Initiatives for Materiality on Business

One of our most important challenges is to continuously create innovative pharmaceuticals and deliver them to as many patients as possible by leveraging our strength in Science & Technology (S&T). The following is an overview of our Materiality on Business initiatives to maximize the value of Enhertu to achieve our goal of becoming a Global Pharma Innovator with a competitive advantage in oncology.

Maximizing the value of Enhertu

We are working to expand the range of indications for Enhertu, our flagship mainstream product, to make it the first cancer drug of choice that can transform treatment and outcomes for patients with HER2-targetable tumors. In FY2022, we received approval for the second-line treatment of HER2 positive metastatic breast cancer and HER2 low metastatic breast cancer (post-chemotherapy treatment) in Japan, the US, and Europe, and for the second-line treatment of HER2 mutant metastatic non-small cell lung cancer in the US. Furthermore, we will continue our activities to deliver new treatments to patients and medical communities as quickly as possible in the field of oncology, where many people still suffer.

Achievements in FY2022

- **Expanded Indications**
  - HER2 positive metastatic breast cancer second- and third-line treatment
  - HER2 low metastatic breast cancer (post-chemotherapy treatment)
  - HER2 positive advanced gastric cancer second- and third-line treatment
  - HER2 mutant metastatic non-small cell lung cancer second-line treatment
  (Approved indications as of end-June 2023)

- **Number of patients treated**
  - Approx. 29,000 as of end-June 2023

- **Expanded number of launched countries/regions**
  - Cumulative total of 35 countries/regions

Creating innovative pharmaceuticals

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Providing a stable supply of top-quality pharmaceutical products

Building a robust global supply chain to meet the increasing demand for the 3ADs

- We are making capital investments in our own plants to maximize the supply of the 3ADs, which is the key to our transformation into a global R&D leader in oncology. Furthermore, to ensure a stable supply in the future, we are implementing measures such as securing production lines from contract manufacturing organizations (CMOs) in addition to boosting our own manufacturing capacity. In FY2022, we made the decision to invest approximately ¥165.1 billion. We will build a global production and supply system with appropriate capital investment to accommodate the increase in 3ADs and other new modality products.

Providing the highest-quality medical information

Timely monitoring and provision of safety information in oncology

With the global launch of oncology products, it has become increasingly important to manage and monitor the enormous amount of safety information in a timely manner. We use the Integrated Data Analysis Platform (IDAP) to streamline data aggregation and to monitor the compliance status of proper use more efficiently. With regard to interstitial lung disease, which is a particularly important component of the safety profile, we have achieved timely monitoring and provision of information to detect the disease at an early stage and prevent it from worsening.

Improving access to healthcare

Sales of Enhertu expanded to 35 countries and regions

Enhertu was first launched in the US in January 2020 for its first indication, third-line treatment of HER2 positive metastatic breast cancer, followed by Japan in May 2020 and Europe in February 2021. Since then, we have been working to accelerate market penetration in Japan, the US, and Europe, as well as to quickly launch the product in other markets and further expand the range of indications. We have a strategic alliance with AstraZeneca, which does business in more than 70 countries and regions in the oncology field, and Enhertu is now available in a total of 35 countries and regions as of the end of March 2023. In addition, we have provided the product to approximately 29,000 patients as of June 2023.

Click here for details on the pipeline of the Daiichi Sankyo Group, in a wide range of cancer indications.