Press Release

Daiichi-Sankyo

Datroway® Recommended for Approval in the EU by CHMP as First-Line Treatment for Patients with Metastatic Triple Negative Breast Cancer Who Are Not Candidates for Immunotherapy

- Recommendation based on TROPION-Breast02 phase 3 trial where Daiichi Sankyo and AstraZeneca'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 potential to be the first TROP2 directed antibody drug conjugate for patients in EU with a demonstrated overall survival benefit as first-line treatment

Tokyo – **(June 26, 2026)** – Datroway® (datopotamab deruxtecan) has been recommended for approval in the European Union (EU) as monotherapy for the first-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.

Datroway is a specifically engineered TROP2 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 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 3 trial, which were presented at the 2025 European Society for Medical Oncology Congress and published in *Annals of Oncology*. The recommendation will now be reviewed by the European Commission, which has the authority to grant marketing authorizations for medicines in the EU.

In TROPION-Breast02, Datroway demonstrated a statistically significant and clinically meaningful 5.0-month improvement in median overall survival (OS) versus investigator's choice of chemotherapy (hazard ratio [HR]=0.79; 95% confidence interval [CI]: 0.64-0.98; p=0.0291). 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). Median progression-free survival (PFS) was 10.8 months for patients treated with Datroway versus 5.6 months for those treated with chemotherapy in patients with metastatic TNBC who are not candidates for PD-1/PD-L1 inhibitor therapy. Datroway was also associated with more robust treatment responses compared to chemotherapy, with an objective response rate (ORR) of 62.5% versus 29.3% for those treated with chemotherapy.

"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," said John Tsai, MD, Global Head, R&D, Daiichi Sankyo. "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."

"As one of the hardest cancers to treat, today only 15% of patients with metastatic triple negative breast cancer survive beyond five years," said Susan Galbraith, MBBChir, PhD, Executive Vice President, Oncology Hematology R&D, AstraZeneca. "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."

The safety profile of Datroway (6 mg/kg) was evaluated in 319 patients with TNBC who received Datroway in TROPION-Breast02. The most common (≥20%) adverse reactions, including laboratory abnormalities, were stomatitis, increased amylase, nausea, alopecia, decreased hemoglobin, decreased white blood cells,

constipation, decreased calcium, decreased lymphocytes, fatigue, decreased neutrophils, increased alanine aminotransferase, increased aspartate aminotransferase, dry eye, keratitis, decreased albumin, vomiting, musculoskeletal pain, decreased sodium and increased blood alkaline phosphatase. Serious adverse reactions occurred in 17% of patients who received Datroway. Serious adverse reactions in more than 1% of patients who received Datroway included pneumonia, vomiting, COVID-19 and anemia. One patient fatality was attributed to interstitial lung disease/pneumonitis.

Datroway was approved in the U.S. 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.

About TROPION-Breast02

TROPION-Breast02 is a global, multicenter, randomized, open-label phase 3 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 tumors did not express PD-L1 as well as patients with PD-L1 expressing tumors who could not receive immunotherapy due to prior exposure in early-stage disease, comorbidities or immunotherapy not being accessible in their geography. Enrollment 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 PFS as assessed by BICR. 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.

About Triple Negative Breast Cancer

TNBC accounts for approximately 15% of all breast cancer cases, with an estimated 345,000 diagnoses globally each year.[1,2] In Europe, there are an estimated 83,000 diagnoses of TNBC each year.[3,4] TNBC is diagnosed more frequently in younger and premenopausal women, and is more prevalent in Black and Hispanic women.[5,6,7] 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.[8,9,10]

While some breast cancers may test positive for estrogen receptors, progesterone receptors or overexpression of HER2, TNBC tests negative for all three.[11] Due to its aggressive nature and absence of common breast cancer receptors, TNBC is characteristically difficult to treat.[12] For patients with metastatic disease with PD-L1 expressing tumors, the addition of immunotherapy to chemotherapy has improved outcomes in the first-line setting.[13,14] However, for approximately 70% of patients with metastatic TNBC who are not candidates for immunotherapy, chemotherapy was the standard first-line treatment.[15]

TROP2 is a protein broadly expressed in several solid tumors, including TNBC.[16] TROP2 is associated with increased tumor progression and poor survival in patients with breast cancer.[17,18]

About Datroway

Datroway (datopotamab deruxtecan; datopotamab deruxtecan-dlnk in the U.S. 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 programs in AstraZeneca's ADC scientific platform. Datroway is comprised of a humanized 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 (6 mg/kg) is approved in Brazil, Russia and the U.S. 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 (6 mg/kg) is 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 the results from the TROPION-Breast01 trial.

Datroway (6 mg/kg) is approved in Russia and the U.S. 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 the results from TROPION-Lung05 and TROPION-Lung01 trials. Continued approval for this indication in the U.S. may be contingent upon verification and description of clinical benefit in a confirmatory trial.

About the Datroway Clinical Development Program

A comprehensive global clinical development program is underway with more than 20 trials evaluating the efficacy and safety of Datroway across multiple cancers, including NSCLC, TNBC and urothelial cancer. The program includes eight phase 3 trials in lung cancer, five phase 3 trials in breast cancer, and one phase 2/3 trial in urothelial cancer evaluating Datroway as a monotherapy and in combination with other cancer treatments in various settings.

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 eight 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.

An additional ADC being developed by Daiichi Sankyo is DS3610, which consists of an antibody attached to a novel payload that acts as an agonist of STING.

Ifinatamab deruxtecan, raludotatug deruxtecan, patritumab deruxtecan, DS-3939, DS3610 and DS3790 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.

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