Press Release

Daiichi-Sankyo

Datroway® Approved in the U.S. as First TROP2 Directed Antibody Drug Conjugate for First-Line Treatment of Patients with Metastatic Triple Negative Breast Cancer Who Are Not PD-1/PD-L1 Inhibitor Candidates

- Daiichi Sankyo and AstraZeneca's Datroway is the only TROP2 directed antibody drug conjugate to prolong overall survival in this setting versus chemotherapy, with an unprecedented median overall survival of approximately two years based on the TROPION-Breast02 phase 3 trial
- Datroway has the potential to become the new standard of care in this setting

Tokyo – **(May 22, 2026)** – Daiichi Sankyo (TSE: 4568) and AstraZeneca's (LSE/STO/NYSE: AZN) Datroway® (datopotamab deruxtecan-dlnk) has been approved in the U.S. for the 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 and being jointly developed and commercialized by Daiichi Sankyo and AstraZeneca.

The approval follows Priority Review by the U.S. Food and Drug Administration (FDA) based 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*. In the trial, 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=0.0290). 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 64% versus 30% for those treated with chemotherapy.

"Datopotamab deruxtecan is the first and only medicine to significantly prolong overall survival in the first-line setting compared to chemotherapy in patients with metastatic triple negative breast cancer who are not candidates for immunotherapy," said Tiffany A. Traina, MD, FASCO, Section Head, Triple Negative Breast Cancer Clinical Research Program, Memorial Sloan Kettering Cancer Center and investigator for the TROPION-Breast02 trial. "This approval will bring a much-needed treatment option for these patients."

"For seven out of 10 patients with metastatic triple negative breast cancer who are not candidates for immunotherapy, chemotherapy has remained the only treatment option," said Arlene Brothers, Executive Director, Triple Negative Breast Cancer Foundation. "Today's approval of Datroway means that for the first time, these patients will have a new standard of care beyond traditional chemotherapy at the outset of their treatment."

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.

"As the first approved antibody drug conjugate to demonstrate a median overall survival of two years in the first-line metastatic setting of triple negative breast cancer, Datroway has the potential to redefine the treatment landscape for these patients," said Ken Keller, Global Head of Oncology Business, and President and CEO, Daiichi Sankyo, Inc. "With this approval, Datroway is now approved for three indications in the U.S., including two for breast cancer, underscoring its potential to play an important role across tumor types."

"Triple negative breast cancer is notoriously difficult to treat. Patients with metastatic disease, especially those who are unable to receive immunotherapy, urgently need more effective, durable and tolerable treatment options, which extend survival," said Dave Fredrickson, Executive Vice President, Oncology Hematology Business Unit, AstraZeneca. "With today's approval, we are proud to bring Datroway to a broad population of advanced triple negative breast cancer patients and we continue to study its promise as a mainstay treatment across tumors, stages and settings."

This application was reviewed under Project Orbis, which provides a framework for concurrent submission and review of oncology medicines among participating international partners. As part of Project Orbis, reviews are ongoing in Australia, Canada, Singapore and Switzerland. This initiative is designed to bring effective cancer treatments to patients as early as possible. Additional reviews are underway in the EU, China and Japan.

Based on the results of TROPION-Breast02, datopotamab deruxtecan-dlnk (Datroway) has been included in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a Category 1 Preferred first-line treatment option for patients with metastatic TNBC who are not candidates for immunotherapy. See NCCN Guidelines® for detailed recommendations.[1]

Daiichi Sankyo and AstraZeneca are committed to ensuring that patients in the U.S. who are prescribed Datroway can access the medication and receive necessary financial support. Provider and patient support, reimbursement and distribution for Datroway in the U.S. will be accessible by visiting www.Datroway4U.com or calling 1-855-Datro4U (1-855-328-7648).

Please visit www.Datroway.com for full Prescribing Information, including the Medication Guide.

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 BICR and OS. 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.[2,3] In the U.S., an estimated 32,000 to 48,000 cases of TNBC were diagnosed in 2025.[4,5] TNBC is

diagnosed more frequently in younger and premenopausal women, and is more prevalent in Black and Hispanic women.[6,7,8] 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.[6,9,10]

While some breast cancers may test positive for estrogen receptors, progesterone receptors or overexpression of HER2, TNBC tests negative for all three.[6] Due to its aggressive nature and absence of common breast cancer receptors, TNBC is characteristically difficult to treat.[6] For patients with metastatic disease with PD-L1 expressing tumors, the addition of immunotherapy to chemotherapy has improved outcomes in the first-line setting.[11,12] However, for approximately 70% of patients with metastatic TNBC who are not candidates for immunotherapy, prior to the approval of Datroway, chemotherapy was the only approved first-line treatment.[13]

TROP2 is a protein broadly expressed in several solid tumors, including TNBC.[14] TROP2 is associated with increased tumor progression and poor survival in patients with breast cancer.[15,16]

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 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 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 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.

Datroway U.S. Indication and Important Safety Information

Indications

DATROWAY® (datopotamab deruxtecan-dlnk) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of:

- adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy.

  This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

- adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy.

- adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (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.

Important Safety Information

Warnings and Precautions

Interstitial Lung Disease/Pneumonitis

DATROWAY can cause severe, life-threatening, or fatal interstitial lung disease (ILD) or pneumonitis.

Locally Advanced or Metastatic NSCLC

In the pooled safety population of 484 patients with NSCLC from TROPION-Lung01, TROPION-Lung05, and TROPION-PanTumor01, ILD/pneumonitis occurred in 7% of patients treated with DATROWAY, including 0.6% of patients with Grade 3 and 0.4% with Grade 4. There were 8 (1.7%) fatal cases. The median time to first onset for ILD was 1.4 months (range: 0.2 months to 9 months). Eleven patients (2.3%) had DATROWAY withheld and 20 patients (4.1%) permanently discontinued DATROWAY due to ILD/pneumonitis. Systemic corticosteroids were required in 79% (26/33) of patients with ILD/pneumonitis. ILD/pneumonitis resolved in 45% of patients.

Unresectable or Metastatic Breast Cancer

In the pooled safety population of 841 patients with breast cancer from TROPION-Breast01, TROPION-Breast02, TROPION-PanTumor01 and TROPION-PanTumor02, ILD/pneumonitis occurred in 3.0% of patients treated with DATROWAY, including 0.4% of patients with Grade 3. There were two fatal cases (0.2%). The median time to first onset for ILD was 5.3 months (range: 1.1 months to 19.3 months) and with a median duration of 1.2 months (range: 0.3 months to 5.2 months). Eight patients (1.0%) had DATROWAY withheld and 10 patients (1.2%) permanently discontinued DATROWAY due to ILD/pneumonitis. Systemic corticosteroids were required in 64% (16/25) of patients with ILD/pneumonitis. ILD/pneumonitis resolved in 40% of patients.

Patients were excluded from clinical studies for a history of ILD/pneumonitis requiring treatment with steroids or for ongoing ILD/pneumonitis.

Monitor patients for new or worsening respiratory symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever) during treatment with DATROWAY. For asymptomatic (Grade 1) ILD/pneumonitis, consider corticosteroid treatment (e.g., ≥0.5 mg/kg/day prednisolone or equivalent). For symptomatic ILD/pneumonitis (Grade 2 or greater), promptly initiate systemic corticosteroid treatment (e.g., ≥1 mg/kg/day prednisolone or equivalent) and continue for at least 14 days followed by gradual taper for at least 4 weeks.

Withhold DATROWAY in patients with suspected ILD/pneumonitis and permanently discontinue DATROWAY if ≥Grade 2 ILD/pneumonitis is confirmed.

Ocular Adverse Reactions
DATROWAY can cause ocular adverse reactions including dry eye, keratitis, blepharitis, meibomian gland dysfunction, increased lacrimation, conjunctivitis, and blurred vision.

In the pooled safety population, ocular adverse reactions occurred in 38% of patients treated with DATROWAY. Forty-two patients (3.1%) experienced Grade 3 ocular adverse reactions, which included keratitis and dry eye, and four patients (0.3%) experienced a Grade 4 ocular adverse reaction of keratitis, corneal epithelium defect, corneal lesion, and conjunctival hemorrhage. The most common (≥5%) ocular adverse reactions were dry eye (18%), keratitis (16%), increased lacrimation (6%), and conjunctivitis (5%). The median time to first onset for ocular adverse reactions was 2.3 months (range: 0.03 months to 30 months) and with a median duration of 2.3 months (range: 0.03 months to 19.5 months). Of the patients who experienced ocular adverse reactions, 39% had complete resolution, and 8% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to dosage interruption in 4.3% of patients, dosage reductions in 2.8% of patients, and permanent discontinuation of DATROWAY in 0.9% of patients.

Patients with clinically significant corneal disease were excluded from clinical studies.

Advise patients to use preservative-free lubricant eye drops at least four times daily and as needed for prophylaxis. Advise patients to avoid use of contact lenses unless directed by an eye care professional.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity testing, slit lamp examination (with fluorescein staining), intraocular pressure, and fundoscopy at treatment initiation, at end of treatment, and as clinically indicated. While on treatment, conduct visual acuity testing and slit lamp examination every 3 cycles.

Promptly refer patients to an eye care professional for any new or worsening ocular adverse reactions. Monitor patients for ocular adverse reactions during treatment with DATROWAY, and if diagnosis is confirmed, withhold, reduce the dose, or permanently discontinue DATROWAY based on severity.

Stomatitis
DATROWAY can cause stomatitis, including mouth ulcers and oral mucositis.

In the pooled safety population, stomatitis occurred in 63% of patients treated with DATROWAY, including 8% of patients with Grade 3 events and one patient with a Grade 4 reaction. The median time to first onset of stomatitis was 0.5 months (range: 0.03 months to 19.8 months) and with a median duration of 1.1 months (range: 0.03 months to 33.2 months). Stomatitis led to dosage interruption in 5% of patients, dosage reductions in 11% of patients, and permanent discontinuation of DATROWAY in 0.4% of patients.

In patients who received DATROWAY in TROPION-Breast01 and TROPION-Breast02, 39% and 51% respectively used a mouthwash containing corticosteroid for management or prophylaxis of stomatitis/oral mucositis at any time during the treatment.

Advise patients to use a steroid-containing mouthwash for prophylaxis and treatment of stomatitis. Instruct the patient to hold ice chips or ice water in the mouth throughout the infusion of DATROWAY.

Monitor patients for signs and symptoms of stomatitis. If stomatitis occurs, increase the frequency of mouthwash and administer other topical treatments as clinically indicated. Based on the severity of the adverse reaction, withhold, reduce the dose, or permanently discontinue DATROWAY.

Embryo-Fetal Toxicity
Based on its mechanism of action, DATROWAY can cause embryo-fetal harm when administered to a pregnant woman because the topoisomerase inhibitor component of DATROWAY, DXd, is genotoxic and affects actively dividing cells.

Advise patients of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment with DATROWAY and for 7 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with DATROWAY and for 4 months after the last dose.

Adverse Reactions
The pooled safety population described in WARNINGS AND PRECAUTIONS reflects exposure to DATROWAY in 1365 patients as a single agent at 6 mg/kg administered as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. This included 137 patients with NSCLC in TROPION-Lung05, 297 patients with NSCLC in TROPION-Lung01, 360 patients with HR-positive, HER2-negative breast cancer in TROPION-Breast01, 319 patients with TNBC in TROPION-Breast02, 50 patients with NSCLC and 83 patients with breast cancer in TROPION-PanTumor01, and 40 patients with NSCLC and 79 patients with breast cancer in TROPION-PanTumor02. Among the 1365 patients who received DATROWAY, 48% were exposed for greater than 6 months and 22% were exposed for greater than one year. In this pooled safety population, the most common (≥20%) adverse reactions were stomatitis (63%), nausea (51%), fatigue (42%), alopecia (38%), constipation (30%), vomiting (23%), decreased appetite (22%), and rash (20%). In this pooled safety population, the most common (≥2%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes (8%), decreased hemoglobin (3.7%), decreased sodium (3.0%), and decreased blood potassium (2.3%).

Locally Advanced or Metastatic EGFR-Mutated Non-Small Cell Lung Cancer

TROPION-Lung05, TROPION-Lung01, TROPION-PanTumor01

The safety of DATROWAY was evaluated in 125 patients with EGFR-mutated NSCLC who received DATROWAY 6 mg/kg administered as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity in TROPION-Lung05 and TROPION-Lung01 as well as TROPION-PanTumor01. Among these patients, the median duration of treatment was 6.1 months (range 0.7 months to 41.7 months).

The median age was 63 years (range: 36 to 81), 56% of patients were <65 years, 62% of patients were female; 66% were Asian, 26% were White, 0.8% were Black, 6% were other races; and 2.4% were of Hispanic ethnicity.

Serious adverse reactions occurred in 26% of patients who received DATROWAY. Serious adverse reactions in >1% of patients who received DATROWAY were COVID-19 (4%), stomatitis (2.4%), and pneumonia (1.6%). Fatal adverse reactions occurred in 1.6% of patients who received DATROWAY, due to death not otherwise specified.

Permanent discontinuation of DATROWAY due to an adverse reaction occurred in 8% of patients. Adverse reactions which resulted in permanent discontinuation of DATROWAY in >1% of patients included ILD/pneumonitis (2.4%) and abnormal hepatic function (1.6%).

Dosage interruptions of DATROWAY due to an adverse reaction occurred in 43% of patients. Adverse reactions which required dosage interruption in >1% of patients included COVID-19 (13%), stomatitis (7%), fatigue (6%), pneumonia (4%), anemia (2.4%), amylase increased (2.4%), keratitis (2.4%), ILD/pneumonitis (1.6%), decreased appetite (1.6%), dyspnea (1.6%), rash (1.6%), and infusion-related reaction (1.6%).

Dose reductions of DATROWAY due to an adverse reaction occurred in 26% of patients. Adverse reactions which required dose reduction in >1% of patients included stomatitis (14%), keratitis (1.6%), fatigue (1.6%), decreased weight (1.6%) and COVID-19 (1.6%).

The most common (≥20%) adverse reactions, including laboratory abnormalities, were stomatitis (71%), nausea (50%), alopecia (49%), fatigue (42%), decreased hemoglobin (34%), decreased lymphocytes (32%), constipation (31%), increased calcium (31%), increased AST (28%), decreased white blood cell count (27%), increased lactate

dehydrogenase (23%), musculoskeletal pain (22%), decreased appetite (20%), increased ALT (20%), and rash (20%).

Clinically relevant adverse reactions occurring in <10% of patients who received DATROWAY included dry skin, blurred vision, abdominal pain, conjunctivitis, dry mouth, ILD/pneumonitis, skin hyperpigmentation, increased lacrimation, and visual impairment.

Unresectable or Metastatic Triple-Negative Breast Cancer (TNBC)

TROPION-Breast02

The safety of DATROWAY was evaluated in 319 patients with triple-negative breast cancer who received at least one dose of DATROWAY 6 mg/kg in TROPION-Breast02. DATROWAY was administered by intravenous infusion once every three weeks. The median duration of treatment was 8.5 months (range: 0.7 months to 38.0 months) for patients who received DATROWAY.

Serious adverse reactions occurred in 17% of patients who received DATROWAY. Serious adverse reactions in >1% of patients who received DATROWAY were pneumonia (2.2%), vomiting (1.9%), COVID-19 (1.6%), and anemia (1.3%). Fatal adverse reactions occurred in one patient (0.3%) who received DATROWAY and was due to ILD/pneumonitis.

Permanent discontinuation of DATROWAY due to an adverse reaction occurred in 4.7% of patients. Adverse reactions which resulted in permanent discontinuation of DATROWAY in >0.5% of patients included ILD/pneumonitis (0.9%) and keratitis (0.9%).

Dosage interruptions of DATROWAY due to an adverse reaction occurred in 35% of patients. Adverse reactions which required dosage interruption in >1% of patients included stomatitis (5%), increased amylase (4.1%), keratitis (3.4%), neutropenia (3.1%), COVID-19 (2.8%), pneumonia (2.2%), dry eye (1.9%), upper respiratory tract infection (1.6%), anemia (1.3%), leukopenia (1.3%), IRR (1.3%), and ILD/pneumonitis (1.3%).

Dose reductions of DATROWAY due to an adverse reaction occurred in 28% of patients. Adverse reactions which required dose reduction in >1% of patients included stomatitis (11%), keratitis (4.1%), fatigue (3.8%), increased amylase (2.8%), and pneumonia (1.3%).

The most common (≥20%) adverse reactions, including laboratory abnormalities in patients receiving DATROWAY, were stomatitis (63%), increased amylase (54%), nausea (48%), alopecia (43%), decreased hemoglobin (43%), decreased white blood cells (41%), constipation (40%), decreased calcium (39%), decreased lymphocytes (36%), fatigue (36%), decreased neutrophils (35%), increased ALT (28%), increased AST (27%), dry eye (26%), keratitis (26%), decreased albumin (25%), vomiting (23%), musculoskeletal pain (22%), decreased sodium (21%), and increased blood alkaline phosphatase (20%).

Clinically relevant adverse reactions occurring in <10% of patients who received DATROWAY included infusion-related reactions including anaphylactic reaction, diarrhea, conjunctivitis, lacrimation increased, dry mouth, dry skin, pruritus, rhinorrhea, blepharitis, meibomian gland dysfunction, blurred vision, ILD/pneumonitis, visual impairment, photophobia, and madarosis.

Unresectable or Metastatic, HR-Positive, HER2-Negative Breast Cancer

TROPION-Breast01

The safety of DATROWAY was evaluated in 360 patients with unresectable or metastatic HR-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who received at least one dose of DATROWAY 6 mg/kg in TROPION-Breast01. DATROWAY was administered by intravenous infusion once every three weeks. The median duration of treatment was 6.7 months (range: 0.7 months to 16.1 months) for patients who received DATROWAY.

Serious adverse reactions occurred in 15% of patients who received DATROWAY. Serious adverse reactions in >0.5% of patients who received DATROWAY were urinary tract infection (1.9%), COVID-19 infection (1.7%), ILD/pneumonitis (1.1%), acute kidney injury, pulmonary embolism, vomiting, diarrhea, hemiparesis, and anemia

(0.6% each). Fatal adverse reactions occurred in 0.3% of patients who received DATROWAY and were due to ILD/pneumonitis.

Permanent discontinuation of DATROWAY due to an adverse reaction occurred in 3.1% of patients. Adverse reactions which resulted in permanent discontinuation of DATROWAY in >0.5% of patients included ILD/pneumonitis (1.7%) and fatigue (0.6%).

Dosage interruptions of DATROWAY due to an adverse reaction occurred in 22% of patients. Adverse reactions which required dosage interruption in >1% of patients included COVID-19 (3.3%), infusion-related reaction (1.4%), ILD/pneumonitis (1.9%), stomatitis (1.9%), fatigue (1.7%), keratitis (1.4%), acute kidney injury (1.1%), and pneumonia (1.1%).

Dose reductions of DATROWAY due to an adverse reaction occurred in 23% of patients. Adverse reactions which required dose reduction in >1% of patients included stomatitis (13%), fatigue (3.1%), nausea (2.5%), and weight decrease (1.9%).

The most common (≥20%) adverse reactions, including laboratory abnormalities, were stomatitis (59%), nausea (56%), fatigue (44%), decreased leukocytes (41%), decreased calcium (39%), alopecia (38%), decreased lymphocytes (36%), decreased hemoglobin (35%), constipation (34%), decreased neutrophils (30%), dry eye (27%), vomiting (24%), increased ALT (24%), keratitis (24%), increased AST (23%), and increased alkaline phosphatase (23%).

Clinically relevant adverse reactions occurring in <10% of patients who received DATROWAY included infusion-related reactions (including bronchospasm), ILD/pneumonitis, headache, pruritus, dry skin, dry mouth, conjunctivitis, blepharitis, meibomian gland dysfunction, blurred vision, increased lacrimation, photophobia, visual impairment, skin hyperpigmentation, and madarosis.

Use in Specific Populations

- **Pregnancy:** Based on its mechanism of action, DATROWAY can cause embryo-fetal harm when administered to a pregnant woman because the topoisomerase inhibitor component of DATROWAY, DXd, is genotoxic and affects actively dividing cells. There are no available data on the use of DATROWAY in pregnant women to inform a drug-associated risk. Advise patients of the potential risks to a fetus.
- **Lactation:** There are no data regarding the presence of datopotamab deruxtecan-dlnk or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with DATROWAY and for 1 month after the last dose.
- **Females and Males of Reproductive Potential:** Pregnancy Testing: Verify pregnancy status of females of reproductive potential prior to initiation of DATROWAY. Contraception: *Females:* Advise females of reproductive potential to use effective contraception during treatment with DATROWAY and for 7 months after the last dose. *Males:* Because of the potential for genotoxicity, advise male patients with female partners of reproductive potential to use effective contraception during treatment with DATROWAY and for 4 months after the last dose. Infertility: Based on findings in animal toxicity studies, DATROWAY may impair male and female reproductive function and fertility. The effects on reproductive organs in animals were irreversible.
- **Pediatric Use:** Safety and effectiveness of DATROWAY have not been established in pediatric patients.
- **Geriatric Use:** Of the 125 patients with EGFR-mutated NSCLC in TROPION-Lung05, TROPION-Lung01, TROPION-PanTumor01 treated with DATROWAY 6 mg/kg, 44% were ≥65 years of age and 10% were ≥75 years of age. No clinically meaningful differences in efficacy and safety were observed between patients ≥65 years of age versus younger patients. Of the 841 patients with breast cancer in TROPION-Breast01, TROPION-Breast02, TROPION-PanTumor01, and TROPION-PanTumor02 treated with DATROWAY 6 mg/kg, 23% were ≥65 years of age and 4.5% were ≥75 years of age. Grade ≥3 and serious adverse reactions were more common in patients ≥65 years (45% and 22%, respectively) compared to patients <65 years (38% and 16%, respectively). No other meaningful differences in efficacy and safety were observed between patients ≥65 years of age versus younger patients.
- **Renal Impairment:** Monitor patients with renal impairment for increased adverse reactions, including respiratory reactions. A higher incidence of ILD/pneumonitis has been observed in patients with creatinine clearance (CLcr) 30 to <90 mL/min (estimated by Cockcroft Gault). No dosage adjustment is recommended in patients with CLcr

30 to <90 mL/min. The pharmacokinetics of datopotamab deruxtecan-dlnk or DXd in patients with CLcr <30 mL/min is unknown.

- **Hepatic Impairment:** Monitor patients with moderate hepatic impairment (total bilirubin >1.5 to 3 times ULN and any AST) for increased adverse reactions. Limited data are available in patients with moderate hepatic impairment. No dosage adjustment is recommended in patients with mild hepatic impairment (total bilirubin ≤ULN and any AST >ULN or total bilirubin >1 to 1.5 times ULN and any AST). The recommended dosage of DATROWAY has not been established for patients with severe hepatic impairment (total bilirubin >3 times ULN and any AST).

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc. at 1-877-437-7763 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see Prescribing Information and Medication Guide for additional Important Safety Information.

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.

Disclosure: Dr. Traina provides consulting and advisory services to Daiichi Sankyo (and AstraZeneca).

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