In April 2021, the Daiichi Sankyo Group announced its current 5-year business plan (FY2021-FY2025) toward realizing our 2030 Vision. Following is an overview of major initiatives under that 5-year plan.

Maximize our 3 Lead ADCs

- Enhertu®/Dato-DXd/HER3-DXd, which are all based on our proprietary DXd-ADC technology. These three medicines are strategic priorities where we are concentrating much of our R&D and human resources. In the oncology area, we expect to achieve revenue of over ¥900 billion in FY2025, well above the ¥600 billion originally expected.

- Enhertu® sales grew to ¥207.5 billion. Research and development to further maximize the value of Enhertu® is steady progressing and we anticipate new indication approvals during the current 5-year business plan. 

- HER3-DXd is progressing faster than originally planned.

- Pivotal trials*1 are progressing, and multiple phase 3 trials for additional indications after launch already initiated. To complete these trials, we expect R&D expenses to exceed our initial plan. However, all of these trials are essential for maximizing these three ADCs for the ultimate benefit of patients with these devastating and difficult types of cancer.

- We are making priority investments in DXd-ADC development with the aim of securing approval and delivering these medicines to patients as soon as possible for further growth in the future.

*1 Tests to ensure the efficacy and safety of pharmaceutical products. Conducted to acquire the data required to apply for regulatory approval.

Identify and build pillars for further growth

- Identify new growth drivers following our 3 Lead ADCs

- Select new modalities for further development, to follow DXd-ADCs

Figure 4 Diverse modalities

- DS-7300 (IgH3-directed ADC) and DS-6000 (CD166-directed ADC) are rising stars in our portfolio, as they have tremendous promise for patients, and therefore to become growth drivers.

- For DS-7300, we obtained interim analysis data suggesting an early efficacy signal in a variety of cancer types in the phase 1 trial. We have also initiated a phase 2 trial for second-line treatment of advanced small cell lung cancer.

- DS-6000, we received interim analysis data suggesting early efficacy signals in ovarian cancer and renal cell cancer in the phase 1 trial.

Given the heightened potential of both products, we have accelerated their development in a variety of cancer types, and updated our R&D strategy from "3 and Alpha" to "3DXd-ADCs and Next Wave" from April 2023 onward.

Furthermore, we are making steady progress in selecting post-DXd-ADC modalities, such as initiating a phase 1 trial of a next-generation Daiichi Sankyo ADC, DS-9661, for the treatment of solid tumors.

Create shared value with stakeholders

- Patients: Contributing to patients through patient centric mindset

- Shareholders: Balanced investment for growth and shareholder returns

- Society: Environmental load reduction across the value chain, and actions against pandemic risks

To promote ESG management from a long-term perspective, we are engaging in creating shared value with our stakeholders, including patients, shareholders, investors, the society and environment, and employees. In terms of co-creating with society, we are making progress in addressing pandemic risk with DS-5670, an mRNA vaccine we are developing to prevent COVID-19. The research and development of DS-5670 has been supported by the Project for Promotion of Vaccine Research and Development of the Japan Agency for Medical Research and Development (AMED) and the Emergency Project for Vaccine Development and Production System Improvement of the Ministry of Health, Labour and Welfare. 

Strategic Pillar 1: Maintain our existing business

- Grow Tarlige®, Nilemdo®, etc. quickly

- Expand work force and supply capacity efficiently in a phased manner depending on changes around product potential

- Maximize Lixiana® profit

- Maximize Enhertu® and Dato-DXd

- Maximize our 3 Lead ADCs

Strategic Pillar 2: Profit growth for current business and products

- Maximize Lixiana’s profit

- Grow Tarlige®, Nilemdo®, etc. quickly

- Transfer to profit structure focused on new products

Strategic Pillar 3: Identify and build pillars for further growth

- Identify new growth drivers following our 3 Lead ADCs

- Select new modalities for further development, to follow DXd-ADCs

Strategic Pillar 4: Create shared value with stakeholders

- Patients: Contributing to patients through patient centric mindset

- Shareholders: Balanced investment for growth and shareholder returns

- Society: Environmental load reduction across the value chain, and actions against pandemic risks

- Employees: Create Our DS Culture through fostering our Care Behavior

After receiving approval of the original strain booster vaccination, and in May 2023 we started phase 3 trials of the mutant strain vaccine. Based on the trial results, we aim to obtain approval for Omronar strain vaccines and supply mRNA vaccines for new variant strains in Japan.

1) Project aimed at developing a production system for biopharmaceuticals, including vaccines, in order to produce vaccines and biopharmaceutical products and secure them for the people of Japan in order to prevent the spread of severe infectious diseases and to prevent serious diseases.