

Message from the CEO

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



Sunao Manabe
Representative Director,
President and CEO

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

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

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

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

Medium-to-Long-Term Initiatives and Challenges

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

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

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

Medium-to-Long-Term Initiatives and Challenges

Promoting Environmental Management

Corporate Governance Aimed at Fulfilling Our Mission

Promoting Compliance Management

Promoting the Success of and Nurturing a Diverse Range of Human Resources Who Can Produce Competitive Advantage

Creating Innovative Pharmaceuticals

Improving Access to Healthcare

Providing the Highest Quality Medical Information

Providing a Stable Supply of Top-Quality Pharmaceutical Products

Message from the CEO

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

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

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

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

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

For details, refer to page 21.

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

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

Submitting NDA for *DS-8201*

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

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

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

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

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

This strategic collaboration has significance in three main areas.

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

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

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








For details, refer to page 59.

The Significance of This Collaboration

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

ADC (Antibody Drug Conjugate) Pipeline

Combinable with a wide range of antibodies

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

Daiichi Sankyo's ADC Technology: Platform Technology

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

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

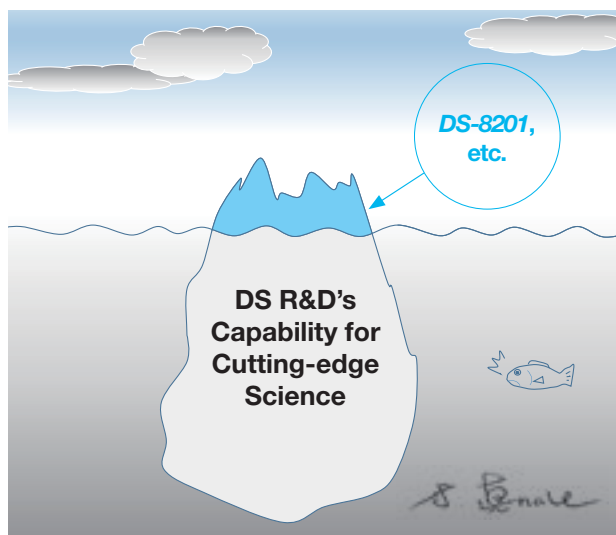
In addition, we plan to start phase 1 trials for our new ADCs, *DS-7300* and *DS-6157*, during this fiscal year. We have more ADC projects scheduled after that as well.

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

Message from the CEO

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

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



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



In Closing

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