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Enhertu approved in the EU as adjuvant treatment for patients with residual disease after neoadjuvant treatment for HER2-positive early breast cancer

Based on DESTINY-Breast05 Phase III trial which showed AstraZeneca and Daiichi Sankyo's Enhertu reduced the risk of invasive disease recurrence or death by 53% vs. T-DM1

First EU approval of Enhertu in the curative-intent early breast cancer setting

AstraZeneca and Daiichi Sankyo's *Enhertu* (trastuzumab deruxtecan) has been approved in the European Union (EU) as a monotherapy for the adjuvant treatment of adult patients with resected HER2-positive breast cancer who have residual invasive disease after neoadjuvant taxane-based and HER2-targeted treatment.

The approval by the European Commission follows the [positive opinion](#) of the Committee for Medicinal Products for Human Use of the European Medicines Agency and is based on results from the [DESTINY-Breast05](#) Phase III trial presented at the 2025 European Society for Medical Oncology Congress and subsequently published in [The New England Journal of Medicine](#).¹

Sibylle Loibl, MD, PhD, German Breast Group (GBG) and Goethe University Medicine Frankfurt, Frankfurt am Main and lead investigator of the DESTINY-Breast05 trial, said: "For patients with HER2-positive early breast cancer and residual invasive disease after neoadjuvant therapy, reducing the risk of disease recurrence is critical for sustained long-term outcomes. The EU approval of trastuzumab deruxtecan, which demonstrated a more than 50 per cent reduction in risk of recurrence compared to standard of care in DESTINY-Breast05, has the potential to change how we treat eligible patients in this setting."

Dave Fredrickson, Executive Vice President, Oncology Haematology Business Unit, AstraZeneca, said: "The goal of treatment in early breast cancer is to help as many patients as possible achieve cure. Unfortunately, despite treatment advances, some patients still face recurrence in the long term. The approval of *Enhertu* in the adjuvant setting for patients with residual disease after neoadjuvant treatment has the potential to establish a new benchmark in this curative-intent setting, with more than 92 per cent of patients alive and free of invasive disease at three years."

Ken Keller, Global Head of Oncology Business, and President and CEO, Daiichi Sankyo, Inc., said: "By bringing *Enhertu* into the adjuvant setting, we are advancing this treatment option earlier in the course of disease for patients with HER2-positive early breast cancer. This first approval of *Enhertu* in early breast cancer in the EU reflects our continued commitment to bringing innovative medicines into earlier treatment settings, where there is significant potential to improve long-term outcomes for patients."

In DESTINY-Breast05, *Enhertu* significantly reduced the risk of invasive disease recurrence or death (invasive disease-free survival [IDFS]) by 53% (based on a hazard ratio [HR] of 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).

The safety profile of *Enhertu* was consistent with the known profile with no new safety concerns identified.

Enhertu is now approved in more than 35 countries 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 is a specifically engineered HER2-directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being jointly developed and commercialised by AstraZeneca and Daiichi Sankyo.

Financial considerations

Following this approval in the EU, an amount of \$75 million is due from AstraZeneca to Daiichi Sankyo as a milestone payment for the adjuvant HER2-positive early breast cancer indication. Sales of *Enhertu* in most EU territories are recognised by Daiichi Sankyo. For further details on the financial arrangements, please consult the collaboration agreement from [March 2019](#).

Notes

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.² Approximately 2.4 million breast cancer cases were diagnosed in 2024, with more than 690,000 deaths globally.² In Europe, approximately 540,000 cases of breast cancer were diagnosed in 2024, with more than 140,000 deaths.³

HER2 is a tyrosine kinase receptor growth-promoting protein expressed on the surface of many types of tumours including breast cancer.⁴ 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.⁴ Approximately one in five cases of breast cancer is considered HER2-positive.⁵

HER2-positive early breast cancer is generally treated across two phases: the neoadjuvant (pre-surgical) phase and the adjuvant or post-neoadjuvant (post-surgical) phase. For patients treated before surgery, achieving pathologic complete response (pCR) – defined as no evidence of invasive cancer cells in the removed breast tissue or lymph nodes following neoadjuvant treatment – is an early indicator of improved long-term survival.⁶ However, approximately half of patients (39-66%) treated before surgery do not achieve pCR, increasing their risk of recurrence.⁷⁻¹¹

Post-surgery therapy offers a key opportunity to reduce this risk and prevent progression to metastatic disease.¹²⁻¹⁴ Yet approximately one in four patients with residual disease treated with the historic adjuvant standard of care still experience invasive disease or death.¹²⁻¹⁵ Once disease becomes metastatic, five-year survival falls from around 90% to approximately 30%.¹⁵

DESTINY-Breast05

DESTINY-Breast05 is a global, multicentre, randomised, open-label, Phase III trial evaluating the efficacy and safety of *Enhertu* (5.4mg/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 randomisation 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 overall survival, 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).

Enhertu

Enhertu 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 programme 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 (5.4mg/kg) followed by THP is approved in more than five countries as a neoadjuvant treatment for adult patients with HER2-positive (IHC 3+ or ISH+) Stage II or Stage III breast cancer based on the results from the [DESTINY-Breast11](#) trial.

Enhertu (5.4mg/kg) is approved in more than 35 countries 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 (5.4mg/kg) in combination with pertuzumab is approved in more than 40 countries worldwide as a 1st-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 (5.4mg/kg) is approved in more than 100 countries 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 (5.4mg/kg) is approved in more than 75 countries 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 has progressed on one or more endocrine therapies in the metastatic setting based on the results from the [DESTINY-Breast06](#) trial.

Enhertu (5.4mg/kg) is approved in more than 100 countries 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 (5.4mg/kg) is approved in more than 80 countries worldwide for the treatment of adult patients with unresectable or metastatic NSCLC whose tumours 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 US for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Enhertu (6.4mg/kg) is approved in more than 90 countries 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 (5.4mg/kg) is approved in more than 50 countries worldwide for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumours who have received prior treatment and 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 the US and China for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

***Enhertu* clinical development programme**

A comprehensive global clinical development programme 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.

Daiichi Sankyo collaboration

AstraZeneca and Daiichi Sankyo entered into a global collaboration to jointly develop and commercialise *Enhertu* in [March 2019](#) and *Datroway* (datopotamab deruxtecan) 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*.

AstraZeneca in breast cancer

AstraZeneca is advancing a leading breast cancer portfolio across subtypes and stages, with five approved medicines across 12 indications and seven ongoing Phase III trials.

In HER2-positive breast cancer, AstraZeneca is aiming to establish new standards of care across the disease continuum with *Enhertu*, with a focus on improving outcomes as early as possible.

In HR-positive metastatic breast cancer, AstraZeneca is focused on extending the benefit of endocrine-based therapies by tackling key resistance mechanisms with *Etcamah* (camizestrant), a next-generation oral SERD, and *Truqap* (capivasertib), a first-in-class AKT inhibitor, while expanding the role of the antibody drug conjugates *Enhertu* and *Datroway* for patients no longer suitable for endocrine-based therapy. *Etcamah* is also being evaluated in early-stage disease.

In triple-negative breast cancer (TNBC), AstraZeneca is advancing the treatment landscape by developing tailored approaches that move more patients beyond conventional chemotherapy. This includes *Datroway*, which is evolving the standard of care in metastatic TNBC and is also being evaluated in earlier settings and in combination with immunotherapy *Imfinzi* (durvalumab) and bispecific antibody ivonescimab.

In germline *BRCA*-mutated (g*BRCA*m) breast cancer, AstraZeneca has redefined treatment with the PARP inhibitor *Lynparza* (olaparib) and is now building on this foundation with saruparib, a PARP1-selective inhibitor being evaluated in combination with *Etcamah* for patients with g*BRCA*m or *PALB2*m, HR-positive, HER2-negative metastatic breast cancer.

Together, these efforts support AstraZeneca's ambition to cure more patients with early breast cancer, improve survival in metastatic disease, and ultimately eliminate breast cancer as a cause of death.

AstraZeneca is collaborating with Daiichi Sankyo to develop and commercialise *Enhertu* and *Datroway*, with MSD (Merck & Co., Inc. in the US and Canada) to develop and commercialise *Lynparza* and with Summit Therapeutics on the clinical development of ivonescimab in combination with *Datroway*.

AstraZeneca in oncology

AstraZeneca is leading a revolution in oncology with the ambition to provide cures for cancer in every form, following the science to understand cancer and all its complexities to discover, develop and deliver life-changing medicines to patients.

The Company's focus is on some of the most challenging cancers. It is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the industry, with the potential to catalyse changes in the practice of medicine and transform the patient experience.

AstraZeneca has the vision to redefine cancer care and, one day, eliminate cancer as a cause of death.

AstraZeneca

AstraZeneca (LSE/STO/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Disease, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Social Media [@AstraZeneca](https://twitter.com/AstraZeneca).

Contacts

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