

Enhertu® Approved in China as First and Only Tumor Agnostic HER2 Directed Medicine and Antibody Drug Conjugate for Previously Treated Patients with HER2 Positive Metastatic Solid Tumors

- Approval based on four phase 2 trial results where Daiichi Sankyo and AstraZeneca's Enhertu demonstrated clinically meaningful responses across a broad range of tumors
- Sixth approval for Enhertu in China in less than a year
- Enhertu now approved for 10 indications in China

Tokyo – (October 22, 2026) – Enhertu® (trastuzumab deruxtecan) has been approved in China as a monotherapy for the treatment of adult patients with unresectable or metastatic solid tumors with HER2 expression (immunohistochemistry [IHC] 3+) who have received prior treatment or have no satisfactory alternative treatment options. This indication was granted as a conditional approval based on the results of single-arm studies. Full approval of this indication will depend on the clinical benefit of a confirmatory trial.

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 four phase 2 trials, including [DESTINY-PanTumor02](#), [DESTINY-Lung01](#), [DESTINY-CRC02](#) and [DESTINY-PanTumor03](#) where Enhertu demonstrated clinically meaningful responses across a broad range of tumors.

In DESTINY-PanTumor02, Enhertu demonstrated a confirmed objective response rate (ORR) of 51.4% (95% confidence interval [CI]: 41.7-61.0) with four complete responses (CRs) and 53 partial responses (PRs) in a subgroup of previously treated patients (n=111) with centrally or locally confirmed HER2 positive (IHC 3+) solid tumors. Median duration of response (DOR) was 19.4 months (95% CI: 10.0-29.9). Median progression-free survival (PFS) was 10.1 months (95% CI: 7.0-14.2) and median overall survival (OS) was 17.7 months (95% CI: 12.8-23.4).

In DESTINY-Lung01, Enhertu demonstrated a confirmed ORR of 52.9% (95% CI: 27.8-77.0) with one CR and eight PRs in a subgroup of previously treated patients (n=17) with centrally confirmed HER2 positive (IHC 3+) non-small cell lung cancer (NSCLC). Median DOR was 6.9 months (95% CI: 4.0-9.8). Median PFS was 7.5 months (95% CI: 3.1-11.0) and median OS was 12.5 months (95% CI: 9.3-not evaluable [NE]).

In DESTINY-CRC02, Enhertu demonstrated a confirmed ORR of 46.9% (95% CI: 34.3-59.8) with zero CRs and 30 PRs in a subgroup of previously treated patients (n=64) with centrally confirmed HER2 positive (IHC 3+) colorectal cancer. Median DOR was 5.5 months (95% CI: 4.2-8.1). Median PFS was 7.0 months (95% CI: 5.7-8.2) and median OS was 15.1 months (95% CI: 12.6-NE).

In DESTINY-PanTumor03, Enhertu demonstrated a confirmed ORR of 58.0% (95% CI: 43.2-71.8) with one CR and 28 PRs in previously treated patients in China (n=50) with centrally confirmed HER2 positive (IHC 3+) solid tumors, including biliary tract, bladder, cervical, colorectal, endometrial, NSCLC, ovarian and parotid gland cancer. Median DOR was 15.4 months (95% CI: 12.5- not calculable [NC]). Median PFS was 15.7 months (95% CI: 7.2-NC) and median OS was not reached (95% CI: 11.0-NC).

"HER2 overexpression occurs across multiple tumor types and is associated with aggressive disease and a poor prognosis," said Xiaohua Wu, MD, Supervisor of Oncology of Fudan University Shanghai Cancer Center,

Chairman and Chief Expert of the Multidisciplinary Team in Gynecologic Oncology, Principal Investigator in China of the DESTINY-PanTumor03 trial. “Until now, HER2 directed therapies were only available for specific tumor types. The approval of trastuzumab deruxtecan as a tumor agnostic HER2 directed therapy, supported by clinically meaningful responses observed across a broad range of HER2 positive solid tumors, offers a new treatment for patients who have historically had limited options.”

The safety profile of Enhertu in DESTINY-PanTumor02, DESTINY-Lung01, DESTINY-CRC02 and DESTINY-PanTumor03 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 4,146 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 treated with Enhertu. The most frequent adverse reaction associated with permanent discontinuation was ILD (7.6%).

“This approval of Enhertu reflects the continued evolution of cancer care toward treatment regimens focused on the underlying biology of the disease rather than where a tumor originates in the body,” said Michio Hayashi, China President, Daiichi Sankyo. “As the first tumor agnostic HER2 directed medicine approved in China, Enhertu has the potential to expand treatment for eligible patients across a broad range of HER2 positive metastatic cancers.”

“Precision medicine is playing an increasingly important role in guiding treatment decisions based on the molecular and biological characteristics of a patient’s disease,” said Mary Guan, General Manager, China Oncology Business, AstraZeneca. “This approval marks the tenth indication for Enhertu in China and provides clinicians with a targeted option for patients with HER2 positive metastatic cancer across tumor types. It also reinforces the importance of biomarker testing to identify patients who may be eligible for HER2 directed treatment, supporting more personalized treatment decisions.”

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 treatment and/or have no satisfactory alternative treatment options based on efficacy results from the DESTINY-PanTumor02, DESTINY-Lung01, DESTINY-CRC02, DESTINY-PanTumor03 and/or HERALD trials.

About DESTINY-PanTumor02

DESTINY-PanTumor02 is a global, multicenter, multi-cohort, open-label, phase 2 trial evaluating the efficacy and safety of Enhertu (5.4 mg/kg) for the treatment of previously treated HER2 expressing tumors, including biliary tract, bladder, cervical, endometrial, ovarian, pancreatic cancer or other tumors.

The primary endpoint of DESTINY-PanTumor02 is confirmed ORR as assessed by investigator. Secondary endpoints include DOR, disease control rate (DCR), PFS, OS, safety, tolerability and pharmacokinetics. Results from DESTINY-PanTumor02 were published in the *Journal of Clinical Oncology*. Results from patients with HER2 positive (IHC 3+) disease identified by local or central testing (n=111) were published in *Advances in Therapy*.

DESTINY-PanTumor02 enrolled 267 patients, including 111 HER2 positive (IHC 3+) adult patients at multiple sites in Asia, Europe, North America, South America and Oceania. For more information about the trial, visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About DESTINY-Lung01

DESTINY-Lung01 is a global, open-label, two-cohort, phase 2 trial evaluating the efficacy and safety of Enhertu (5.4 mg/kg or 6.4 mg/kg) in patients with *HER2* mutant (Cohort 2, n=91) or *HER2* overexpressing (defined as IHC

3+ or IHC 2+) (Cohort 1 and 1a, n=90) unresectable or metastatic NSCLC who had progressed after one or more systemic therapies.

The primary endpoint of DESTINY-Lung01 is confirmed ORR by independent central review. Key secondary endpoints include DOR, DCR, PFS, OS and safety. Results from the *HER2* mutant cohort were published in *The New England Journal of Medicine* and results from the *HER2* overexpressing cohort were published in *The Lancet Oncology*.

DESTINY-Lung01 enrolled 181 patients, including 17 *HER2* positive (IHC 3+) adult patients at multiple sites in Asia, Europe and North America. For more information about the trial, visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About DESTINY-CRC02

DESTINY-CRC02 is a global, randomized, two arm, parallel, multicenter, phase 2 trial evaluating the efficacy and safety of two doses (5.4 mg/kg or 6.4 mg/kg) of Enhertu in patients with locally advanced, unresectable or metastatic *HER2* positive colorectal cancer of *BRAF* wild-type, *RAS* wild-type or *RAS* mutant tumor types previously treated with standard therapy. The trial was conducted in two stages. In the first stage, patients (n=80) were randomized 1:1 to receive either 5.4 mg/kg or 6.4 mg/kg of Enhertu. In the second stage, additional patients (n=42) were enrolled in the 5.4 mg/kg arm.

The primary endpoint in DESTINY-CRC02 is confirmed ORR as assessed by blinded independent central review. Secondary endpoints include DOR, DCR, investigator-assessed confirmed ORR, clinical benefit ratio, PFS, OS and safety. Results from DESTINY-CRC02 were published in *The Lancet Oncology*.

DESTINY-CRC02 enrolled 122 patients, including 64 *HER2* positive (IHC 3+) adult patients at multiple sites in Asia, Europe, North America and Oceania. For more information about the trial, visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About DESTINY-PanTumor03

DESTINY-PanTumor03 is a multicenter, open-label, phase 2 trial in China evaluating the efficacy and safety of Enhertu (5.4 mg/kg) as a monotherapy or in combination with anti-cancer agents for the treatment of patients with *HER2* expressing (IHC 3+) locally advanced, unresectable or metastatic solid tumors that have progressed following at least one prior systemic regimen or have no satisfactory alternative treatment options.

The primary endpoint of DESTINY-PanTumor03 is confirmed ORR as assessed by independent central review. Secondary endpoints include DOR, PFS, OS, DCR, best objective response and safety. Results from DESTINY-PanTumor03 were published in the *Journal of Clinical Oncology*.

DESTINY-PanTumor03 enrolled 50 patients at multiple sites in China. For more information about the trial, visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About HER2 Expression in Solid Tumors

HER2 is a tyrosine kinase receptor growth-promoting protein expressed on the surface of various tissue cells throughout the body and is involved in normal cell growth.¹ *HER2* protein overexpression may occur as a result of *HER2* gene amplification and is often associated with aggressive disease and poor prognosis in some cancers.² *HER2* overexpression occurs in a range of solid tumors with the prevalence varying by tumor type.³

HER2 directed therapies have been used to treat *HER2* overexpression in bladder, breast, colorectal, gastric, NSCLC and biliary tract cancers in China.^{1,4,5,6,7,8,9} Although *HER2* is overexpressed in additional solid tumor types including lung, cervical, endometrial, ovarian, salivary gland and pancreatic cancers, *HER2* testing is not routinely performed in these additional tumor types. Prior to this approval of Enhertu, there were no *HER2* directed treatments approved in China to treat a broad range of solid tumors.^{2,10,11,12}

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 more than five countries/regions worldwide 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 more than five countries/regions worldwide 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 treatment and/or

have no satisfactory alternative treatment options based on efficacy results from the [DESTINY-PanTumor02](#), [DESTINY-Lung01](#), [DESTINY-CRC02](#), [DESTINY-PanTumor03](#) and/or [HERALD](#) 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.

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:

INVESTOR RELATIONS CONTACT:

DaiichiSankyoIR_jp@daiichisankyo.com

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

REFERENCES:

- ¹ Iqbal N, et al. *Mol Biol Int*. 2014;852748.
- ² Cheng X. *Genes (Basel)*. 2024;15(7):903.
- ³ Yan M, et al. *Cancer Metastasis Rev*. 2015;34(1):157-164.
- ⁴ Zhu K, et al. *Front Pharmacol*. 2024; 15:1355081.
- ⁵ Li J, et al. *Transl Breast Cancer Res*. 2025;6:21.
- ⁶ Wang F, et al. *Cancer Commun*. 2024 Nov; 45(3):332-379.
- ⁷ Yu Y, et al. *Clin Cancer Bull*. 2026; 5(1).
- ⁸ Zhang S, et al. *Thorac Cancer*. 2022 Nov 28;14(1):91–104.
- ⁹ Pant S et al. *JAMA Oncol*. 2026;12;(1):106-109.
- ¹⁰ Omar N, et al. *Pathogenesis*. 2015;2(3):1-9.
- ¹¹ Ismail A, et al. *Oncologist*. 2025;30(9):258.
- ¹² Wang Z, et al. *Cancer Innov*. 2026; Apr 21;5(2):e70060.