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Datroway recommended for approval in the EU by CHMP as 1st-line treatment for patients with metastatic triple-negative breast cancer who are not candidates for immunotherapy

Recommendation based on TROPION-Breast02 Phase III trial where AstraZeneca and Daiichi Sankyo's Datroway showed a statistically significant and clinically meaningful improvement for the dual primary endpoints of overall survival and progression-free survival

If approved, Datroway has the potential to be the first TROP2-directed antibody drug conjugate for patients in the EU with a demonstrated overall survival benefit as 1st-line treatment

AstraZeneca and Daiichi Sankyo's *Datroway* (datopotamab deruxtecan) has been recommended for approval in the European Union (EU) as monotherapy for the 1st-line treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) based its positive opinion on results from the TROPION-Breast02 Phase III trial, which were [presented](#) at the 2025 European Society for Medical Oncology Congress and published in [Annals of Oncology](#).

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: "As one of the hardest cancers to treat, today only 15% of patients with metastatic triple-negative breast cancer survive beyond five years. This positive opinion from the CHMP marks an important step forward in bringing the potential of *Datroway* to transform outcomes for patients with this type of cancer in the EU."

John Tsai, MD, Global Head, R&D, Daiichi Sankyo, said: "Triple-negative breast cancer remains one of the most aggressive types of breast cancer, with limited treatment options for patients with metastatic disease who are not candidates for immunotherapy and are currently treated with traditional chemotherapy. This positive recommendation by the CHMP underscores the potential for *Datroway* to replace traditional chemotherapy in this setting and we look forward to working closely with the EMA to bring this new indication to patients in the EU."

In the trial, *Datroway* demonstrated a statistically significant and clinically meaningful 5.0-month improvement in median overall survival (OS) (hazard ratio [HR] 0.79; 95% confidence interval [CI] 0.64-0.98; p=0.0291) compared to chemotherapy as 1st-line treatment in this patient population. Median OS was 23.7 months for patients treated with *Datroway* versus 18.7 months for those treated with chemotherapy. *Datroway* reduced the risk of disease progression or death by 43% compared to chemotherapy (HR 0.57; 95% CI 0.47-0.69; p<0.0001) as assessed by blinded independent central review (BICR). *Datroway* was also associated with more robust treatment responses, including an objective response rate (ORR) of 62.5% compared to an ORR of 29.3% with chemotherapy.¹

The safety profile of *Datroway* in TROPION-Breast02 was consistent with previous clinical trials of *Datroway* in breast cancer.

Datroway was approved in the US in May 2026 for the treatment of adult patients with unresectable or metastatic TNBC who are not candidates for PD-1/PD-L1 inhibitor therapy. Additional reviews are underway in China and Japan, as well as Australia, Canada, Singapore and Switzerland as part of Project Orbis.

Datroway is a specifically engineered TROP2-directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being jointly developed and commercialised by AstraZeneca and Daiichi Sankyo.

Notes

Triple-negative breast cancer

TNBC accounts for approximately 15% of all breast cancer cases, with an estimated 345,000 diagnoses globally each year.^{2,3} In Europe, there are an estimated 83,000 diagnoses of TNBC each year.^{2,4} TNBC is diagnosed more frequently in younger and premenopausal women, and is more prevalent in Black and Hispanic women.⁵⁻⁷ Metastatic TNBC is the most aggressive type of breast cancer and has one of the worst prognoses, with median OS of just 12 to 18 months and only about 15% of patients living five years following diagnosis.^{5,8,9}

While some breast cancers may test positive for oestrogen receptors, progesterone receptors or overexpression of HER2, TNBC tests negative for all three.⁵ Due to its aggressive nature and absence of common breast cancer receptors, TNBC is characteristically difficult to treat.⁵ For patients with metastatic disease with PD-L1 expressing tumours, the addition of immunotherapy to chemotherapy has improved outcomes in the 1st-line setting.^{10,11} However, for approximately 70% of patients with metastatic TNBC who are not candidates for immunotherapy, prior to the approval of *Datroway*, chemotherapy was the standard 1st-line treatment.¹²

TROP2 is a protein broadly expressed in several solid tumours, including TNBC.¹³ TROP2 is associated with increased tumour progression and poor survival in patients with breast cancer.^{14,15}

TROPION-Breast02

TROPION-Breast02 is a global, multicentre, randomised, open-label Phase III trial evaluating the efficacy and safety of *Datroway* versus investigator's choice of chemotherapy (paclitaxel, nab-paclitaxel, capecitabine, carboplatin or eribulin) in patients with previously untreated locally recurrent inoperable or metastatic TNBC for whom immunotherapy was not an option. This included patients whose tumours did not express PD-L1 as well as patients with PD-L1 expressing tumours who could not receive immunotherapy due to prior exposure in early-stage disease, comorbidities or immunotherapy not being accessible in their geography. Enrolment included patients with de novo or recurrent disease, regardless of disease-free interval, and those with poor prognostic factors such as stable brain metastases.

The dual primary endpoints of TROPION-Breast02 are OS and progression-free survival (PFS) as assessed by blinded independent central review. Secondary endpoints include PFS as assessed by investigator, ORR, duration of response, disease control rate, pharmacokinetics and safety.

TROPION-Breast02 enrolled 644 patients at sites in Africa, Asia, Europe, North America and South America. For more information, visit [ClinicalTrials.gov](https://clinicaltrials.gov).

Datroway

Datroway (datopotamab deruxtecan; datopotamab deruxtecan-dlnk in the US only) is a TROP2-directed ADC. Designed using Daiichi Sankyo's proprietary DXd ADC Technology, *Datroway* is one of seven DXd ADCs in the oncology pipeline of Daiichi Sankyo, and one of the most advanced programmes in AstraZeneca's ADC scientific platform. *Datroway* is comprised of a humanised anti-TROP2 IgG1 monoclonal antibody, developed in collaboration with Sapporo Medical University, attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

Datroway is also approved in more than 40 countries/regions worldwide for the treatment of adult patients with unresectable or metastatic HR-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease based on results from the [TROPION-Breast01](#) trial.

Datroway is approved in the US for the treatment of adult patients with unresectable or metastatic TNBC who are not candidates for PD-1/PD-L1 inhibitor therapy based on the results from the TROPION-Breast02 trial.

Datroway is available in the US under accelerated approval for the treatment of adult patients with locally advanced or metastatic *EGFR*-mutated non-small cell lung cancer (NSCLC) who have received prior *EGFR*-directed therapy and platinum-based chemotherapy based on results from the [TROPION-](#)

[Lung05](#) and [TROPION-Lung01](#) trials. Continued approval for this indication in the US may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Datroway clinical development programme

A comprehensive global clinical development programme is underway with more than 20 trials evaluating the efficacy and safety of *Datroway* across multiple cancers, including NSCLC, TNBC and urothelial cancer. The programme includes eight Phase III trials in lung cancer, five Phase III trials in breast cancer, and one Phase II/III trial in urothelial cancer evaluating *Datroway* as a monotherapy and in combination with other cancer treatments in various settings.

Daiichi Sankyo collaboration

AstraZeneca and Daiichi Sankyo entered into a global collaboration to jointly develop and commercialise *Enhertu* (trastuzumab deruxtecan) 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*.

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* (capiivasertib), the TROP2-directed ADC, *Datroway*, and next-generation oral SERD, *Etcamah*.

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 camizestran 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 Disease, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory &

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Contacts

For details on how to contact the Investor Relations Team, please click [here](#). For Media contacts, click [here](#).

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Matthew Bowden
Company Secretary
AstraZeneca PLC

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