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Daiichi-Sankyo

Press Release

TROPION-Lung17 TROP2 Biomarker Directed Phase 3 Trial of DATROWAY® Initiated in Patients with Previously Treated Advanced Nonsquamous Non-Small Cell Lung Cancer

- First phase 3 trial to prospectively enroll patients with tumors that test positively for TROP2 NMR, a novel computational pathology biomarker to identify those most likely to benefit from Daiichi Sankyo and AstraZeneca's DATROWAY

Tokyo and Basking Ridge, NJ – (January 13, 2026) – The first patient has been dosed in the TROPION-Lung17 phase 3 trial evaluating DATROWAY® (datopotamab deruxtecan) compared to docetaxel in patients with TROP2 NMR positive locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) without actionable genomic alterations previously treated with immunotherapy and platinum-based chemotherapy.

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).

The current standard first-line treatment for advanced NSCLC without actionable genomic alterations is immunotherapy with or without platinum-based chemotherapy.[1] However, most patients will eventually experience disease progression and traditional chemotherapy remains the current standard of care in the second-line and beyond settings.[2,3,4,5] While TROP2 is a protein broadly expressed on the surface and inside of NSCLC cells, there is no established predictive biomarker that can identify patients who may benefit from a TROP2 directed antibody drug conjugate.[6,7] TROPION-Lung17 is the first phase 3 clinical trial to prospectively enroll patients with tumors that test positively for TROP2 NMR, a biomarker measured using Quantitative Continuous Scoring (QCS), which is AstraZeneca's computational pathology platform.

"We initiated TROPION-Lung17 to further evaluate DATROWAY in this patient population, building on results from retrospective analyses of several clinical trials, including TROPION-Lung01, which showed a correlation between TROP2 NMR positivity and outcomes for patients with lung cancer," said Abderrahmane Laadem, MD, Head, Late-Stage Oncology Clinical Development, Daiichi Sankyo.

"TROPION-Lung17 is the first phase 3 trial to prospectively enroll patients using a TROP2 biomarker to determine whether DATROWAY can improve survival compared to current standard of care chemotherapy."

"TROPION-Lung17 aspires to bring a precision medicine approach to patients with advanced lung cancer in the second-line setting, where traditional chemotherapy remains the standard of care," said Leora Horn, MD, MSC, FRCPC, Senior Vice President, Late Development Oncology, AstraZeneca. "Research has shown DATROWAY has the potential to improve outcomes in this setting, and we are confident the TROP2 NMR biomarker and its investigational AI-powered companion diagnostic – previously granted a Breakthrough Device Designation in the U.S. – can help us bring this medicine to the patients most likely to benefit."

TROPION-Lung17 is the ninth phase 3 trial evaluating DATROWAY in NSCLC. Ongoing trials in advanced NSCLC include four phase 3 trials in the first-line metastatic setting evaluating DATROWAY in combination with immunotherapy in tumors without actionable genomic alterations (AVANZAR, TROPION-Lung07, TROPION-Lung08 and TROPION-Lung10) and one phase 3 trial of DATROWAY in combination with osimertinib, AstraZeneca's EGFR tyrosine kinase inhibitor (TKI), (TROPION-Lung14) in EGFR-mutated NSCLC. Additional later-line phase 3 trials include evaluating DATROWAY with or without osimertinib (TROPION-Lung15) and DATROWAY alone (TROPION-Lung17).

About TROPION-Lung17

TROPION-Lung17 is a global, multicenter, randomized, open-label, phase 3 trial evaluating the efficacy and safety of DATROWAY (6 mg/kg) versus docetaxel in patients with TROP2 NMR positive locally advanced or metastatic nonsquamous NSCLC without actionable genomic alterations previously treated with PD-1/PD-L1 inhibitor therapy and platinum-based chemotherapy. All patients will undergo prospective and central tumor testing for TROP2 NMR using the investigational VENTANA® TROP2 (EPR20043) RxDx Device (comprised of the companion diagnostic assay and computational pathology algorithm) and those with TROP2 NMR positive tumors will be randomized in a 1:1 ratio to receive either DATROWAY or docetaxel.

The dual primary endpoints of TROPION-Lung17 are progression-free survival as assessed by blinded independent central review and overall survival. Key secondary endpoints include overall response rate, duration of response and safety.

TROPION-Lung17 will enroll approximately 400 patients across multiple sites in Asia, Europe and North America. For more information visit ClinicalTrials.gov.

About TROP2 NMR

TROP2 is a protein broadly expressed in NSCLC tumors.[6,7] TROP2 expression on the surface of tumor cells, as measurable with conventional pathology methods, has not been predictive of patient responses to TROP2 directed therapies.[8,9] Normalized membrane ratio (NMR) refers to the QCS enabled measure of a tumor cell's surface TROP2 expression, relative to its surface and cytoplasm TROP2 expression. NSCLC is considered TROP2 NMR positive if at least 75% of tumor cells have a greater proportion of TROP2 in the cytoplasm. TROP2 NMR is being developed to identify patients with NSCLC most likely to benefit from treatment with DATROWAY.

Exploratory analyses of the TROPION-Lung01 phase 3, TROPION-Lung02 phase 2 and TROPION-PanTumor02 phase 2 trials have shown a correlation between TROP2 NMR positivity and improved clinical outcomes in patients with NSCLC treated with DATROWAY.

Daiichi Sankyo and AstraZeneca are collaborating with Roche Tissue Diagnostics to co-develop and commercialize the VENTANA TROP2 (EPR20043) RxDx Device as a novel AI-powered companion diagnostic for DATROWAY in lung cancer. The device was granted Breakthrough Device Designation by the U.S. Food and Drug Administration. In addition to TROPION-Lung17, it is being used to analyze tissue samples in the TROPION-Lung10 and AVANZAR phase 3 trials.

About Non-Small Cell Lung Cancer

Lung cancer is the most common cancer globally and is the leading cause of cancer-related death in both men and women.[10] More than 2.48 million lung cancer cases were diagnosed in 2022, with 1.8 million deaths globally. NSCLC is the most common type of lung cancer, accounting for approximately 85% of cases.[11]

For patients with advanced NSCLC without actionable genomic alterations, immunotherapy with or without platinum-based chemotherapy is the standard first-line treatment.[1] While these medicines have improved outcomes in the first-line metastatic setting, most patients experience disease progression and traditional chemotherapy remains the standard of care in the second-line and beyond setting.[2,3,4,5]

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 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 urothelial cancer. The program includes nine phase 3 trials in lung cancer, five phase 3 trials in breast cancer and one phase 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 six 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 is being developed by Daiichi Sankyo.

Additional ADCs being developed by Daiichi Sankyo include DS-9606, which consists of a monoclonal antibody attached to a modified pyrrolobenzodiazepine (PBD) payload and DS3610, which consists of an antibody attached to a novel immunomodulatory payload that acts as an agonist of STING.

Ifinatamab deruxtecan, raludotatug deruxtecan, patritumab deruxtecan, DS-3939, DS-9606 and DS3610 are investigational medicines that have not been approved for any indication in any country. Safety and efficacy have not been established.

DATROWAY U.S. Important Safety Information

Indications
DATROWAY® 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, 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.

Contraindications
None.

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 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 443 patients with breast cancer from TROPION-Breast01 and TROPION-PanTumor01, ILD/pneumonitis occurred in 3.6% of patients treated with DATROWAY, including 0.7% of patients with Grade 3. There was one fatal case (0.2%). The median time to onset for ILD was 2.8 months (range: 1.1 months to 10.8 months). Four patients (0.9%) had DATROWAY withheld and 7 patients (1.6%) permanently discontinued DATROWAY due to ILD/pneumonitis. Systemic corticosteroids were required in 60% (9/15) 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 36% of patients treated with DATROWAY. Twenty patients (2.2%) experienced Grade 3 ocular adverse reactions, which included keratitis, dry eye, and blurred vision, and one patient experienced a Grade 4 ocular adverse reaction of conjunctival hemorrhage. The most common (≥5%) ocular adverse reactions were dry eye (17%), keratitis (14%), and increased lacrimation (7%). The median time to onset for ocular adverse reactions was 2.3 months (range: 0.03 months to 23.2 months). Of the patients who experienced ocular adverse reactions, 39% had complete resolution, and 10% 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 3.6% of patients, dosage reductions in 2.5% of patients, and permanent discontinuation of DATROWAY in 1% of patients.

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

Advise patients to use preservative-free lubricant eye drops several times daily 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, annually while on treatment, at end of treatment, and as clinically indicated.

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 18.6 months). Stomatitis led to dosage interruption in 6% of patients, dosage reductions in 11% of patients, and permanent discontinuation of DATROWAY in 0.5% of patients.

In patients who received DATROWAY in TROPION-Breast01, 39% 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 927 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, and 50 patients with NSCLC and 83 patients with breast cancer in TROPION-PanTumor01 (NCT03401385). Among 927 patients who received DATROWAY, 45% were exposed for 6 months or longer and 19% were exposed for greater than one year. In this pooled safety population, the most common (≥20%) adverse reactions were stomatitis (63%), nausea (52%), fatigue (45%), alopecia (38%), constipation (28%), decreased appetite (23%), rash (23%), vomiting (22%), and musculoskeletal pain (20%). In this pooled safety population, the most common (≥2%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes (9%) and decreased hemoglobin (3.5%).

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 (NCT03401385). 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, 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, IHC1+ or IHC2+/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 365 patients in TROPION-Breast01 treated with DATROWAY 6 mg/kg, 25% were ≥65 years of age and 5% were ≥75 years of age. Grade ≥3 and serious adverse reactions were more common in patients ≥65 years (42% and 25%, respectively) compared to patients <65 years (33% and 15%, respectively). In TROPION-Breast01, no other meaningful differences in safety or efficacy were observed between patients ≥65 years of age versus younger patients.
- **Renal Impairment:** A higher incidence of ILD/pneumonitis has been observed in patients with mild and moderate renal impairment (creatinine clearance [CLcr] 30 to <90 mL/min). Monitor patients with renal impairment for increased adverse reactions, including respiratory reactions. No dosage adjustment is recommended in patients with mild to moderate renal impairment. The effect of severe renal impairment (CLcr <30 mL/min) on the pharmacokinetics of datopotamab deruxtecan-dlnk or DXd is unknown.
- **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). Limited data are available in patients with moderate hepatic impairment (total bilirubin >1.5 to 3 times ULN and any AST). Monitor patients with moderate hepatic impairment for increased adverse reactions. 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 accompanying full Prescribing Information, including WARNINGS AND PRECAUTIONS, and Medication Guide.

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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