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

DATROWAY® is now FDA-approved for adults 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[1]

DATROWAY approval was based on the results of the TROPION-Breast01 trial, a global, phase 3 trial for 2L+ HR+/HER2- mBC

DATROWAY was evaluated in **732 patients** with unresectable or metastatic HR+/HER2- breast cancer (IHC 0, IHC 1+ or IHC 2+/ISH–) who had **progressed on and were deemed not suitable for further endocrine therapy.**

- Patients were randomized 1:1 to receive either **DATROWAY 6 mg/kg IV Q3W (n=365)** or **investigator's choice of chemotherapy**[a] **(ICC)** [eribulin, capecitabine, vinorelbine, OR gemcitabine] (n=367)
- Dual primary endpoints were **progression free survival (PFS)** as assessed by blinded independent central review (BICR) and **overall survival (OS)**[b]
- Use of DATROWAY **does not require** Trop-2 biomarker testing
- During the study, ADCs were approved for use in HR+/HER2- mBC. After treatment discontinuation, some patients in both arms received subsequent ADC therapy[2-4]

Indication and Important Safety Information

Indication

DATROWAY® is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH−) breast cancer who have received prior endocrine-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.

In TROPION-Breast01, ILD/pneumonitis occurred in 4.2% of patients treated with DATROWAY, including 0.5% of patients with Grade 3-4 ILD/pneumonitis, and 0.3% with fatal ILD/pneumonitis.

2L+=second-line and later; ADC=antibody-drug conjugate; FDA=Food and Drug Administration; HER2=human epidermal growth factor receptor 2; HR=hormone receptor; IV=intravenous; mBC=metastatic breast cancer; Q3W=every three weeks; Trop-2=trophoblast cell-surface antigen 2.

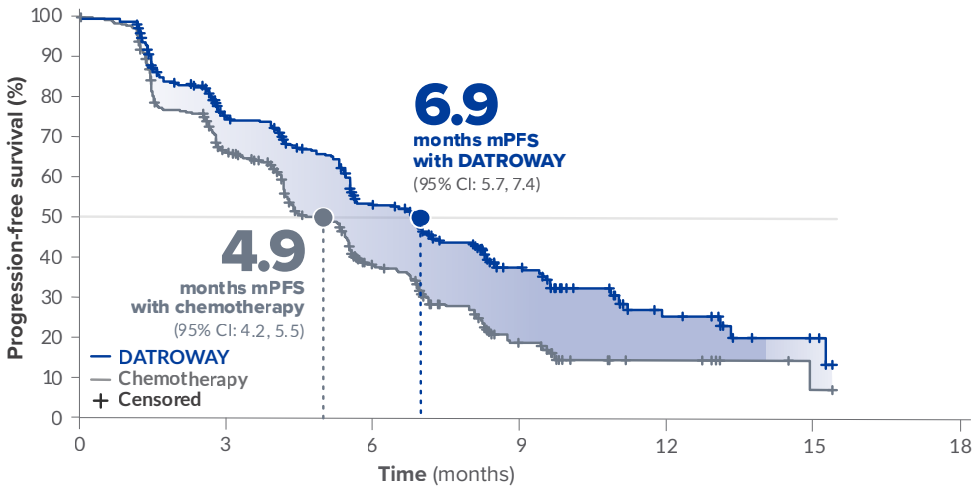
[a]ICC was administered as follows: eribulin 1.4 mg/m^2 IV on Days 1 and 8, Q3W; capecitabine, 1000 or 1250 mg/m^2 orally twice daily on Days 1 to 14, Q3W; vinorelbine, 25 mg/m^2 IV on Days 1 and 8, Q3W; or gemcitabine, 1000 mg/m^2 IV on Days 1 and 8, Q3W.[2]

[b]The study was considered positive if either the PFS analysis results or the OS analysis results were statistically significant.[1,2]

Clinical efficacy results

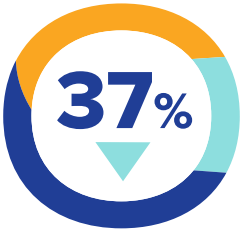
DATROWAY achieved a statistically significant and clinically meaningful mPFS benefit[1]

Median progression-free survival[1]



Number at Risk

DATROWAY	365	249	158	66	15	4	0
Chemotherapy	367	205	93	26	8	1	0



reduction in risk of disease progression or death vs chemotherapy

HR=0.63 (95% CI: 0.52, 0.76)
P<0.0001

Exploratory landmark data: The following analysis is descriptive only, as the trial was not powered to assess a statistical difference between treatment groups at these time points. Therefore, the clinical significance of these data is not known.[2]

- **At 9 months, 38%** of patients were **progression free** with DATROWAY and **19%** with chemotherapy[2]
- **At 12 months, 26%** and **15%** were **progression free**, respectively[2]

Median duration of study follow up was 10.8 months.[2]

Median overall survival[1]

18.6 months with DATROWAY and 18.3 months with chemotherapy

HR=1.01 (95% CI: 0.83, 1.22). Data was not statistically significant

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Interstitial Lung Disease/Pneumonitis (cont'd)

Monitor patients for new or worsening respiratory symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever) during treatment with DATROWAY. For asymptomatic (Grade 1) ILD/pneumonitis, consider corticosteroid treatment (eg, ≥0.5 mg/kg/day prednisolone or equivalent). For symptomatic ILD/pneumonitis (Grade 2 or greater), promptly initiate systemic corticosteroid treatment (eg, ≥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.

CI=confidence interval; HR=hazard ratio; mOS=median overall survival; mPFS= median progression-free survival.

Common adverse reactions[1,2]

The majority of common adverse reactions were Grade 1 or 2 with DATROWAY

Adverse reactions (≥10%) in patients who received DATROWAY in TROPION-Breast01[1]

Adverse reactions, %		DATROWAY (n=360)		Chemotherapy (n=351)	
		All Grades	Grades 3 or 4	All Grades	Grades 3 or 4
Gastrointestinal disorders	Stomatitis[a]	59	7	17	2.6
	Nausea	56	1.4	27	0.6
	Constipation	34	0.3	17	0
	Vomiting	24	1.1	12	1.1
	Diarrhea	11	0.6	19	1.4
	Abdominal pain[a]	11	0.6	15	1.4
General disorders	Fatigue[b]	44	4.2	40	3.7
Skin and subcutaneous tissue disorders	Alopecia	38	0	22	0
	Rash[a]	19	0	17	2.3
Eye disorders	Dry eye	27	0.8	13	0
	Keratitis[c]	24	1.1	10	0
Metabolism and nutrition disorders	Decreased appetite	16	1.4	16	0.9
Infections and infestations	COVID-19[a]	16	1.4	13	0.9
Respiratory, thoracic, and mediastinal disorders	Cough[a]	15	0	10	0

Grade ≥3 TRAEs[2]

21% with DATROWAY

45% with CT[d]

Discontinuation rate due to ARs[1]

3% with DATROWAY

Grade ≥3 neutropenia[2]

1% with DATROWAY

31% with CT

G-CSF treatment required[2]

3% with DATROWAY

22% with CT

- **Dose modifications due to ARs:** Dosage interruptions and dose reductions of DATROWAY due to ARs occurred in 22% and 23% of patients, respectively[1]

Events were graded using National Cancer Institute Common Terminology Criteria (NCI CTCAE) version 5.0.[1]

TRAEs refer to adverse events possibly related to treatment as assessed by the investigator. Adverse reactions refer to adverse events which have a likely basis for a causal relationship between the drug and the occurrence of the adverse event.[2,5]

AR=adverse reaction; CT=chemotherapy; G-CSF=granulocyte-colony stimulating factor; TRAE=treatment-related adverse event.

[a]Includes other related terms.[1]

[b]Includes fatigue, asthenia, lethargy, malaise.[1]

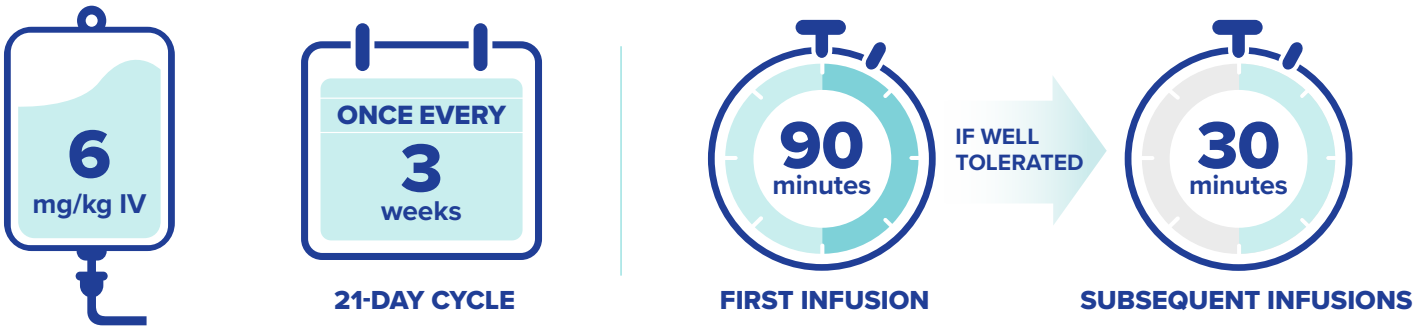
[c]Includes corneal disorder, corneal erosion, corneal infiltrates, corneal lesion, corneal toxicity, injury corneal, keratitis, keratopathy, punctate keratitis, and ulcerative keratitis.[1]

[d]The most common Grade ≥3 TRAEs with chemotherapy were neutropenia (31%), leukopenia (7%), and stomatitis (3%).[2]

Product information[1]

DATROWAY is the first and only Trop-2-directed ADC with Q3W dosing[1,6-8]

The **recommended dose of DATROWAY is 6 mg/kg**[a] until disease progression or unacceptable toxicity.



DATROWAY supply and distribution information

NDC: 65597-801-01 for one 100 mg single-dose vial of DATROWAY

Specialty distributors:

DATROWAY will primarily be distributed through the following specialty distributors via the buy-and-bill process:

- ASD Healthcare, BioCare, Cardinal Health Specialty Distribution, CuraScript, DMS Pharmaceutical, McKesson Plasma and Biologics, McKesson Specialty Health, Oncology Supply, Morris & Dickson Specialty Distribution

Specialty pharmacy providers:

DATROWAY may be dispersed through specialty pharmacy providers. If a provider prefers, they may also work directly with the specialty pharmacy providers if:

- They have already identified the specialty pharmacy provider that is in the patient's network
- They currently use a specialty pharmacy provider that is in the patient's network

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Ocular Adverse Reactions

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

In TROPION-Breast01, ocular adverse reactions occurred in 51% of patients treated with DATROWAY. Seven patients (1.9%) experienced Grade 3 ocular adverse reactions, including dry eye, keratitis, and blurred vision. The most common (≥5%) ocular adverse reactions were dry eye (27%), keratitis (24%), blepharitis and increased lacrimation (8% each), and meibomian gland dysfunction (7%). Patients with clinically significant corneal disease were excluded from TROPION-Breast01.

NDC=national drug code.
[a]Up to a maximum of 540 mg for patients ≥90 kg.[1]

Premedication, concomitant medications, and required eye care for DATROWAY[1]

- Administer DATROWAY in a setting where cardiopulmonary resuscitation medication and equipment are available
- Conduct an ophthalmic exam including visual acuity testing, slit lamp examination (with fluorescein staining), intraocular pressure, and fundoscopy at initiation of DATROWAY, annually while on treatment, at end of treatment, and as clinically indicated
- Administer DATROWAY with the premedication and concomitant medications described in the table below
- Monitor patients for infusion-related reactions for at least 1 hour for the first 2 cycles of DATROWAY. If there are no infusion-related reactions observed, monitor patients for at least 30 minutes for all subsequent cycles of infusions

Premedication and concomitant medications

Premedication[a]	Examples (or equivalent)	Timing of treatment/duration
Eye drops *[see Warnings and Precautions section 5.2 of PI]*	Preservative-free lubricant eyedrops	• Administer at least 4 times daily and as needed
Mouthwash *[see Warnings and Precautions section 5.3 of PI]*	Steroid-containing mouthwash (dexamethasone oral solution 0.1mg/mL	• Administer 4 times daily and as needed
Antihistamine *[see Adverse Reactions section 6.1 of PI]*	Diphenhydramine (25 to 50 mg) administered intravenously or orally	• Administer 30-60 minutes prior to each infusion
Antipyretic *[see Adverse Reactions section 6.1 of PI]*	Acetaminophen (650 mg to 1,000 mg) administered intravenously or orally	• Administer 30-60 minutes prior to each infusion
Antiemetics *[see Adverse Reactions section 6.1 of PI]*	5-HT3 serotonin receptor antagonist or appropriate alternatives intravenously or oral	• Prior to each infusion and thereafter as needed

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Ocular Adverse Reactions (cont'd)

The median time to onset for ocular adverse reactions was 2.1 months (range: 0.03 months to 23.2 months). Of the patients who experienced ocular adverse reactions, 45% had complete resolution; 9% 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 permanent discontinuation of DATROWAY in 0.8% of patients.

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.

5-HT3=5-hydroxytryptamine 3; PI= prescribing information.
NDC=national drug code.
[a]With or without systemic corticosteroids.

Patient support

DATROWAY4U provides support resources for patients prescribed DATROWAY

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

Comprehensive Access Support

- DATROWAY4U can help with benefit verification, prior authorization assistance, and pharmacy research and coordination
- If there is a delay in a patient's coverage decision, DATROWAY4U may be able to provide the first dose at no cost

Patient Savings Program

- Eligible patients may pay as little as $0 per DATROWAY prescription
- The annual benefit can be used for the cost of the drug itself, and may also cover up to $100 in infusion costs per administration and may also cover an eye exam related to the use of DATROWAY up to $250 per exam[a]
- There are no income requirements to participate in the program

Patient Assistance Program

- Designed to help uninsured or underinsured patients who meet the financial requirements

To receive support for patients and obtain more information about reimbursement, call 1-855-DATRO4U (1-855-328-7648)

Eligibility: The patient may be eligible for this offer if he or she is insured by commercial insurance and his or her insurance does not cover the full cost of his or her prescription. Patients who are enrolled in a state or federally funded prescription insurance program are not eligible for this offer. This includes patients enrolled in Medicare Part B, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), Department of Defense (DoD) programs or TriCare, and patients who are Medicare eligible and enrolled in an employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees. If the patient is enrolled in a state or federally funded prescription insurance program, he or she may not use this program even if he or she elects to be processed as an uninsured (cash paying) patient. This offer is not insurance and is restricted to residents of the United States and Puerto Rico.

Terms of use: Eligible patients with a valid prescription for DATROWAY may pay as little as $0 per infusion and $0 in out-of-pocket costs for DATROWAY. The out-of-pocket costs covered by the program can include the cost of the product itself, the cost of infusion of the product (program maximum $100) per infusion assistance) and may also cover an eye exam related to the use of DATROWAY (program maximum $250) per exam).[a,b] Other restrictions may apply. Patient is responsible for applicable taxes, if any. Patient must be enrolled in the program before use. If you have any questions regarding this offer, please call 1-855-DATRO4U (1-855-328-7648). Non-transferable, limited to one per person, cannot be combined with any other offer. Void where prohibited by law, taxed or restricted. Patients, pharmacists, and prescribers cannot seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this offer. Daiichi Sankyo and AstraZeneca reserve the right to rescind, revoke, or amend this offer, eligibility, and terms of use at any time without notice. This offer is not conditioned on any past, present, or future purchase, including refills. Offer must be presented along with a valid prescription for DATROWAY at the time of purchase. Patients must have commercial health insurance that covers medication costs for DATROWAY, but not the full cost to the patient. Program covers the cost of the drug and administration and does not cover costs for office visits or any other associated costs. Offer is invalid for claims or transactions more than 180 days from the date on the explanation of benefits.

[a]Patients who are residents of Massachusetts or Rhode Island are not eligible for infusion administration or eye exam assistance.

[b]Patients are responsible for any cost associated with the infusion above the $100 per infusion assistance provided by the program. Patients are responsible for any cost associated with an eye exam related to the use of DATROWAY above the $250 per eye exam assistance provided by the program.

BY USING THIS PROGRAM, YOU AND YOUR PHARMACIST AND/OR PHYSICIAN UNDERSTAND AND AGREE TO COMPLY WITH THESE ELIGIBILITY REQUIREMENTS AND TERMS OF USE.

Indication and Important Safety Information

Indication

DATROWAY® is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH−) breast cancer who have received prior endocrine-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.

In TROPION-Breast01, ILD/pneumonitis occurred in 4.2% of patients treated with DATROWAY, including 0.5% of patients with Grade 3-4 ILD/pneumonitis, and 0.3% with fatal ILD/pneumonitis. Six patients (1.7%) permanently discontinued DATROWAY due to ILD/pneumonitis. The median time to onset of ILD/pneumonitis was 3.5 months (range: 1.2 months to 10.8 months). Patients were excluded from TROPION-Breast01 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 (eg, dyspnea, cough, fever) during treatment with DATROWAY. For asymptomatic (Grade 1) ILD/pneumonitis, consider corticosteroid treatment (eg, ≥0.5 mg/kg/day prednisolone or equivalent). For symptomatic ILD/pneumonitis (Grade 2 or greater), promptly initiate systemic corticosteroid treatment (eg, ≥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 TROPION-Breast01, ocular adverse reactions occurred in 51% of patients treated with DATROWAY. Seven patients (1.9%) experienced Grade 3 ocular adverse reactions, including dry eye, keratitis, and blurred vision. The most common (≥5%) ocular adverse reactions were dry eye (27%), keratitis (24%), blepharitis and increased lacrimation (8% each), and meibomian gland dysfunction (7%). Patients with clinically significant corneal disease were excluded from TROPION-Breast01.

The median time to onset for ocular adverse reactions was 2.1 months (range: 0.03 months to 23.2 months). Of the patients who experienced ocular adverse reactions, 45% had complete resolution; 9% 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 permanent discontinuation of DATROWAY in 0.8% of patients.

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, dose delay, dose reduce, or permanently discontinue DATROWAY based on severity.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Stomatitis

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

In the TROPION-Breast01 study, stomatitis occurred in 59% of patients treated with DATROWAY, including 7% of patients with Grade 3-4 events. Median time to first onset was 0.7 months (range: 0.03 months to 8.8 months). Stomatitis led to interruption of DATROWAY in 1.9%, dosage reductions in 13%, and permanent discontinuation in 0.3% of patients.

In patients who received DATROWAY, 38% 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, dose reduce, 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 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%).

Important Safety Information (cont'd)

Adverse Reactions (cont'd)

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 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.

Important Safety Information (cont'd)

Use in Specific Populations (cont'd)

- **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 click here for full Prescribing Information, including Warnings and Precautions, and click here for Medication Guide.

References: 1. DATROWAY. Prescribing Information. Daiichi Sankyo, Inc.; 2025. **2.** Bardia A, et al. *J Clin Oncol*. 2024; doi:10.1200.JCO.24.00920. **3.** FDA approves fam-trastuzumab deruxtecan-nxki for HER2-low breast cancer. U.S. Food and Drug Administration. August 5, 2022. Accessed January 8, 2025. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-fam-trastuzumab-deruxtecan-nxki-her2-low-breast-cancer **4.** FDA approves sacituzumab govitecan-hziy for HR-positive breast cancer. U.S. Food and Drug Administration. Updated February 3, 2023. Accessed January 16, 2025. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-sacituzumab-govitecan-hziy-hr-positive-breast-cancer **5.** Herndon J. Adverse reaction information in the prescribing information. Presented at: Regulatory Education for Industry (REdI): CDER Prescription Drug Labeling Conference; December 4-5, 2019; U.S. Food and Drug Administration, Silver Spring, MD. **6.** Nelson BE, et al. *Annu Rev Med*. 2024;75:31-48. **7.** Rugo HS, et al. *Lancet*. 2023;402(10411):1423-1433. **8.** NCT05347134. Updated December 12, 2024. Accessed January 9, 2024. https://www.clinicaltrials.gov/study/NCT05347134

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