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Daiichi-Sankyo

Press Release

DATROWAY® Approved in China for Patients with Previously Treated Metastatic HR Positive, HER2 Negative Breast Cancer

- First approval in China for Daiichi Sankyo and AstraZeneca's DATROWAY based on TROPION-Breast01 results showing 37% reduction in risk of disease progression or death versus chemotherapy
- Second DXd antibody drug conjugate approved in China based on Daiichi Sankyo's DXd technology

Tokyo – (August 25, 2025) – DATROWAY® (datopotamab deruxtecan) has been approved in China for the treatment of adult patients with unresectable or metastatic hormone receptor (HR) positive, HER2 negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine therapy and at least one line of chemotherapy in the advanced setting.

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/Nasdaq: AZN).

Breast cancer is the second most common cancer in women in China.[1] Approximately 357,000 cases of breast cancer were diagnosed in China in 2022, with nearly 75,000 deaths.[1] It is estimated that 70% of diagnosed cases are considered what has been historically called HR positive, HER2 negative breast cancer (measured as HER2 score of IHC 0, IHC 1+ or IHC 2+/ISH-).[2]

The approval of DATROWAY by China's National Medical Products Administration (NMPA) is based on results from the TROPION-Breast01 phase 3 trial. In the trial, DATROWAY significantly reduced the risk of disease progression or death by 37% compared to investigator's choice of chemotherapy (hazard ratio [HR]=0.63; 95% confidence interval [CI]: 0.52-0.76; p<0.0001) in patients with HR positive, HER2 negative metastatic breast cancer as assessed by blinded independent central review (BICR). Median progression free survival (PFS) was 6.9 months in patients treated with DATROWAY versus 4.9 months with chemotherapy. A confirmed objective response rate (ORR) of 36% was observed in the DATROWAY arm compared to an ORR of 23% observed in the chemotherapy arm. There were two (0.5%) complete responses (CRs) and 131 partial responses (PRs) (36%) seen in the DATROWAY arm compared to zero (0%) CRs and 84 (23%) PRs in the chemotherapy arm. The median duration of response (DoR) was 6.7 months (95% CI: 5.6-9.8) in the DATROWAY arm compared to 5.7 months (95% CI: 4.9-6.8) in the chemotherapy arm. The final overall survival (OS) results of the trial did not achieve statistical significance (HR 1.01; 95% CI: 0.83-1.22). In an exploratory sensitivity analysis, OS

adjusted for subsequent ADC treatment was 19.1 months in the DATROWAY arm versus 17.5 months in the chemotherapy arm (HR 0.86; 95% CI: 0.70-1.06).[3]

In an exploratory analysis of the 83 patients enrolled in TROPION-Breast01 in China, median PFS was 8.1 months in patients treated with DATROWAY versus 4.2 months with chemotherapy (HR 0.54; 95% CI: 0.30-0.96) and a confirmed ORR of 38.6% was observed in the DATROWAY arm compared to an ORR of 17.9% in the chemotherapy arm.[4]

"Despite the progress we have made in managing HR positive, HER2 negative metastatic breast cancer, many patients still face limited options once their disease progresses after endocrine therapy and chemotherapy," said Professor Binghe Xu, Director of Clinical Trial Center (GCP) of National Cancer Center, Cancer Hospital Chinese Academy of Medical Sciences, and China leading PI of TROPION-Breast01. "The approval of datopotamab deruxtecan, a novel TROP2 directed antibody drug conjugate, represents a meaningful step forward in expanding therapeutic choices for patients with breast cancer."

"The approval of DATROWAY provides a new treatment option for patients with metastatic HR positive, HER2 negative breast cancer, enabling timely access to an innovative TROP2 targeted antibody drug conjugate in China," said Michio Hayashi, China President, Daiichi Sankyo. "DATROWAY is now the second DXd antibody drug conjugate approved in China following ENHERTU and expands our portfolio to meet the evolving treatment needs of patients with a range of breast cancer subtypes."

"Despite considerable advancements in the treatment of HR positive breast cancer, new medicines are still needed to tackle the frequent and complex challenge of disease progression following initial therapies," said Dave Fredrickson, Executive Vice President, Oncology Hematology Business Unit, AstraZeneca. "We are proud to bring DATROWAY to patients in China for the first time, offering those with metastatic HR positive, HER2 negative breast cancer a new and needed option."

In TROPION-Breast01, the most common (≥20%) adverse reactions, including laboratory abnormalities were stomatitis, nausea, fatigue, decreased leukocytes, decreased calcium, alopecia, decreased lymphocytes, decreased hemoglobin, constipation, decreased neutrophils, dry eye, vomiting, increased ALT, keratitis, increased AST and increased alkaline phosphatase. Grade 3 or higher adverse reactions in patients (>0.5%) receiving DATROWAY were urinary tract infection (1.9%), COVID-19 infection (1.7%), interstitial lung disease (ILD)/pneumonitis (1.1%), acute kidney injury (0.6%), pulmonary

embolism (0.6%), vomiting (0.6%), diarrhea (0.6%), hemiparesis (0.6%) and anemia (0.6%). A grade 5 adverse reaction occurred in one patient (0.3%) and was attributed to ILD/pneumonitis.

About TROPION-Breast01

TROPION-Breast01 is a global, randomized, multicenter, open-label phase 3 trial evaluating the efficacy and safety of intravenous DATROWAY (6 mg/kg) once per 21-day cycle versus investigator's choice of single-agent chemotherapy (eribulin, capecitabine, vinorelbine or gemcitabine) in adult patients with unresectable or metastatic HR positive, HER2 negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have progressed on and are not suitable for endocrine therapy per investigator assessment and have received at least one prior line of chemotherapy for unresectable or metastatic disease.

Following disease progression or discontinuation of DATROWAY or chemotherapy, patients had the option to receive a subsequent treatment at the discretion of their physician. Crossover between trial arms was not permitted.

The dual primary endpoints of TROPION-Breast01 are PFS as assessed by BICR and OS. Key secondary endpoints include ORR, DoR, investigator-assessed PFS, disease control rate, time to first subsequent therapy and safety. The PFS data and additional results for key secondary endpoints of TROPION-Breast01 were published in the *Journal of Clinical Oncology* and OS results were presented at a Virtual Plenary session hosted by the European Society for Medical Oncology in February 2025.

TROPION-Breast01 enrolled 732 patients in Africa, Asia, Europe, North America and South America. For more information visit ClinicalTrials.gov.

About Hormone Receptor Positive, HER2 Negative Breast Cancer

Breast cancer is the second most common cancer and one of the leading causes of cancer-related deaths worldwide.[5] More than two million breast cancer cases were diagnosed in 2022 with more than 665,000 deaths globally.[5] While survival rates are high for those diagnosed with early breast cancer, only about 30% of patients diagnosed with or progress to metastatic disease are expected to live five years following diagnosis.[2] Approximately 357,000 cases of breast cancer are diagnosed annually in China, representing the most cases diagnosed anywhere in the world, and of these about 20% are diagnosed in the advanced or metastatic setting.[1,6]

Approximately 70% of diagnosed cases are considered what has been historically called HR positive, HER2 negative breast cancer (measured as HER2 score of IHC 0, IHC 1+ or IHC 2+/ISH-).[2] Endocrine therapy is widely given consecutively in the early lines of treatment for metastatic HR positive breast cancer.[7] However, after initial treatment, further efficacy from endocrine therapy is often limited.[7]

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 35 countries 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 the 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 the 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, triple negative breast cancer and HR positive, HER2 negative breast cancer. The program includes eight phase 3 trials in lung cancer and five phase 3 trials in breast cancer evaluating DATROWAY as a monotherapy and in combination with other cancer medicines 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 seven ADCs in clinical development crafted from two distinct ADC technology platforms discovered in-house by Daiichi Sankyo.

The ADC platform furthest in clinical development is Daiichi Sankyo's DXd ADC Technology where each ADC consists of a monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers. The DXd ADC portfolio currently consists of ENHERTU, a HER2 directed ADC, and DATROWAY, a TROP2 directed ADC, which are being jointly developed and commercialized globally with AstraZeneca. Patritumab deruxtecan (HER3-DXd), a HER3 directed ADC, ifinatamab deruxtecan (I-DXd), a B7-H3 directed ADC, and raludotatug deruxtecan (R-DXd), a CDH6 directed ADC, are being jointly developed and commercialized globally with Merck & Co., Inc, Rahway, NJ, USA. DS-3939, a TA-MUC1 directed ADC, is being developed by Daiichi Sankyo.

The second Daiichi Sankyo ADC platform consists of a monoclonal antibody attached to a modified pyrrolobenzodiazepine (PBD) payload. DS-9606, a CLDN6 directed PBD ADC, is the first of several planned ADCs in clinical development utilizing this platform.

Ifinatamab deruxtecan, patritumab deruxtecan, raludotatug deruxtecan, DS-3939 and DS-9606 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 need. For more information, please visit www.daiichisankyo.com.

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