

Press Release

EMA Validates and Grants Accelerated Assessment for Trastuzumab Deruxtecan for the Treatment of HER2 Positive Metastatic Breast Cancer

Tokyo and Munich - (July 6, 2020) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the European Medicines Agency (EMA) has validated the Marketing Authorization Application (MAA) for trastuzumab deruxtecan, a HER2 directed antibody drug conjugate (ADC), for the treatment of adults with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti-HER2 based regimens. Trastuzumab deruxtecan was granted accelerated assessment by the EMA’s Committee for Medicinal Products for Human Use (CHMP).

Validation confirms that the application is complete and commences the scientific review process by the EMA’s CHMP. Accelerated assessment is granted by the CHMP to products expected to be of major interest for public health and therapeutic innovation and can significantly reduce the review timelines.

“The accelerated assessment highlights the significant unmet need for patients with HER2 positive metastatic breast cancer that trastuzumab deruxtecan aims at addressing,” said Gilles Gallant, BPharm, PhD, FOPQ, Senior Vice President, Global Head, Oncology Development, Oncology R&D, Daiichi Sankyo. “Trastuzumab deruxtecan is already available for patients in the U.S. and Japan, and we look forward to working with the EMA to bring this important new medicine to patients in the EU as quickly as possible.”

The MAA is based on the positive results from the pivotal phase 2 DESTINY-Breast01 trial of trastuzumab deruxtecan monotherapy in patients with HER2 positive metastatic breast cancer who had received two or more prior anti-HER2 regimens. The results of the DESTINY-Breast01 trial are published in *The New England Journal of Medicine*.

About HER2

HER2 is a tyrosine kinase receptor growth-promoting protein expressed on the surface of many types of tumors including gastric, breast and lung cancers. HER2 overexpression is associated with a specific HER2 gene alteration known as HER2 amplification and is often associated with aggressive disease and poorer prognosis.¹

About HER2 Positive Breast Cancer

Approximately one in five breast cancers are HER2 positive.^{2,3} Despite recent improvements and approvals of new medicines, there remain significant clinical needs for patients with HER2 positive metastatic breast cancer.^{4,5} This disease remains incurable with patients eventually progressing after available treatment.⁵

About Trastuzumab Deruxtecan

Trastuzumab deruxtecan (fam-trastuzumab deruxtecan-nxki in the U.S. only) is a HER2 directed ADC and is the lead ADC in the oncology portfolio of Daiichi Sankyo and the most advanced program in AstraZeneca's ADC scientific platform.

ADCs are targeted cancer medicines that deliver cytotoxic chemotherapy (“payload”) to cancer cells via a linker attached to a monoclonal antibody that binds to a specific target expressed on cancer cells. Designed using Daiichi Sankyo's proprietary DXd ADC technology, trastuzumab deruxtecan is comprised of a HER2 monoclonal antibody attached to a novel topoisomerase I inhibitor payload by a tetrapeptide-based linker.

Trastuzumab deruxtecan (5.4 mg/kg) is approved in the U.S. and Japan for the treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who received two or more prior anti-HER2-based regimens based on the DESTINY-Breast01 trial.

Trastuzumab deruxtecan has not been approved in the EU, or countries outside of Japan and the U.S., for any indication. It is an investigational agent globally for various indications.

About the Trastuzumab Deruxtecan Clinical Development Program

A comprehensive development program for trastuzumab deruxtecan is underway globally with six pivotal trials evaluating the efficacy and safety of trastuzumab deruxtecan monotherapy across multiple HER2 cancers including breast, gastric, and lung cancers. Trials in combination with other anticancer treatments, such as immunotherapy, also are underway.

In May 2020, trastuzumab deruxtecan received [Breakthrough Therapy Designation](#) from the U.S. Food and Drug Administration (FDA) for the treatment of patients with HER2 positive unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma who have received two or more prior regimens including trastuzumab, and [Orphan Drug Designation](#) for gastric cancer, including gastroesophageal junction cancer. In March 2018, trastuzumab deruxtecan received a SAKIGAKE designation for potential use in the same HER2positive patient population and a [supplemental New Drug Application](#) was submitted to the Japan Ministry of Health, Labour and Welfare (MHLW) for approval in April 2020.

In May 2020, trastuzumab deruxtecan also received [Breakthrough Therapy Designation](#) for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a HER2 mutation and with disease progression on or after platinum-based therapy.

About the Collaboration between Daiichi Sankyo and AstraZeneca

In March 2019, Daiichi Sankyo and AstraZeneca entered into a global collaboration to jointly develop and commercialize trastuzumab deruxtecan worldwide, except in Japan where Daiichi Sankyo maintains exclusive rights. Daiichi Sankyo is solely responsible for the manufacturing and supply.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com

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