

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

5-Year Business Plan

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

1) ADC Franchise

2) AML Franchise

3) Breakthrough Science

Submit Applications for Approval of 7 NMEs by 2025

About Cancer

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

Cancer death (all types of cancer) 2018

<table>
<thead>
<tr>
<th>Year</th>
<th>Japan</th>
<th>U.S.</th>
<th>Europe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9,555</td>
<td>409</td>
<td>617</td>
</tr>
</tbody>
</table>

Source: GLOBOCAN 2018, FACT SHEET

Cancer is an Innovator with competitive advantage in oncology.* The Oncology R&D sub unit has established three pillars, antibody drug conjugate (ADC) franchise, acute myeloid leukemia (AML) franchise, and breakthrough science* that we will focus on.

We are aiming to become a world-leading science Leader with breakthrough innovation that changes cancer treatment by applying innovative science and technology.

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

Cancer can be cured if it remains in the primary lesion. Chemotherapeutic drugs play a principal role in drug therapy. Chemotherapeutic drugs are small molecule drugs that produce therapeutic effects on highly proliferative cells. They also affect to maintain function, such as gastrointestinal and bone marrow cells. This impact on normal cells is the cause of most of the chemotherapy-induced side effects.

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

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

<table>
<thead>
<tr>
<th>Cancer</th>
<th>Japan</th>
<th>U.S.</th>
<th>Europe</th>
</tr>
</thead>
<tbody>
<tr>
<td>New cancer cases (n)</td>
<td>144,000</td>
<td>4,300</td>
<td>2,390,000</td>
</tr>
<tr>
<td>Recurrent cancer cases (n)</td>
<td>6,000</td>
<td>44,000</td>
<td>244,000</td>
</tr>
<tr>
<td>5-year survival (%)</td>
<td>38%</td>
<td>16%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Source: CancerMPact, Kanzer Health/Syne Inc. (Strict division of confidential information)

Cancer Treatment

1) Cancer treatment

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

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

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

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

1. What is ADC?

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

<table>
<thead>
<tr>
<th>Antibody drug</th>
<th>Chemotherapeutic drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>High target selectivity</td>
<td>Low target selectivity</td>
</tr>
<tr>
<td>Fewer side effects, relative to chemotherapeutic drugs</td>
<td>Many potential side effects of chemotherapeutic drugs</td>
</tr>
<tr>
<td>Sometimes insufﬁcient activity</td>
<td>Potent anti-tumor activity (cytotoxic)</td>
</tr>
</tbody>
</table>

2. Mechanism of Action with ADC

ADC exerts its therapeutic effects through the following steps:

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

3. Structure of Daiichi Sankyo’s ADC

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

4. Characteristics of Daiichi Sankyo’s ADC

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

- **New payload**
- **High potency of payload**
- **Payload with a short systemic half-life**
- **Stable linker**
- **Tumor selective cleavable linker**
- **High drug-antibody ratio**

5. Selectively cleaved linker in cancer cells

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

6. High drug-antibody ratio

The drug antibody ratios (the number of payloads held on a single antibody) for currently approved ADCs range unevenly between two and seven, whereas Daiichi Sankyo’s ADC can load a maximum of eight payloads with high uniformity. Historically, ADCs bearing more payloads per antibody cause aggregation after being formulated. But Daiichi Sankyo’s ADC construct and its formulation minimizes aggregation, even with the high DAR. For example, DS-8201 and L3-1402 have a DAR of eight, but they are highly uniformed. Furthermore, we possess technology to control the drug-antibody ratios according to antigen expression and internalization rates. For example, DS-1062 is optimized as a DAR of four.

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

The graph below demonstrates that the linker is stable by showing that the blue line representing the blood concentration of DS-8201, showing that the blue line representing the blood concentration of DS-8201.

8. Overview and Progress of 5-Year Business Plan: Establish Oncology Business

Establish Oncology Business

- **Pharmacokinetics profile of DS-8201 Phase 1 6.4mg/kg**
- **DS-8201**
- **Payload**
- **Total antibody (incl. DS-8201)**

Source: Tamura K et al., Abstract #4585 (LBA17), ESMO 2016
Daiichi Sankyo’s ADC Franchise

At present, Daiichi Sankyo has seven ADC projects for different antibody targets with the same linker and payload. Clinical trials began for DS-8201, U3-1402, and DS-1062 are in progress, with data presented at numerous medical conferences. Phase 1 studies are slated to start in fiscal 2019 for DS-7300 and DS-6157.

1. **DS-8201 (anti-HER2-ADC)**

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

(1) What is HER2?

HER2 is an antigen found on the cell surface. It has a structure similar to the epidermal growth factor receptor (HER1/EGFR). It is a receptor tyrosine kinase associated with cell proliferation, HER2, which is overexpressed on the surface of cancer cells, such as those of breast cancer, gastric cancer, colorectal cancer, lung cancer, and bladder cancer, induces cancer cell proliferation by activating signal transmission. DS-8201 exerts its efficacy by binding to this HER2.

(2) **DS-8201 overall development plan**

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

**Phase 1 study breast cancer, comparison to similar drugs**

<table>
<thead>
<tr>
<th>Breast</th>
<th>Pertuzumab + trastuzumab + chemo (1L)</th>
<th>T-DM1 (1L, failed study)</th>
<th>T-DM1 (3L)</th>
<th>T-DM1 (3L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mPFS</td>
<td>18.5m</td>
<td>14.1m</td>
<td>9.6m</td>
<td>6.3m</td>
</tr>
<tr>
<td>DoR</td>
<td>20.2m</td>
<td>20.7m</td>
<td>12.6m</td>
<td>9.7m</td>
</tr>
<tr>
<td>OS</td>
<td>56.5m</td>
<td>53.7m</td>
<td>30.9m</td>
<td>22.7m</td>
</tr>
<tr>
<td>ORR</td>
<td>80%</td>
<td>60%</td>
<td>43.6%</td>
<td>31%</td>
</tr>
<tr>
<td>Median prior Rx for adv. disease</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>


**Phase 1 study gastric cancer, comparison to similar drugs**

<table>
<thead>
<tr>
<th>Gastric</th>
<th>Trastuzumab + Chemotherapy (1L)</th>
<th>Ramucirumab + Chemotherapy (1L)</th>
<th>T-DM1 (failed study; 2L)</th>
<th>DS-8201**</th>
</tr>
</thead>
<tbody>
<tr>
<td>mPFS</td>
<td>6.7m</td>
<td>4.4m</td>
<td>2.7m</td>
<td>5.6m</td>
</tr>
<tr>
<td>DoR</td>
<td>6.9m</td>
<td>4.4m</td>
<td>4.3m</td>
<td>7.0m</td>
</tr>
<tr>
<td>OS</td>
<td>13.8m</td>
<td>9.9m</td>
<td>7.9m</td>
<td>12.8m</td>
</tr>
<tr>
<td>ORR</td>
<td>47%</td>
<td>28%</td>
<td>21%</td>
<td>43.2%</td>
</tr>
<tr>
<td>Median prior LoT</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>


**Listing of abbreviations**

<table>
<thead>
<tr>
<th>Abbreviations</th>
<th>Language</th>
<th>English</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR</td>
<td>Complete response</td>
<td>Complete response (complete resolution of cancer)</td>
<td></td>
</tr>
<tr>
<td>DCR</td>
<td>Disease control rate</td>
<td>Disease control rate (percentage of patients with controlled disease status)</td>
<td></td>
</tr>
<tr>
<td>DOR</td>
<td>Duration of response</td>
<td>Duration of response (duration of response)</td>
<td></td>
</tr>
<tr>
<td>DLT</td>
<td>Dose limiting toxicity</td>
<td>Dose limiting toxicity (toxicities that may explain the inability to escalate doses)</td>
<td></td>
</tr>
<tr>
<td>MTD</td>
<td>Maximum tolerated dose</td>
<td>Maximum tolerated dose (maximum dose that is a drug that can be administered without causing unacceptable side effects)</td>
<td></td>
</tr>
<tr>
<td>OS</td>
<td>Overall survival</td>
<td>Overall survival (time from start of treatment to death)</td>
<td></td>
</tr>
<tr>
<td>PD</td>
<td>Progression disease</td>
<td>Progression occurring despite treatment (progression despite treatment)</td>
<td></td>
</tr>
<tr>
<td>PR</td>
<td>Progression-free survival</td>
<td>Progression-free survival (without cancer progression)</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>Stable disease</td>
<td>Stable disease (the size of the cancer is almost unchanged before and after treatment)</td>
<td></td>
</tr>
</tbody>
</table>
(4) Interstitial lung disease

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

ILD has been recognized as a critical adverse event for DS-8201 from the earliest stage of the program. And a decision was taken to evaluate all suspected ILD cases via investigator to be potential ILD cases. Of these, a lower number of cases presented for the 665 cases treated with DS-8201.

The 665 cases, 66 cases (9.9%) were reported by the investigator to be potential ILD cases. Of these, a lower occurrence of 15 out of 269 cases (5.6%) was found in breast cancer patients treated with the low dose of 5.4 mg/kg. As a result, the dosage be used to be used in breast cancer phase 3 trials was set to 5.4 mg/kg.

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

These changes of protocol are made to all our ADC projects. We continue to recognize ILD as critical adverse events and continue monitoring safety. At the same time, we are actively organizing a broad campaign to further drive awareness of safety use.

Number of ILDs by severity in all patients

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

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

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

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

How to Read Graphs

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

**Spider Plot**
Relationship between percent change in tumor size and duration of treatment. Each line represents the outcome of each patient.
(6) Progress of HER2 low expression breast cancer clinical study
To date, breast cancers HER2 status has been classified into two types by immunostaining that detects expression: HER2-positive and HER2-negative. However, it has been revealed that HER2 is expressed (IHC2+/ISH-, IHC1+) in some types of breast cancers classified as HER2-negative. For the purposes of our clinical development program, we are now calling these patients "HER2 low". It is said that HER2 low accounts for approximately 44% of breast cancer patients. To date, there are no approved HER2 targeted agents that have shown clinical benefit for patients with HER2-low tumors.

The graph below is a waterfall chart representing efficacy in HER2 low metastatic breast cancer patients. Even though some patients were heavily pre-treated, favorable effects, ORR 44%, are suggested.

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

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

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

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

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

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

(8) Progress of colorectal cancer clinical study
About 1% to 2% of colorectal cancer patients express HER2. However, no HER2-targeting drug has been approved so far.

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

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

Staining methods used in pathology
- Measurement of proteins and nucleic acids that you want to detect in tissues and cells
- Staining or Histology
  - A technique that enables microscopic observation through staining using pigments and enzymes
  - Immunohistochemistry
  - Observes protein expression levels including HER2 (surface of cancer cell)
  - In situmutation (ISH): abbreviation of in situ hybridization
  - Detects amplification levels of HER2 genes (DNA) etc (nucleus of cancer cell)
  - FISH (Fluorescence in situ hybridization)

COLUMNS

<table>
<thead>
<tr>
<th>HER2 status</th>
<th>Commonly used</th>
<th>DS terminology for future line</th>
<th>Percentage in Total Breast Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>HER2 positive or HER2 expression</td>
<td>HER2 3+</td>
<td>HER2 positive HER2 overexpressing</td>
<td>20.3%</td>
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<tr>
<td>HER2 negative</td>
<td>HER2 2+/ISH+</td>
<td>43.9%</td>
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<tr>
<td>HER2 low</td>
<td>HER2 0/ISH+</td>
<td>35.8%</td>
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</table>

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

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

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

Staining methods used in pathology
- Measurement of proteins and nucleic acids that you want to detect in tissues and cells
- A technique that enables microscopic observation through staining using pigments and enzymes
- Immunohistochemistry
  - Observes protein expression levels including HER2 (surface of cancer cell)
- In situmutation (ISH): abbreviation of in situ hybridization
- Detects amplification levels of HER2 genes (DNA) etc (nucleus of cancer cell)
- FISH (Fluorescence in situ hybridization)

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<tr>
<td>HER2 low</td>
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<td>35.8%</td>
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(10) Progress of studies on combinations with immune checkpoint inhibitors
The results of pre-clinical studies show that the efficacy of DS-8201 can be increased by combining with immune checkpoint inhibitors such as nivolumab without compromising safety.

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

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

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

<table>
<thead>
<tr>
<th>DS-8201a + Anti-PD-1 Ab</th>
<th>N</th>
<th>OS, range</th>
<th>PFS, median</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=19</td>
<td></td>
<td>72.7% (6.7, 17.9)</td>
<td>14.1 (4.0, 14.1)</td>
</tr>
</tbody>
</table>

* Endpoint was set as >3000mm3 of tumor volume or any ethical reasons

<table>
<thead>
<tr>
<th>HER2-expressing NSCLC</th>
<th>OS, range</th>
<th>PFS, median</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=11</td>
<td>100% (11/11)</td>
<td>15.8% (16/19)</td>
</tr>
</tbody>
</table>

* Endpoint was set as i.v. Anti-PD-1 Ab (0.0+, 5.5+)

Value Creation Story
Overview and progress of 5-Year Business Plan: Establish Oncology Business
Concerning the safety, U3-1402 was tolerated over the 7.6-month median exposure period. The dose was also increased to 8 mg/kg, but the maximum tolerated dose was not reached. Currently, recommended dose for expansion was selected and the drug is undergoing the dose expansion part of the phase 1 study.

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

Concerning safety, most of the adverse events were of grade 1 or 2, and while there is dose-limiting toxicity, the maximum tolerated dose had not yet been reached. The drug will undergo the dose expansion part of the phase 1 study in the second half of fiscal 2019.

In addition, HER3 is highly expressed in cancers such as colorectal cancer and prostate cancer, so expansion into other types of cancer is being considered.

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

The graph below is a waterfall chart representing efficacy. Favorable antitumor effects are suggested with ORR 42.9%, despite the condition that most patients were enrolled without prior HER3 selection. Although there are a limited number of cases, some exhibited antitumor activity against mutated cancer cells that appear after treatment with tyrosine kinase inhibitors such as osimertinib. We will evaluate further.

Concerning safety, most of the adverse events were of grade 1 or 2, and while there is dose-limiting toxicity, the maximum tolerated dose had not yet been reached. The drug will undergo the dose expansion part of the phase 1 study in the second half of fiscal 2019.

In addition, HER3 is highly expressed in cancers such as colorectal cancer and prostate cancer, so expansion into other types of cancer is being considered.

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

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

This study was conducted in NSCLC patients who were unresponsive to standard treatments, experienced recurrence with standard treatments, or where a standard treatment does not exist. In addition, as TROP2 is highly expressed in non-small-cell lung cancer, and as such, presence or absence of TROP2 expression was not measured prospectively. Regardless of this condition, this study is notable that it displays dose-dependent antitumor effect.
Concerning safety, of the 39 non-small-cell lung cancer (NSCLC) patients, 16 (41.0%) experienced adverse events grade 3 or higher at least once. Although dose-limiting toxicity was observed as a grade 3 rash (in one patient), the maximum toleratated dose had not yet been reached (at the data cut-off date).

Stage III
( thousand people )

Stage IV

2019/10/01   9:43:32

Stage II

Stage I

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

The drug linker of these compounds are the same as the DS-8201, U3-1402 and DS-1062. Since Daiichi Sankyo’s ADC technologies are applicable to a wide variety of antibodies, we are always examining possibilities for collaboration with other companies to increase the range of antibodies we can apply our ADC technologies to.

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

6 Other ADCs

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

The drug linker of these compounds are the same as the DS-8201, U3-1402 and DS-1062. Since Daiichi Sankyo’s ADC technologies are applicable to a wide variety of antibodies, we are always examining possibilities for collaboration with other companies to increase the range of antibodies we can apply our ADC technologies to.

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ADClncipe line

Project code

Preclinical promising indications

Stage 0

Stage I

Stage II

Stage III

Stage IV

Preclinical promising indications

Stage 0

Stage I

Stage II

Stage III

Stage IV

Pertinent indications

Start date

End date

Other ADCs

Project code

Preclinical promising indications

Stage 0

Stage I

Stage II

Stage III

Stage IV

Pertinent indications

Start date

End date

Breast Cancer

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

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

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

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

Breast Cancer subtype classification and our pipeline

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

We are conducting clinical studies in DS-8201 for HER2 positive and HER2 low metastatic breast cancer and in U3-1402 for HER3 positive refractory/metastatic breast cancer.
Disease in which plasma cells in bone marrow multiply at an abnormal rate and then become cancerous. Leukemia is classified into four types: acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphocytic leukemia (ALL) and chronic lymphocytic leukemia (CLL). Although there are cancer types such as CML for which remission can be expected with molecular targeted drugs, the five-year survival rate of AML is still about 26%, which is very low. Daiichi Sankyo is developing AML therapeutics with various targets, aiming to eliminate AML unmet medical needs.

**Quazartinib (FLT3 inhibitor)**

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

In 2018, we applied for approval in Japan, the United States, and Europe, based on the results of the QUANTUM-R study in patients with relapsed/refractory AML. In Japan, the Ministry of Health, Labour and Welfare approved quazartinib for the treatment of relapsed/refractory FLT3-ITD AML in June 2019. We will launch it under the brand name VANFLYTA®.

In the United States, we received a Complete Response Letter in June 2019. We plan to decide upon our next step in the United States after detailed review of the contents of the Complete Response Letter. In Europe, quazartinib is under review, with approval expected in the second half of fiscal 2019.

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

* A document issued by the FDA when the approval application has been reviewed and the current content does not result in approval.
2. **DS-3201 (EZH1/2 inhibitor)**

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

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

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

### Oncolytic virus therapy

**Virus proliferation and destruction of cancer cells**

- **Cancer cell**
- **Virus infection**
- **Virus proliferation and destruction of cancer cells**
- **Spread of viruses to the surrounding cells**

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

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

We obtained approval in the United States in August 2019 based on the results of a placebo-controlled phase 3 study (ENLIVEN) in patients with tenosynovial giant cell tumor (TGCT) and launched under the brand name Turalio.

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

### Oncolytic virus therapy

**Cancer cell**

- **Virus infection**
- **Virus proliferation and destruction of cancer cells**
- **Spread of viruses to the surrounding cells**

**2. **DS-1647 (oncolytic virus G47Δ)**

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

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

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

**3. DS-1001 (mutant IDH1 inhibitor)**

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

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**Table: Classification of gliomas**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Type of Glioma</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Diffuse astrocytoma, oligodendroglioma</td>
</tr>
<tr>
<td>II</td>
<td>Anaplastic astrocytoma, anaplastic oligodendroglioma</td>
</tr>
<tr>
<td>III</td>
<td>Glioblastoma</td>
</tr>
</tbody>
</table>
Strategic Collaboration to Maximize the Value of DS-8201

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

Overview of the Collaboration

Our collaborator:
AstraZeneca plc
(headquarters: Cambridge, UK)

Content of collaboration:
Joint development and commercialization for DS-8201

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

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

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

Manufacturing and supply
- Daiichi Sankyo manufactures and supplies DS-8201

Financial Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Amount (in billion yen)</th>
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<tbody>
<tr>
<td>Upfront payment</td>
<td>1.35 (148.5 billion yen)</td>
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<tr>
<td>Regulatory and other contingencies</td>
<td>3.80 (418.0 billion yen)</td>
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<tr>
<td>Sales-related milestones (Maximum)</td>
<td>1.75 (192.5 billion yen)</td>
</tr>
<tr>
<td>Total</td>
<td>6.90 (759.0 billion yen)</td>
</tr>
</tbody>
</table>

Accelerate DS-8201 commercialization and development

Early market penetration
- Cancer types and indications currently under development
  - Accelerating market penetration in U.S. and Europe
  - Early launch in other markets other than Japan, U.S and Europe

Accelerate and expand development
- Cancer types and indications for future development
  - Advancing development plans
  - Further expansion of cancer types and indications

Maximizing the product value of DS-8201

Revenue
- Expand revenue by the collaboration
- Revenue without collaboration (stand-alone case)

Accessing resources for other ADC projects following DS-8201

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

Governance with AstraZeneca

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

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

The Daiichi Sankyo Group aims to realize its 2025 Vision to become “Global Pharma Innovator with competitive advantage in oncology” and to sustainably increase its corporate value by bringing out the best in our strengths which are Science & Technology, Global Organization & Talent, and Presence in Japan.

As for global circumstances, the frameworks such as the Sustainable Development Goals (SDGs), the UN Guiding Principles on Business Human Rights, and the Paris Agreement, all led by the United Nations are becoming more important. Moreover, the flow toward ESG investment including the Principles for Responsible Investment (PRI) has been significantly affecting our business environment. We will make contributions to realize a sustainable society by actively tackling social issues indicated by such global movements.

In order to sustainably increase the corporate value, we have to establish a management structure capable of responding flexibly and timely to changes in the business environment.

At Daiichi Sankyo, the Board appropriately makes important business decisions while establishes and operates properly the internal control system that ensures efficient execution under delegation of directors’ authority.

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

The Daiichi Sankyo Group is creating a management structure that can respond speedily and flexibly to changes in the business environment, in addition to working to secure legal compliance and management transparency, and to strengthen oversight of management and the conduct of operations. In this way, we have been advancing the corporate governance structure for achieving our mission.

Since its establishment of joint holding company of Sankyo Co., Ltd. and Daiichi Pharmaceutical Co., Ltd. in 2005, the Daiichi Sankyo Group has been striving to strengthen corporate governance. We are committed to establishing the system for the Board of Directors to appropriately make important business decisions and oversight its management, establishing the internal control system that ensures proper operation under delegation of Board of Directors’ authority, and operating and implementing measures for the board to be effective and to improve its function.

Daiichi Sankyo has complied with and implemented all of the Principles of the Corporate Governance Code, which came into force in 2015, including those revised in June 2018 as of June 17, 2019.

Daiichi Sankyo will continue to implement initiatives for enhancing its corporate governance systems going forward, as well as securing and improving the functions and effectiveness of the Board of Directors.

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

The Group’s initiatives for corporate governance

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<tr>
<td>Chairman of the Board</td>
<td>Kiyoshi Morita</td>
<td>Takashi Shoda</td>
<td>George Nakayama</td>
<td>George Nakayama</td>
<td>George Nakayama</td>
<td>Sunao Manabe</td>
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<td>Members of the Board</td>
<td>Outside 4 persons</td>
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<td>Outside 2 persons</td>
<td>Outside 4 persons</td>
<td>1 observer (outside)</td>
<td>1 observer (outside)</td>
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<td>Inside 2 persons</td>
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<td>Outside 4 outside persons</td>
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<td>Inside 2 persons (including two female members)</td>
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<td>Nomination Committee</td>
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<td>Inside 2 outside persons and 1 internal person</td>
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<td>Share remuneration-type stock option plan</td>
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<td>Restricted share-based remuneration plan</td>
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George Nakayama
Representative Director and Chairman of the board
I Securing and enhancing the effectiveness of the important business decision and oversight functions of the Board of Directors

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

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

(1) The Company has nine Members of the Board, of which four are outside members. Each Member of the Board (Outside) actively makes suggestions and appropriate remarks in the Board of Directors Meeting, based on insight as corporate managers in various industries and sectors, including the telecommunication, general heavy industries, IT, business strategy and marketing strategy, and/or expert knowledge and insight as medical doctor, playing important roles in enhancing the decision-making and oversight functions of the Board.

(2) The Audit and Supervisory Board has five members, of which three are outside members and conducts audits of legal compliance and appropriateness of management.

(3) Both of the Nomination and the Compensation Committees are established to ensure management transparency.

The four Members of the Board (Outside) serve as members and one Member of the Audit and Supervisory Board (Outside) participates in each committee as the observer.

(4) In addition to the qualification and performance requirements, etc. defined in the Member of the Board Regulations of the Company, and The Code of Audit and Supervisory Board Member Auditing Standards, both Members of the Board (Outside) and Member of the Audit and Supervisory Board (Outside) meet the independence criteria of the Tokyo Stock Exchange (TSE) and the independence judgment criteria for outside directors set forth by the Company. All the members are reported as independent directors to the TSE.

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

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

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

3. the Board of Directors’ address at ESG issues

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

(1) Corporate Ethics Committee

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

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

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

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

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

* TCFD (Task Force on Climate-related Financial Disclosures): This task force was established in December 2015 by the FSB (Financial Stability Board). The FSB is an international organization joined by central banks and financial regulators from the major powers.
Corporate Function (Secondary Control), and internal audit including monitoring by the Internal Audit Department (Tertiary Control).

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

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

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

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

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

2. Evaluation of the Board of Directors

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

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

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

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

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

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

3. Nomination Committee and Compensation Committee

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

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

1. Nomination Committee

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

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

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

(2) Compensation Committee

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

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

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

The remuneration to Members of the Board (excluding Members of the Board (Outside)) is designed to provide remuneration that contributes to maximize corporate value. Specifically, in addition to a basic remuneration as fixed remuneration, performance-based bonuses serving as short-term incentive and restricted share-based remuneration serving as long-term incentive are adopted as variable remuneration. The percentage of each remuneration component is designed to be 60% for basic remuneration, 20% for performance-based bonus, and 20% for restricted share-based remuneration if 100% of the performance goal is achieved.

The performance-based bonuses serving as short-term incentives are calculated by adopting revenue, indicating the size of the business, as an index with a high correlation to the maximization of corporate value, ratio of operating income to revenue, indicating the efficiency of business activities, and profit attributable to owners of the Company, indicating the final outcome of corporate activities, as the relevant indices.

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

Message from Chairperson of the Compensation Committee

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

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

In light of Daiichi Sankyo’s system created through experience, I will examine the system for more appropriate remuneration from a new point of view.
There is a clear need for management systems capable of offering a swift and flexible response to changes in the business environment and a Board of Directors’ structure that sufficiently incorporates external viewpoints. I therefore feel immense responsibility to live up to expectations with this regard as a Member of the Board (Outside).

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

I am committed to offering valuable advice and suggestions based on my experience as a manager in the information and communication industry and the insight gained through this experience, thereby contributing to the overall management strategy. Furthermore, I will strive to facilitate effective corporate governance with regard to such areas as transforming digital transformation and conducting appropriate investments for future growth and selecting members of the management team.

I am delighted to engage in the management of the Company as a Member of the Board (Outside). From the viewpoint of a machinery manufacturer in a directly opposite position of the Company as well as the expertise and understanding of such a circumstance while adhering to laws and the Corporate Governance Code.

I understand the role of the Board of Directors as “conducting monitoring for sustainable growth and increased corporate value,” the specific, decision-making on the management policy (management board) and monitoring and supervising the conduct of operations by Members of the Board and Corporate Officers (monitoring board). Members of the Board (Outside) are required to assess the effectiveness of the management strategy and risks associated with the implementation of the strategy and to constantly verify the effectiveness of governance and internal control to prevent damage to corporate value, from the standpoint of a third party who is not involved in the conduct of operations.

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

Taking risks is necessary for the growth of a company. Daiichi Sankyo is also looking to take risks in pursuit of growth. Members of the Board (Outside) tend to be negative when it comes to implementing a strategy for taking risks. I will fulfill my role from the standpoint of supporting the Corporate Officers by taking a positive stance in implementing strategies and monitoring the PDCA cycle for implementing the strategies.

I was appointed a Member of the Board (Outside) in June 2019. I think our 2025 Vision of becoming a “Global Pharma Innovator with competitive advantage in oncology” is an excellent vision that is socially beneficial as well as gives people great hope in terms of cancer prevention. People all around the world are wishing to overcome cancer. I am delighted to engage in the management of the Company as a Member of the Board (Outside).

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

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

Members of the Board

**High Representative Director and Chairman**

George Nakayama

**Representative Director**

Toshiaki Toyoda

**Chairperson of the Board**

Masaaki Himi

**Representative Director**

Toshikazu Hori

**Chair of the Corporate Governance Committee**

Yes, Notomi

**Representative Director**

Toshio Sato

**Executive Director**

Toshihide Yamamoto

**Executive Director**

Yuji Kato

**Executive Director**

Kazutaka Aoki

**Executive Director**

Seiichiro Eguchi

**Executive Director**

Takeshi Higuchi

**Executive Director**

Satoshi Aoki

**Executive Director**

Masaaki Himi

**Executive Director**

Toshiro Kamada

**Executive Director**

Koichi Nakayama

**Executive Director**

Koji Izumi

**Executive Director**

Hidenori Otake

**Executive Director**

Mitsuo Matsumoto

**Executive Director**

Takeshi Hata

**Executive Director**

Takashi Ueno

**Executive Director**

Masayuki Tsuchida

**Executive Director**

Hiroyuki Tani

**Executive Director**

Masahiro Sato

**Executive Director**

Takayuki Fukuoka

**Executive Director**

Kazumasa Kama

**Executive Director**

Sawako Nohara

**Executive Director**

Tatsuya Sakamura

**Executive Director**

Takashi Ishikawa

**Executive Director**

Tatsuhiko Kurosawa

**Executive Director**

Takashi Hasegawa

**Executive Director**

Masahiro Kano

**Executive Director**

Toshiyuki Nakamoto

**Executive Director**

Takashi Takahashi

**Executive Director**

Masahito Kato

**Executive Director**

Takashi Takahashi

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Takashi Takahashi

**Executive Director**

Masahito Kato
Risk Management

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

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

Risk Management System

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

Annual Cycle for the Management of Material Risks

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

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

Key material risks selected by the Group

- Risks related to sales of rival products
- Litigation-related risks
- Risks related to laws, regulations, and regulatory trends to limit healthcare expenditures
- Risks related to R&D and alliances
- Risks related to business development overseas
- Risks related to manufacturing
- Risks related to the financial market and foreign exchange rate fluctuations
- Risks related to information management, etc.

Conceptual diagram of the Group’s risk level classification

<table>
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<th>Material risk identified in the Management Executive Meeting and the Board of Directors Meeting and managed by the entire company</th>
<th>Managed by each business unit/functional unit</th>
<th>Managed by each division</th>
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<tr>
<td>High Impact</td>
<td>Low Likelihood of occurrence</td>
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Business Continuity Plan

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

Based on its experiences following the Great East Japan Earthquake, the Group revised its BCP in 2012. Since then, we have continued to improve upon the BCP through such means as incorporating revisions to national disaster response plans and adjusting for changes in workflow procedures and organizations related to drugs for which supply should be prioritized based on social needs. In this manner, we strive to ensure effective response measures are taken in the event that a risk occurs. In addition, we regularly review the list of priority supply drugs to guarantee we can quickly supply drugs used by a large number of patients, drugs needed in emergencies, and drugs with no substitutes.

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

Crisis Management

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

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

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