

Enhertu® Approved in China as Adjuvant Treatment for Patients with Residual Disease After Neoadjuvant Treatment for HER2 Positive Early Breast Cancer

- Approval based on DESTINY-Breast05 phase 3 trial results which showed Daiichi Sankyo and AstraZeneca's Enhertu reduced the risk of invasive disease recurrence or death by 53% compared to T-DM1
- Second approval in early breast cancer for Enhertu in China marking the fifth approval in less than a year
- Enhertu now approved for nine indications in China

Tokyo – (October 8, 2026) – Enhertu® (trastuzumab deruxtecan) has been approved in China for the adjuvant treatment of adult patients with HER2 positive (immunohistochemistry [IHC] 3+ or *in-situ* hybridization [ISH]+) early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.

Enhertu is a specifically engineered HER2 directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo (TSE: 4568) and being jointly developed and commercialized by Daiichi Sankyo and AstraZeneca (LSE/STO/NYSE: AZN).

The approval by China's National Medical Products Administration (NMPA) is based on results from the [DESTINY-Breast05](#) phase 3 trial [presented](#) at the 2025 European Society for Medical Oncology (#ESMO25) Congress and subsequently published in [The New England Journal of Medicine](#). DESTINY-Breast05 also is the confirmatory trial for the Enhertu neoadjuvant breast cancer indication in China, which was granted [conditional approval](#) based on the [DESTINY-Breast11](#) phase 3 trial. Based on the results of DESTINY-Breast05, Enhertu followed by paclitaxel, trastuzumab and pertuzumab (THP) as neoadjuvant treatment (before surgery) of adult patients with HER2 positive stage 2 (high risk) or stage 3 breast cancer is now converted to regular approval.

In DESTINY-Breast05, Enhertu significantly reduced the risk of invasive disease recurrence or death (invasive disease-free survival [IDFS]) by 53% (hazard ratio [HR]=0.47; 95% confidence interval [CI]: 0.34-0.66; $p<0.0001$) compared to trastuzumab emtansine (T-DM1) in patients with HER2 positive breast cancer with residual invasive disease following neoadjuvant therapy. Enhertu demonstrated a three-year IDFS rate of 92.4% (95% CI: 89.7-94.4) compared to 83.7% with T-DM1 (95% CI: 80.2-86.7). Data also showed that Enhertu significantly reduced the risk of disease recurrence or death (disease-free survival [DFS]) by 53% (HR=0.47; 95% CI: 0.34-0.66; $p<0.0001$) compared to T-DM1. Results showed a three-year DFS rate of 92.3% (95% CI: 89.5-94.3) in the Enhertu arm and 83.5% with T-DM1 (95% CI: 79.9-86.4).

"For patients with HER2 positive early breast cancer that have residual invasive disease following neoadjuvant therapy, these findings represent an important step toward reducing the risk of recurrence and advancing the goal of cure," said Zhimin Shao, MD, Director, Fudan University Cancer Institute and Breast Cancer, China, and lead investigator in China of the DESTINY-Breast05 trial. "The results from DESTINY-Breast05 underscore the potential of Enhertu to change clinical practice in the adjuvant setting as demonstrated by the significant improvement in invasive disease-free survival compared to T-DM1."

The safety profile of Enhertu in DESTINY-Breast05 was consistent with previous clinical trials with no new safety concerns identified. Grade 3 or grade 4 adverse reactions from a pooled safety analysis of patients treated with Enhertu (5.4 mg/kg) across multiple tumor types in clinical studies included neutropenia (18.7%), anemia (8.2%), fatigue (7.4%), leukopenia (6.6%), thrombocytopenia (5.4%), lymphopenia (5.0%), nausea (4.5%), increased transaminases (3.3%), hypokalemia (3.1%), diarrhea (2.1%), vomiting (2.0%), decreased appetite (1.4%) and pneumonia (1.2%). Grade 5 adverse reactions occurred in 0.9% of patients, including interstitial lung disease (ILD)

(0.7%). Discontinuation of treatment due to an adverse reaction occurred in 10.1% of patients. The most frequent adverse reaction associated with permanent discontinuation was ILD (7.6%).

“Following the approval in China earlier this year for the neoadjuvant treatment of HER2 positive early breast cancer, this new indication highlights the expanding role of Enhertu across multiple stages of HER2 positive disease including in the curative-intent setting,” said Michio Hayashi, China President, Daiichi Sankyo. “This approval represents the fifth approval of Enhertu in less than a year, which supports our goal of bringing new indications of this important medicine to patients as quickly as possible.”

“For patients with early breast cancer who have residual invasive disease after neoadjuvant treatment, the adjuvant setting is a critical opportunity to reduce the risk of recurrence and progression to metastatic disease. With more than 92% of patients free of invasive disease at three years in DESTINY-Breast05, Enhertu has the potential to set a new benchmark in the adjuvant setting,” said Mary Guan, General Manager, China Oncology Business, AstraZeneca. “Today’s approval in China, following the neoadjuvant approval earlier this year, further establishes the important role for Enhertu across early-stage HER2 positive breast cancer, helping improve outcomes and increasing the likelihood of cure for more patients.”

Enhertu also is approved in Australia, Brazil, Canada, Chile, India Switzerland and the U.S for the adjuvant treatment of adult patients with HER2 positive breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment based on the DESTINY-Breast05 trial. Additional regulatory submissions for Enhertu based on DESTINY-Breast05 are under review in the EU and Japan.

An additional regulatory submission for Enhertu also is underway in China for the treatment of patients with unresectable or metastatic solid tumors with HER2 expression (IHC 3+) who have received prior treatment or have no satisfactory alternative treatment options based on [DESTINY-PanTumor02](#), [DESTINY-Lung01](#), [DESTINY-CRC02](#) and [DESTINY-PanTumor03](#).

About DESTINY-Breast05

[DESTINY-Breast05](#) is a global, multicenter, randomized, open-label, phase 3 trial evaluating the efficacy and safety of Enhertu (5.4 mg/kg) versus T-DM1 in patients with HER2 positive early breast cancer with residual invasive disease in breast or axillary lymph nodes following neoadjuvant therapy and a high risk of recurrence. High risk of recurrence was defined as presentation with inoperable cancer (prior to neoadjuvant therapy) or pathologically positive axillary lymph nodes following neoadjuvant therapy.

The primary endpoint of DESTINY-Breast05 is investigator-assessed IDFS, which is defined as the time from randomization until first invasive local, axillary or distant recurrence or death from any cause. The key secondary endpoint is investigator-assessed DFS. Other secondary endpoints include OS, distant recurrence-free interval, brain metastases-free interval and safety.

DESTINY-Breast05 enrolled 1,635 patients in Asia, Europe, North America, Oceania and South America. For more information about the trial, visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About HER2 Positive Early Breast Cancer

Breast cancer is the most common cancer in women worldwide and the leading cause of cancer-related deaths among women.¹ Approximately 2.4 million breast cancer cases were diagnosed in 2024, with more than 690,000 deaths globally.¹ In China, approximately 376,000 cases of breast cancer were diagnosed in 2024, with nearly 73,000 deaths.²

HER2 is a tyrosine kinase receptor growth-promoting protein expressed on the surface of many types of tumors including breast cancer.³ HER2 protein overexpression may occur as a result of *HER2* gene amplification and is often associated with aggressive disease and poor prognosis in breast cancer.³ Approximately one in five cases of breast cancer is considered HER2 positive.⁴

Approximately one in three patients with HER2 positive early-stage breast cancer is considered high-risk, meaning they are more likely to experience disease recurrence and have a poor prognosis.⁵ The current standard of care in the HER2 positive adjuvant (after surgery) setting in China is trastuzumab emtansine (T-DM1) for patients who do not achieve a pathologic complete response (pCR) after neoadjuvant treatment.⁶

Despite receiving additional treatment with current standard of care for residual disease, some patients still experience invasive disease or death.⁷ Once patients are diagnosed with metastatic disease, the five-year survival rate drops from nearly 100% to approximately 34%.⁸ Adjuvant therapy represents a key opportunity to minimize the risk of recurrence and prevent progression to metastatic disease for patients with residual disease.^{9,10}

About Enhertu

Enhertu (trastuzumab deruxtecan; fam-trastuzumab deruxtecan-nxki in the U.S. only) is a HER2 directed ADC. Designed using the proprietary DXd ADC Technology of Daiichi Sankyo, Enhertu is the lead ADC in the oncology portfolio of Daiichi Sankyo and the most advanced program in AstraZeneca's ADC scientific platform. Enhertu consists of a HER2 monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

Enhertu (5.4 mg/kg) followed by THP is approved in Brazil, China, India, Singapore, Taiwan and the U.S. as a neoadjuvant treatment for adult patients with HER2 positive (IHC 3+ or ISH+) stage 2 or stage 3 breast cancer based on the results from the [DESTINY-Breast11](#) trial.

Enhertu (5.4 mg/kg) is approved in Australia, Brazil, Canada, Chile, China, India Switzerland and the U.S. for the adjuvant treatment of adult patients with HER2 positive breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment based on the [DESTINY-Breast05](#) trial.

Enhertu (5.4 mg/kg) in combination with pertuzumab is approved in more than 40 countries/regions worldwide as a first-line treatment for adult patients with unresectable or metastatic HER2 positive (IHC 3+ or ISH+) breast cancer, as determined by a locally or regionally approved test, based on the results from the [DESTINY-Breast09](#) trial.

Enhertu (5.4 mg/kg) is approved in more than 100 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic HER2 positive (IHC 3+ or ISH+) breast cancer who have received a prior anti-HER2-based regimen, either in the metastatic setting or in the neoadjuvant or adjuvant setting, and have developed disease recurrence during or within six months of completing therapy based on the results from the [DESTINY-Breast03](#) trial.

Enhertu (5.4 mg/kg) is approved in more than 75 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic hormone receptor (HR) positive, HER2 low (IHC 1+ or IHC 2+/ ISH-) or HER2 ultralow (IHC 0 with membrane staining) breast cancer, as determined by a locally or regionally approved test, that have progressed on one or more endocrine therapies in the metastatic setting based on the results from the [DESTINY-Breast06](#) trial.

Enhertu (5.4 mg/kg) is approved in more than 100 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic HER2 low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior

systemic therapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy based on the results from the [DESTINY-Breast04](#) trial.

Enhertu (5.4 mg/kg) is approved in more than 80 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic NSCLC whose tumors have activating *HER2* (*ERBB2*) mutations, as detected by a locally or regionally approved test, and who have received a prior systemic therapy based on the results from the [DESTINY-Lung02](#) and/or [DESTINY-Lung05](#) trials. Continued approval in China and the U.S. for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Enhertu (6.4 mg/kg) is approved in more than 90 countries/regions worldwide for the treatment of adult patients with locally advanced or metastatic HER2 positive (IHC 3+ or IHC 2+/ISH+) gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen based on the results from the [DESTINY-Gastric01](#), [DESTINY-Gastric02](#) and/or [DESTINY-Gastric04](#) trials.

Enhertu (5.4 mg/kg) is approved in more than 50 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic HER2 positive (IHC 3+) solid tumors who have received prior systemic treatment and/or have no satisfactory alternative treatment options based on efficacy results from the [DESTINY-PanTumor02](#), [DESTINY-Lung01](#), [DESTINY-CRC02](#) and/or [HERALD](#) trials. Continued approval in the U.S. for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

About the Enhertu Clinical Development Program

A comprehensive global clinical development program is underway evaluating the efficacy and safety of Enhertu as a monotherapy or in combination or sequentially with other cancer medicines across multiple HER2 targetable cancers.

About the Daiichi Sankyo and AstraZeneca Collaboration

Daiichi Sankyo and AstraZeneca entered into a global collaboration to jointly develop and commercialize Enhertu in [March 2019](#) and Datroway® in [July 2020](#), except in Japan where Daiichi Sankyo maintains exclusive rights for each ADC. Daiichi Sankyo is responsible for the manufacturing and supply of Enhertu and Datroway.

About the ADC Portfolio of Daiichi Sankyo

The Daiichi Sankyo ADC portfolio consists of nine ADCs in clinical development crafted from ADC technology discovered in-house by Daiichi Sankyo.

The DXd ADC Technology platform of Daiichi Sankyo consists of seven ADCs in clinical development where each ADC is comprised of a monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers. The DXd ADCs include Enhertu and Datroway, which are being jointly developed and commercialized globally with AstraZeneca, and ifinatamab deruxtecan (I-DXd), raludotatug deruxtecan (R-DXd) and patritumab deruxtecan (HER3-DXd), which are being jointly developed and commercialized globally with Merck & Co., Inc, Rahway, NJ, USA. DS-3939 and DS3790 are being developed by Daiichi Sankyo.

Additional ADCs being developed by Daiichi Sankyo include DS3610, which consists of an antibody attached to a novel payload that acts as an agonist of STING, and DS1025, which consists of a CD25 directed antibody attached to an immuno-oncology optimized cytotoxic payload.

Ifinatamab deruxtecan, raludotatug deruxtecan, patritumab deruxtecan, DS-3939, DS3610, DS3790 and DS1025 are investigational medicines that have not been approved for any indication in any country. Safety and efficacy have not been established.

About Daiichi Sankyo

Daiichi Sankyo (TSE: 4568) is a global healthcare company committed to becoming a trusted healthcare innovator, transforming the lives of people through its strength in science and technology. The company discovers and develops new standards of care to address diverse medical needs to fulfill its purpose of contributing to the enrichment of quality of life around the world. With a strategic focus on oncology, Daiichi Sankyo is advancing an industry-leading antibody drug conjugate portfolio along with identifying new breakthrough generating technologies to deliver practice-changing medicines to patients, healthcare professionals and society. For more information, please visit www.daiichisankyo.com.

MEDIA CONTACTS:

Global:

Jennifer Brennan

Jennifer.brennan@daiichisankyo.com

+1 908 900 3183 (mobile)

China:

Lingling Zhang

Zhang.lingling.dg@daiichisankyo.com.cn

+86 21 6039 7200 (office)

Japan:

DS-PR_jp@daiichisankyo.com

INVESTOR RELATIONS CONTACT:

DaiichiSankyoIR_jp@daiichisankyo.com

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