26 May 2026

**_Enhertu_ recommended for approval in the EU by CHMP for patients with previously treated HER2-positive metastatic solid tumours**

***Based on three Phase II trials of AstraZeneca and Daiichi Sankyo's Enhertu which showed clinically meaningful responses across a broad range of tumours***

***If approved, Enhertu would become the first HER2-directed therapy and antibody drug conjugate to receive a tumour agnostic indication in the EU***

AstraZeneca and Daiichi Sankyo's *Enhertu* (trastuzumab deruxtecan) has been recommended for approval in the European Union (EU) as a monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive (immunohistochemistry [IHC] 3+) solid tumours who have received prior treatment and who have no satisfactory treatment options.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) based its positive opinion on results from a subgroup of patients with HER2-positive (IHC 3+) tumours across three Phase II trials, DESTINY-PanTumor02, DESTINY-Lung01 and DESTINY-CRC02, in which *Enhertu* demonstrated clinically meaningful responses across a broad range of tumours.

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: "HER2-directed therapies have already transformed care for certain HER2-expressing cancers, including breast and gastric cancers. However, many other cancers overexpress HER2, and targeted treatment options remain unavailable for most of these tumour types. This positive CHMP opinion underscores the importance of precision oncology and marks an important step toward bringing a new targeted option to more patients in the EU living with HER2-positive solid tumours."

John Tsai, Global Head, R&D, Daiichi Sankyo, said: "This positive CHMP opinion acknowledges the clinical value of *Enhertu* as the potential first HER2-directed medicine and antibody drug conjugate available for patients with HER2-positive metastatic solid tumours in the EU. *Enhertu* offers meaningful responses for patients with advanced cancers that overexpress HER2 who have limited treatment options. We look forward to continuing to work with the EMA to bring *Enhertu* to these patients."

In the DESTINY-PanTumor02 Phase II trial, *Enhertu* demonstrated a confirmed objective response rate (ORR) of 51.4% and median duration of response (DOR) of 14.2 months in previously treated patients with centrally or locally assessed IHC 3+ solid tumours (n=111) including either biliary tract, bladder, cervical, endometrial, ovarian, pancreatic or other tumours. In DESTINY-Lung01, *Enhertu* demonstrated a confirmed ORR of 52.9% and median DOR of 6.9 months in patients with centrally confirmed IHC 3+ non-small cell lung cancer (NSCLC) (n=17). In DESTINY-CRC02, *Enhertu* demonstrated a confirmed ORR of 46.9% and median DOR of 5.5 months in patients with centrally confirmed IHC 3+ colorectal cancer (n=64).

The safety profile of *Enhertu* was consistent with previous clinical trials with no new safety concerns identified.

*Enhertu* has received a tumour agnostic indication in the US and other countries based on the DESTINY-PanTumor02 trial.

Additional regulatory submissions for *Enhertu* are under review in the EU, including in combination with pertuzumab for the 1st-line treatment of patients with unresectable or metastatic HER2-positive (IHC 3+ and ISH+) breast cancer based on data from the DESTINY-Breast09 Phase III trial and for patients with HER2-positive (IHC 3+ and ISH+) breast cancer who have residual invasive disease after neoadjuvant HER2-targeted treatment based on data from the DESTINY-Breast05 Phase III 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.

## Notes

### HER2 expression in solid tumours

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-directed therapies have been used to treat HER2 overexpression in breast, gastric and salivary gland cancers in the EU.[1,3-5] Although HER2 is overexpressed in additional solid tumour types including biliary tract, lung, bladder, cervical, colorectal, endometrial, ovarian and pancreatic cancers, HER2 testing is not routinely performed for these additional tumour types and there are currently no HER2 directed treatments approved in the EU to treat a broad range of solid tumours.[6,7]

**DESTINY-PanTumor02**

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

The primary endpoint of DESTINY-PanTumor02 is confirmed ORR as assessed by investigator. Secondary endpoints include DOR, disease control rate (DCR), progression-free survival (PFS), overall survival (OS), safety, tolerability and pharmacokinetics. Results from DESTINY-PanTumor02 were published in the *Journal of Clinical Oncology*.[8]

DESTINY-PanTumor02 enrolled 267 HER2-positive (IHC 3+ [n=111] and IHC 2+ [n=156]) adult patients at multiple sites in Asia, Europe, North America, South America and Oceania. For more information about the trial, visit ClinicalTrials.gov.

**DESTINY-Lung01**

DESTINY-Lung01 is a global, open-label, two-cohort, Phase II trial evaluating the efficacy and safety of *Enhertu* (5.4mg/kg or 6.4mg/kg) in patients with *HER2*-mutant or HER2-overexpressing 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*.[9,10]

DESTINY-Lung01 enrolled 181 adult patients (HER2-mutant [n=91] and HER2-overexpressing [n=90; IHC 3+, n=17 and IHC 2+, n=73]) at multiple sites in Asia, Europe and North America. For more information about the trial, visit ClinicalTrials.gov.

**DESTINY-CRC02**

DESTINY-CRC02 is a global, randomised, two-arm, parallel, multicentre, Phase II trial evaluating the efficacy and safety of two doses (5.4mg/kg or 6.4mg/kg) of *Enhertu* in patients with locally advanced, unresectable or metastatic HER2-positive (IHC 3+ or IHC 2+) colorectal cancer of BRAF wild-type, RAS wild-type or RAS mutant tumour types previously treated with standard therapy. The trial was conducted in two stages. In the first stage, patients (n=80) were randomised 1:1 to receive either 5.4mg/kg or 6.4mg/kg of *Enhertu*. In the second stage, additional patients (n=42) were enrolled in the 5.4mg/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*.[11]

DESTINY-CRC02 enrolled 122 adult patients (including 64 patients with IHC 3+ receiving 5.4mg/kg) at multiple sites in Asia, Europe, North America and Oceania. For more information about the trial, visit ClinicalTrials.gov.

***Enhertu***

*Enhertu* is a HER2-directed ADC. Designed using Daiichi Sankyo's proprietary DXd ADC Technology, *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) is approved in the US as an adjuvant treatment for adult patients with HER2-positive breast cancer who have residual invasive disease following trastuzumab (with or without pertuzumab) and taxane-based treatment based on the DESTINY-Breast05 trial.

*Enhertu* (5.4mg/kg) followed by THP is approved in China and the US 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. Continued approval in China for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

*Enhertu* (5.4mg/kg) in combination with pertuzumab is approved in the US, Switzerland, United Arab Emirates and Saudi Arabia as a first-line treatment for adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer, as determined by an FDA-approved test, based on the results from the DESTINY-Breast09 trial.

*Enhertu* (5.4mg/kg) is approved in more than 95 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* (5.4mg/kg) is approved in more than 95 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* (5.4mg/kg) is approved in more than 70 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* (5.4mg/kg) is approved in more than 75 countries/regions 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 85 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* (5.4mg/kg) is approved in more than 15 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumours who have received prior systemic treatment and 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 US 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, 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**
Driven by a growing understanding of breast cancer biology, AstraZeneca is challenging, and redefining, the current clinical paradigm for how breast cancer is classified and treated to deliver even more effective treatments to patients in need - with the bold ambition to one day eliminate breast cancer as a cause of death.

AstraZeneca has a comprehensive portfolio of approved and promising compounds in development that leverage different mechanisms of action to address the biologically diverse breast cancer tumour environment.

With *Enhertu*, AstraZeneca and Daiichi Sankyo are aiming to improve outcomes in previously treated HER2-positive, HER2-low and HER2-ultralow metastatic breast cancer, and expanding its potential in earlier lines of treatment and in new breast cancer settings.

In HR-positive breast cancer, AstraZeneca continues to improve outcomes with foundational medicines *Faslodex* (fulvestrant) and *Zoladex* (goserelin) and aims to reshape the HR-positive space with first-in-class AKT inhibitor, *Truqap* (capivasertib), the TROP-2-directed ADC, *Datroway*, and next-generation oral SERD and potential new medicine camizestrant.

PARP inhibitor *Lynparza* (olaparib) is a targeted treatment option that has been studied in early and metastatic breast cancer patients with an inherited *BRCA* mutation. AstraZeneca with MSD (Merck & Co., Inc. in the US and Canada) continue to research *Lynparza* in these settings. AstraZeneca is also exploring the potential of saruparib, a potent and selective inhibitor of PARP1, in combination with camizestrant in *BRCA*-mutated, HR-positive, HER2-negative advanced breast cancer.

To bring much-needed treatment options to patients with triple-negative breast cancer, an aggressive form of breast cancer, AstraZeneca is collaborating with Daiichi Sankyo to evaluate the potential of *Datroway* alone and in combination with immunotherapy *Imfinzi* (durvalumab).

**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 Diseases, 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.

## Contacts

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