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Daiichi-Sankyo

Press Release

DATROWAY® Supplemental New Drug Application Submitted in Japan for Patients with Metastatic Triple Negative Breast Cancer Who Are Not Candidates for Immunotherapy

- Based on results from TROPION-Breast02 showing DATROWAY significantly improved overall survival versus chemotherapy in this patient population
- If approved, DATROWAY could become the first TROP2 directed antibody drug conjugate approved in Japan in the first-line metastatic triple negative breast cancer setting

Tokyo – (February 12, 2026) – Daiichi Sankyo (TSE: 4568) has submitted a supplemental New Drug Application (sNDA) to Japan's Ministry of Health, Labour and Welfare (MHLW) for DATROWAY® (datopotamab deruxtecan) for the treatment of adult patients with hormone receptor negative and HER2 negative unresectable or recurrent breast cancer, a subtype commonly referred to as triple negative breast cancer (TNBC).

DATROWAY is a specifically engineered TROP2 directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being developed and commercialized by Daiichi Sankyo in Japan.

The sNDA is based on data from the TROPION-Breast02 phase 3 trial presented at the 2025 European Society for Medical Oncology (#ESMO25) Congress. In the trial, DATROWAY demonstrated a statistically significant and clinically meaningful improvement for the dual primary endpoints of overall survival (OS) and progression-free survival (PFS) compared to investigator's choice of chemotherapy as first-line treatment for patients with metastatic TNBC for whom immunotherapy was not an option.

"Metastatic triple negative breast cancer is highly aggressive and has one of the worst prognoses of any subtype of breast cancer," said Yuki Abe, PhD, Head of R&D Division in Japan and Head of Research, Daiichi Sankyo. "We are working as quickly as possible with the Japan health authority to make DATROWAY the first TROP2 directed antibody drug conjugate to become available in Japan for first-line triple negative breast cancer, addressing the unmet need for the seventy percent of patients in this setting who are not candidates for immunotherapy."

Additional regulatory submissions for DATROWAY in breast and lung cancer are underway globally.

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 PFS as assessed by blinded independent central review and OS. Secondary endpoints include PFS as assessed by investigator, objective response rate, 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 Japan, an estimated 12,700 cases of TNBC were diagnosed in 2024.[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]

While some breast cancers may test positive for estrogen receptors, progesterone receptors or overexpression of HER2, TNBC tests negative for all three.[1] Due to its aggressive nature and absence of common breast cancer receptors, TNBC is characteristically difficult to treat.[1] For patients with metastatic disease with PD-L1 expressing tumors, the addition of immunotherapy to chemotherapy has improved outcomes in the first-line setting.[2,3] However, for approximately 70% of patients with metastatic TNBC who are not candidates for immunotherapy, chemotherapy remains the only approved first-line treatment.[4,5]

TROP2 is a protein broadly expressed in several solid tumors, including TNBC.[6] TROP2 is associated with increased tumor progression and poor survival in patients with breast cancer.[7,8]

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 six 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 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® (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.

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 is an innovative global healthcare company contributing to the sustainable development of society that discovers, develops and delivers new standards of care to enrich the quality of life around the world. With more than 120 years of experience, Daiichi Sankyo leverages its world-class science and technology to create new modalities and innovative medicines for people with cancer, cardiovascular and other diseases with high unmet medical needs. For more information, please visit www.daiichisankyo.com.

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