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.

Purpose
Contribute to the enrichment of quality of life around the world

Maximizing the value of *Enhertu*

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

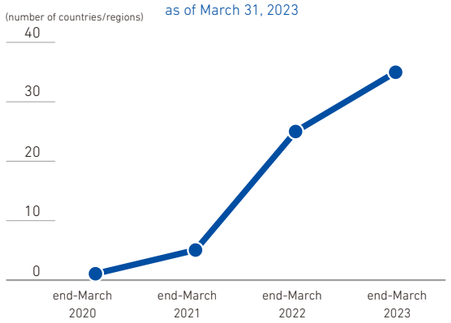
(Approved indications as of end-June, 2023)

Click here for details on the pipeline of the Daiichi Sankyo Group, in a wide range of cancer types and indications.
https://www.daiichisankyo.com/files/rd/pipeline/index/pdf/pipeline_2307_e.pdf

Expanded number of launched countries/regions

Cumulative total of 35 countries/regions

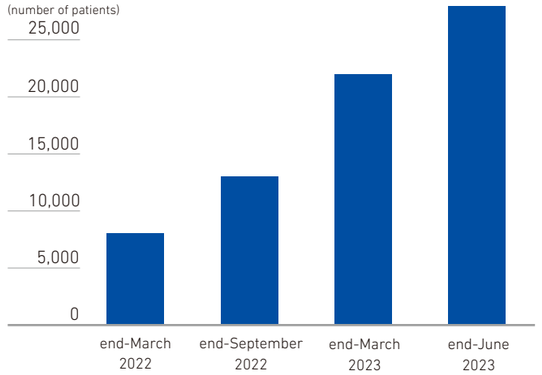
as of March 31, 2023



Number of patients treated

Approx. 29,000

as of end-June 2023



Achievements in FY2022

May 2022
6: Approved as HER2 positive metastatic breast cancer second-line treatment in the US

June
22: Submitted application for HER2 low metastatic breast cancer (post-chemotherapy treatment) in Europe
27: Submitted application for HER2 low metastatic breast cancer (post-chemotherapy treatment) in Japan

July
19: Approved as HER2 positive metastatic breast cancer second-line treatment in Europe
25: Submitted application for HER2 low metastatic breast cancer (post-chemotherapy treatment) in the US

August
8: Approved as HER2 low metastatic breast cancer (post-chemotherapy treatment) in the US
12: Approved as HER2 mutant metastatic non-small cell lung cancer second-line treatment in the US

November
19: Approved as HER2 positive metastatic breast cancer second-line treatment in Japan

December
13: Submitted application for HER2 mutant metastatic non-small cell lung cancer second-line treatment in Japan
19: Approved as HER2 positive advanced gastric cancer second-line treatment in Europe

January 2023
5: Submitted application for HER2 mutant metastatic non-small cell lung cancer second-line treatment in Europe
26: Approved as HER2 low metastatic breast cancer (post-chemotherapy treatment) in Europe

March
27: Approved as HER2 low metastatic breast cancer (post-chemotherapy treatment) in Japan

Creating innovative pharmaceuticals

Toward Expanding Indications for *Enhertu*

We are working to expand the range of indications for *Enhertu*, our flagship mainstay 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.

Added cumulative number of designations to the priority review system as a new KPI item

To embody the Group's Mission of delivering "innovative pharmaceuticals" to patients as quickly as possible, and as an indicator demonstrating our progress toward fulfilling our Purpose, we have added the number of projects designated to the priority review system in Japan, the US, Europe, and China as a KPI item beginning in FY2022, and are continuously monitoring this metric. Since FY2021, we have had 20 such projects.

Region	Primary priority review system
Japan	Orphan drug Priority review Rapid review SAKIGAKE designation
the United States	Priority Review Accelerated Approval Fast Track Breakthrough Therapy
Europe	Accelerated Assessment Conditional Approval PRIME
China	Conditional Approval Procedure Priority Review and Approval Procedure Breakthrough Therapeutic Drug

Providing a stable supply of top-quality pharmaceutical products

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

We are making capital investments in our own plants to maximize the supply of the 3ADCs, 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 ¥65.1 billion. We will build a global production and supply system with appropriate capital investment to accommodate the increase in ADCs 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.