DATROWAY4U Enrollment Form

DATROWAY® 4U
datopotamab deruxtecan-dlnk
20 mg/mL INJECTION FOR INTRAVENOUS USE

Support Requested (check only those that apply)

- ☐ Benefits Investigation (Please indicate your preferred acquisition method. Based on the preference, DATROWAY4U will research the pharmacy and/or medical benefits for your patient)
  - ☐ Buy & Bill
  - ☐ Specialty Pharmacy Provider (SPP). Preferred SPP: _____
  - ☐ Unknown
- ☐ Prior Authorization Support
- ☐ Claims/Billing/Reimbursement Support (Please attach a copy of the claim submitted and Explanation of Benefits)
- ☐ Appeals Support (Please attach a copy of the denial letter)

Please complete form, sign, and fax to **1-866-760-5917.**

For questions or assistance, please call DATROWAY4U Monday through Friday, 8 am – 6 pm ET, at **1-855-DATRO4U (1-855-328-7648).**

To enroll in the DATROWAY Patient Assistance Program, visit www.DATROWAY4U.com/hcp/affordability. (Eligibility rules apply)
To enroll in the DATROWAY Patient Copay Savings Program, visit www.patientsavings4u.com

1 Patient Information

First Name: _____ Last Name: _____ Patient DOB: ___/___/_____ Gender: ☐ M ☐ F

Address: _____ City: _____ State: _____ ZIP: _____

Preferred Phone #: ☐ Home ☐ Mobile _____ Patient Email: _____

Alternate Contact Name: _____ Relationship to Patient: _____

Alternate Contact Phone #: _____ Patient preferred language (if other than English): _____

Okay to contact patient? ☐ Yes ☐ No Okay to leave a detailed voicemail? ☐ Yes ☐ No

Patient Authorization

I have read and agree to the Patient Authorization included on page 2

_____ / / _____

Patient Signature/Legal Representative MM DD YYYY

_____

Printed Name/Relationship to Patient (if applicable)

Support Programs (Savings Program and Additional Services)

I have read and agree to the Support Programs Authorization included on page 2

_____ / / _____

Patient Signature/Legal Representative MM DD YYYY

_____

Printed Name/Relationship to Patient (if applicable)

2 Insurance Information

Please include front and back copies of all medical and pharmacy cards or complete this section.

☐ Commercial/Private Insurance ☐ Medicare/Medicaid/Tricare ☐ No insurance

	Primary Medical Insurance	Secondary Medical Insurance	Pharmacy Insurance
Insurance Provider			
Insurance Phone #			
Cardholder Name (if not the patient)			
Cardholder DOB			
Policy #			
Group #			
BIN/PCN	X	X	

3 Provider Information

Prescriber Name: _____ Specialty: _____

Practice Name: _____ Office Contact Name: _____

Address: _____ City: _____ State: _____ ZIP: _____

Phone #: _____ Fax #: _____ Email: _____

Prescriber NPI #: _____ Site Tax ID #: _____

PTAN: _____ Other Provider ID (if applicable): _____

Alternate Office Contact Name: _____ Alternate Office Contact Phone #: _____ Alternate Office Contact Email: _____

Please see Important Safety Information on pages 4-6, and see full Prescribing Information, including WARNINGS AND PRECAUTIONS, and Medication Guide.

Patient Authorization

I authorize my health care providers (HCPs) and staff, my health plan, and my pharmacies to use and share Protected Health Information (my "Information") with AstraZeneca and Daiichi Sankyo (AZ/DSI) and its affiliates, as well as its contractors. My Information includes my prescription-related health records, Information about my health care plan benefits, demographic, contact, and any other Information bearing on my health. My Information may be used to verify treatment and payment decisions with my HCPs; investigate and assist with coordination of coverage for AZ/DSI Alliance Product; coordinate prescription fulfillment and financial assistance; and perform internal analysis at AZ/DSI to better meet patient needs. I understand and agree that AZ/DSI may contact me by mail, email, and telephone. I understand that federal privacy laws may not protect my Information once it is disclosed; however, AZ/DSI agrees to protect my Information by using and disclosing it only for purposes specified. I understand that I can refuse to sign this Authorization and that this will not affect my treatment or payment for treatment, insurance coverage, or eligibility for benefits. However, if I do not sign this Authorization, I will not be able to receive AZ/DSI Alliance Product support. I understand that I may cancel this Authorization at any time by calling **1-855-DATRO4U(1-855-328-7648)**. I understand that any such cancellation will not apply to any Information already used or disclosed based on this Authorization prior to their receipt of the cancellation. This Authorization expires two (2) years from the date signed, unless a shorter period is required by state law.

Support Programs Authorization

By providing consent, I understand that I may receive ongoing information and support related to my condition which includes, but is not limited to, providing me with educational and promotional materials, information, special offers, and services related to my medical condition or therapy, as well as for market research purposes which includes contacting me to participate in focus groups, surveys or interviews. This may include AZ/DSI or a third party working on AZ/DSI's behalf contacting me by mail, telephone, email and/or text message regarding AZ/DSI support programs that may be of interest to me. I consent to receive marketing and non-marketing calls and texts from and on behalf of AZ/DSI, made with an auto-dialer or prerecorded voice, at the phone number(s) provided. Message and data rates may apply. My Information may also be used to perform internal analysis at AZ/DSI. I understand that I can refuse to provide this Authorization and that this will not affect my treatment or payment for treatment, insurance coverage, or eligibility for benefits. I understand that my consent is not required or a condition of purchase. I understand that I may cancel this Authorization at any time by calling 1-855-DATRO4U (1 855-328-7648). Information provided by AZ/DSI does not take the place of talking to your health care provider about your treatment or condition. AZ/DSI will not knowingly collect, use, or disclose personally identifiable information from a minor under the age of 18. If you are under the age of 18, please have your parent, guardian, or health care provider request the information on your behalf. Please visit https://dsi.com/privacy-notice to review our Privacy Notice.

DATROWAY4U Enrollment Form

DATROWAY® 4U
datopotamab deruxtecan-dlnk
20 mg/mL INJECTION FOR INTRAVENOUS USE

Patient First Name: _____

Patient Last Name: _____ **Patient DOB:** ____/____/____

4 Clinical Information

Diagnosis ICD-10 code(s): _____

By signing this form, I certify that (1) I have received the necessary authorization to release the information included on this form and other related Protected Health Information (as defined by HIPAA) to AZ/DSI Alliance Programs, including employees, contractors, or affiliates of AstraZeneca/Daiichi Sankyo, and health care plans for programs, dispensing pharmacy(ies), or other entities, for the purposes of treatment and payment support; and (2) I have obtained any necessary authorization to allow AZ/DSI Alliance Programs to contact the patient, if not included with this submission, to obtain a signed AZ/DSI Alliance Programs Patient Authorization.

HCP Name: _____

HCP Signature: _____ Date: _____

5 Alternate Site of Care

If administering practice differs from provider practice, complete this section with administering practice information:

Practice Name: _____ Office Contact Name: _____

Phone #: _____ Fax #: _____ Site Tax ID #: _____ NPI #: _____

Place of Service Code: _____ Address: _____ City: _____ State: _____ ZIP: _____

6 Free Limited Supply

The Free Limited Supply program is available for eligible patients who are experiencing a coverage delay of more than 5 business days. Please complete the optional prescription below to help expedite access to DATROWAY in the case of a coverage delay.

DATROWAY® (datopotamab deruxtecan-dlnk) 100 mg single-dose vial quantity: _____ No refills.

I verify that the information provided on this form is accurate. I understand that the patient must have an FDA-approved diagnosis to be eligible for free limited supply. I also understand I must submit a prescription compliant with my state law. Reimbursement for the cost of the product administered to the above patient on the date(s) indicated has not been sought and will not be sought from any source. Additionally, I understand that DATROWAY4U reserves the right to conduct periodic audits of the records, excluding patient-identifiable data (unless patient authorization is on file with DATROWAY4U), of all entities receiving free limited supply. I understand that DATROWAY4U reserves the right to modify or revoke this program at any time without notice. My signature confirms that this product was provided free of charge to this patient. (Using signature stamp or signing on behalf of the prescriber is not permitted.)

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

1-855-DATRO4U
(1-855-328-7648)

www.DATROWAY4U.com

1-866-760-5917

Please complete form, sign, and fax all pages to 1-866-760-5917.

DATROWAY4U provides patients and their providers access and reimbursement support for DATROWAY. Reimbursement is not guaranteed.

Please see Important Safety Information on pages 4-6, and see full Prescribing Information, including WARNINGS AND PRECAUTIONS, and Medication Guide.

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.

Please see Important Safety Information on pages 4-6, and see full Prescribing Information, including WARNINGS AND PRECAUTIONS, and Medication Guide.

WARNINGS AND PRECAUTIONS (cont'd)

Unresectable or Metastatic Breast Cancer (cont'd)
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.

Please see Important Safety Information on pages 4-6, and see full Prescribing Information, including WARNINGS AND PRECAUTIONS, and Medication Guide.

WARNINGS AND PRECAUTIONS (cont'd)

Stomatitis (cont'd)

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.

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ADVERSE REACTIONS (cont'd)

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%).

ADVERSE REACTIONS (cont'd)

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.

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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 full Prescribing Information, including Medication Guide.

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PP-US-DT-0117-2 US-109777 Last Updated 04/26

Daiichi-Sankyo | AstraZeneca