TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

Potential Management Strategies for Select Side Effects

INDICATIONS

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with:

- Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- Unresectable locally advanced 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 endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **TRODELVY can cause severe, life-threatening, or fatal neutropenia. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Primary prophylaxis with G-CSF is recommended for all patients at increased risk of febrile neutropenia. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **TRODELVY can cause severe diarrhea. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

WARNINGS AND PRECAUTIONS

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur as early as the first cycle of treatment and may require dose modification. Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6%. Neutropenic colitis occurred in 1.4%. Primary prophylaxis with G-CSF is recommended starting in the first cycle of treatment in all patients at increased risk of febrile neutropenia, including older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities. Monitor absolute neutrophil count (ANC) during treatment. Withhold TRODELVY for ANC below 1500/mm^3 on Day 1 of any cycle or below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Treat neutropenia with G-CSF and administer prophylaxis in subsequent cycles as clinically indicated or indicated in Table 2 of USPI.

Please see full Important Safety Information throughout, and click to see full Prescribing Information, including BOXED WARNING.

What to expect with side effects[1]

Among patients treated with TRODELVY in the clinical trials, the most common adverse reactions (including laboratory abnormalities) reported in ≥25% of patients were

- Decreased leukocyte count
- Decreased neutrophil count
- Decreased hemoglobin
- Diarrhea
- Nausea
- Decreased lymphocyte count
- Fatigue
- Alopecia
- Constipation
- Increased glucose
- Decreased albumin
- Vomiting
- Decreased appetite
- Decreased creatinine clearance
- Increased alkaline phosphatase
- Decreased magnesium
- Decreased potassium
- Decreased sodium

Advise your patients to contact their healthcare provider right away if they experience any of the following side effects

Neutropenia	Diarrhea	Hypersensitivity and infusion-related reactions	Nausea and vomiting
• Fever • Chills • Cough • Shortness of breath • Burning or pain when they urinate	• Patients should contact their healthcare provider the first time they experience diarrhea during treatment with TRODELVY • Black or bloody stools • Symptoms of dehydration, such as lightheadedness, dizziness, or faintness • Inability to take fluids by mouth due to nausea or vomiting • Diarrhea that is not under control within 24 hours	**If they experience the following symptoms during their infusion or within 24 hours afterward:** • Swelling of face, lips, tongue, or throat • Hives • Skin rash, itching, or flushing of their skin • Fever • Difficulty breathing or wheezing • Hypotension • Chills or shaking chills (rigors)	• Nausea or vomiting that is not controlled with the medicines prescribed for them

Note: These are not all the possible side effects of TRODELVY. Information provided does not constitute the provision of medical advice and should not substitute for clinical decision-making.

On the following pages, select side effects from the clinical trials of TRODELVY will be discussed.[a-c]

Develop a side effect management plan to help support your patients[1]

Before administering TRODELVY

BE AWARE

Learn when side effects can occur and how long they were shown to last in the clinical trials.

PREPARE

Consider which premedications you may need and how to counsel your patients.

After administering TRODELVY

MONITOR

Know how to monitor your patients and what counseling or supportive measures they may need.

MANAGE

Help manage certain adverse reactions with appropriate medication and/or by lowering, withholding, or discontinuing doses of TRODELVY.

[a]TROPiCS-02 was a Phase 3, randomized, active-controlled, open label trial (N=543) that assessed patients with HR+/HER2- mBC who were previously treated with endocrine therapy, a CDK4/6i, and a taxane in any setting and who had received 2 to 4 lines of chemotherapy in the metastatic setting.[2]

[b]ASCENT was a Phase 3, randomized, active-controlled, open label trial (N=529) that assessed patients with unresectable locally advanced or mTNBC who had relapsed after at least 2 prior chemotherapies, at least one of them for metastatic disease.[3]

[c]Patients were randomized (1:1) to receive TRODELVY 10 mg/kg as an IV infusion on Days 1 and 8 of a 21-day cycle or single-agent chemotherapy of investigator's choice, which included eribulin, vinorelbine, gemcitabine, or capecitabine. Patients were treated until disease progression or unacceptable toxicity.[1]

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CDK4/6i=cyclin-dependent kinase 4/6 inhibitor; HER2-=human epidermal growth factor receptor 2-negative; HR+=hormone receptor-positive; IV=intravenous; mBC=metastatic breast cancer; mTNBC=metastatic triple-negative breast cancer.

Neutropenia side effect management plan

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BE AWARE

TRODELVY can cause severe, life-threatening, or fatal neutropenia as early as the first cycle of treatment.[1]

Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6% of patients. Neutropenic colitis occurred in 1.4% of patients.

- The median time to first onset of neutropenia (including febrile neutropenia) in patients receiving TRODELVY was 16 days (range: 1 to 435 days), but it has occurred earlier patients with reduced UGT1A1 activity[1,d]
- In a prespecified descriptive analysis of the TROPiCS-02 study, median time to onset for any grade neutropenia[e] related to TRODELVY was 20 days, and the median duration was 8 days[4]
- In a post hoc descriptive analysis of the ASCENT study, median time to onset for any grade neutropenia[e] related to TRODELVY was 20 days, and the median duration was 7 days[5]

PREPARE

It is important to develop a proactive plan for neutropenia management. Prior to initiating TRODELVY, assess your patient's risk for febrile neutropenia.

Withhold TRODELVY for neutropenic fever.[1]

Primary prophylaxis with G-CSF is recommended starting in the first cycle for all patients at increased risk of febrile neutropenia including older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities.[1]

If patients do not receive primary prophylaxis with G-CSF and experience neutropenia, be ready with G-CSF support to help patients stay on therapy if clinically indicated.

Considerations for management with G-CSF[1]

When starting a patient on TRODELVY, consider

- Which G-CSF products are covered by the patient's insurance plan?
- Will prior authorization be required?
- When is it prudent to have G-CSF products on hand?
- For G-CSF use with the treatment of TRODELVY, what are factors to consider?

There are different types of G-CSF, including various formulations of[6,7]

- Filgrastim (short-acting)
- Pegfilgrastim (a longer-acting formulation)

Longer-acting G-CSF may require treatment less frequently than shorter-acting G-CSF.[7]

Important patient counseling information[1]

Advise patients of the risk of neutropenia. Instruct and remind patients to contact their healthcare provider immediately if they experience any of these signs of infection: fever, chills, cough, shortness of breath, or burning/pain when they urinate.

MONITOR

Monitor blood cell counts periodically during treatment[1]

Neutropenia grade scale[8]	
Grade 1	ANC <LLN to 1500/mm^3
Grade 2	ANC <1500 to 1000/mm^3
Grade 3	ANC <1000 to 500/mm^3
Grade 4	ANC <500/mm^3
Febrile neutropenia grade scale[8]	
Grade 1-2	—
Grade 3	ANC <1000/mm^3 with a single temperature of >38.3 °C (101 °F) or a sustained temperature of ≥38 °C (100.4 °F) for more than 1 hour
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death

MANAGE

Dose modification[1]

- Doses of TRODELVY can be reduced, interrupted, or discontinued to help manage neutropenia
- TRODELVY should be withheld if ANC is below 1500/mm^3 on Day 1 of any cycle, the neutrophil count is below 1000/mm^3 on Day 8 of any cycle, or the patient develops neutropenic fever
- Administer G-CSF during treatment as clinically indicated
- Reduce one dose level for each occurrence of febrile neutropenia or prolonged Grade 3-4 neutropenia. **Please see page 7 for dosage reduction levels**

Note: Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made.

[d]Includes patients from 4 trials (IMMU-132-01, ASCENT, TROPiCS-02, and a phase 2 trial in another tumor type).[1] [e]Events of "neutropenia" included the preferred terms "neutropenia" and "neutrophil count decreased" in both studies, as well as "febrile neutropenia" in TROPiCS-02.[4,5]

ANC=absolute neutrophil count; G-CSF=granulocyte-colony stimulating factor ; LLN=lower limit of normal.

Diarrhea side effect management plan

BE AWARE

TRODELVY can cause severe diarrhea.[1]

Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of all patients treated with TRODELVY. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients.

- In a prespecified descriptive analysis of the TROPiCS-02 study, median time to onset for any grade diarrhea related to TRODELVY was 15 days, and the median duration was 8 days[4]
- In a post hoc descriptive analysis of the ASCENT study, median time to onset for any grade diarrhea related to TRODELVY was 12 days, and the median duration was 5 days[5]

PREPARE

Important patient counseling information[1]

Be sure to advise patients of the risk of diarrhea. Instruct your patients to contact their healthcare provider immediately if they experience any of the following symptoms

- Diarrhea for the first time
- Black or bloody stools
- Symptoms of dehydration such as lightheadedness, dizziness, or faintness
- Inability to take fluids by mouth due to nausea or vomiting
- Inability to control diarrhea within 24 hours

Premedication[1]

Patients who exhibit an excessive cholinergic response to treatment with TRODELVY (eg, abdominal cramping, diarrhea, salivation, etc) can receive appropriate premedication (eg, atropine) for subsequent treatments.

MONITOR

Diarrhea grade scale[8]	
Grade 1	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
Grade 2	Increase of 4 to 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental activities of daily living
Grade 3	Increase of ≥7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care activities of daily living
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death

MANAGE

Evaluate for infectious causes[1]

Should diarrhea occur, evaluate for infectious causes. If no infectious cause is found, initiate loperamide.

Initiate loperamide[1]

Initiate 4 mg of loperamide followed by 2 mg with each episode of diarrhea (up to 16 mg/day). Discontinue loperamide 12 hours after diarrhea resolves.

Ongoing supportive care[1]

Additional supportive measures such as fluid and electrolyte support may be employed as clinically indicated.

Dose modification[1]

- Doses of TRODELVY can be reduced, interrupted, or discontinued to help manage diarrhea
- For Grade 3-4 diarrhea that is not controlled with antidiarrheal agents, withhold TRODELVY until resolved to ≤Grade 1. Reduce 1 dose level for each occurrence. **Please see page 7 for dosage reduction levels**

Note: Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made.

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Hypersensitivity and infusion-related reactions side effect management plan

BE AWARE

TRODELVY can cause serious hypersensitivity reactions including life-threatening anaphylactic reactions.

Severe signs and symptoms include cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions.[1]

Hypersensitivity reactions within 24 hours of dosing occurred in 35% of patients treated with TRODELVY. Grade 3-4 hypersensitivity occurred in 2% of patients treated with TRODELVY. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%.[1]

In a prespecified descriptive analysis of the TROPiCS-02 study, median time to onset for any grade hypersensitivity related to TRODELVY was 29 days, and the median duration was 15 days.[4]

PREPARE

Premedication[1]

Premedication for infusion reactions is recommended. Premedicate with antipyretics, H1 and H2 blockers prior to infusion. Corticosteroids may be used for patients who had prior infusion reactions.

Have medications and emergency equipment immediately available to treat infusion-related reactions, including anaphylaxis.

Note: Be sure to advise patients of the risk of serious infusion reactions and anaphylaxis.

Important patient counseling information[1]

Instruct patients to self-monitor during the infusion and 24 hours following the infusion. Patients should immediately contact their healthcare provider should they experience any of the following

- Swelling of the face, lips, tongue, or throat
- Urticaria (hives)
- Difficulty breathing
- Lightheadedness
- Dizziness, feeling faint, or pass out
- Chills
- Rigors (shaking chills)
- Wheezing
- Rash, itching, or flushing
- Hypotension
- Fever

MONITOR

Closely monitor patients for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after the infusion is complete.[1]

MANAGE

Dose modification[1]

- Doses of TRODELVY can be reduced, interrupted, or discontinued to help manage infusion-related reactions
- For Grade 1-3 infusion-related reactions, slow or interrupt the infusion rate of TRODELVY
- For Grade 4 infusion-related reactions, permanently discontinue TRODELVY

Have medications and emergency equipment immediately available to treat infusion-related reactions, including anaphylaxis.[1]

H1=histamine receptor 1; H2=histamine receptor 2.

Nausea and vomiting
side effect management plan

BE AWARE

TRODELVY is emetogenic and can cause severe nausea and vomiting.[1]

Nausea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 nausea occurred in 3% of patients.[1]

Vomiting occurred in 35% of all patients treated with TRODELVY. Grade 3-4 vomiting occurred in 2% of these patients.[1]

Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting at the time of scheduled treatment administration and resume with additional supportive measures when resolved to ≤Grade 1.[1]

In a post hoc descriptive analysis of the ASCENT study, median time to onset for any grade nausea reactions related to TRODELVY was 8 days, and the median duration was 5.5 days. The median time to onset for any grade vomiting related to TRODELVY was 24.5 days, and the median duration was 1.5 days.[5]

PREPARE

Premedication[1]

Prior to each dose of TRODELVY, premedication for prevention of CINV is recommended.

- Premedicate with a 2- or 3-drug combination (eg, dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist, as well as other drugs as needed)

Ongoing supportive care[1]

All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Important patient counseling information[1]

Be sure to advise patients of the risk of nausea and vomiting. Instruct patients to immediately contact their healthcare provider if they experience uncontrolled nausea or vomiting.

MONITOR

Nausea and vomiting grade scales[8]

	Nausea	Vomiting
Grade 1	Loss of appetite without alteration in eating habits	Intervention not indicated
Grade 2	Oral intake decreased without significant weight loss, dehydration, or malnutrition	Outpatient IV hydration; medical intervention indicated
Grade 3	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	Tube feeding, TPN, or hospitalization indicated
Grade 4	–	Life-threatening consequences
Grade 5	–	Death

MANAGE

Dose modification[1]

- Doses of TRODELVY can be reduced, interrupted, or discontinued to help manage nausea and vomiting
- For Grade 3-4 nausea or vomiting that is not controlled with antiemetics, withhold TRODELVY until resolved to ≤Grade 1. Reduce 1 dose level for each occurrence. **Please see page 7 for dosage reduction levels**

Note: Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made.

Ongoing supportive care[1]

- Additional antiemetics and other supportive measures may also be employed as clinically indicated
- All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting

5-HT3=5-hydroxytryptamine 3 receptor; CINV=chemotherapy-induced nausea and vomiting; IV=intravenous; NK_1=neurokinin-1; TPN=total parenteral nutrition.

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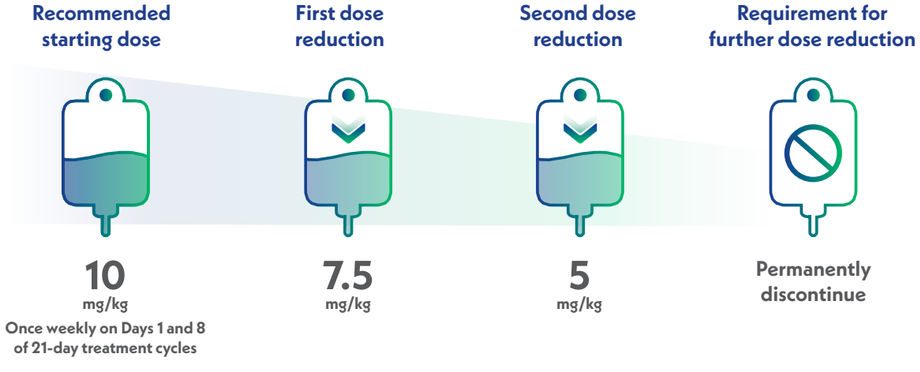
Dose modifications
for adverse reactions[1]

Management of adverse reactions may require temporary interruption, dose reduction, or treatment discontinuation of TRODELVY.

Adverse reactions	Severity	Dose modification
Neutropenia	Grade 3-4 neutropenia (absolute neutrophil count [ANC] <1000/mm³) or febrile neutropenia	• Withhold TRODELVY until ANC ≥1500/mm³ for Day 1 dose or ANC ≥1000/mm³ for Day 8 dose • Administer G-CSF during treatment as clinically indicated • Reduce 1 dose level for each occurrence of febrile neutropenia or prolonged Grade 3-4 neutropenia, or discontinue according to the dosage reduction levels information below
Nausea/vomiting/ diarrhea	Grade 3-4 nausea, vomiting, or diarrhea that is not controlled with antiemetics or anti-diarrheal agents	• Withhold TRODELVY until resolved to ≤Grade 1 • Reduce 1 dose level with each occurrence, or discontinue according to the dosage reduction levels information below
Infusion-related reaction	Grade 1-3 infusion-related reactions	Slow infusion rate or interrupt the infusion
	Grade 4 infusion-related reactions	Discontinue TRODELVY
Other toxicities	Other Grade 3-4 toxicities of any duration despite optimal medical management	• Withhold TRODELVY until resolved to ≤Grade 1 • Reduce 1 dose level with each occurrence or discontinue according to the dosage reduction levels information below

Dosage Reduction Levels[1]



Note: Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made.

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ANC=absolute neutrophil count; G-CSF=granulocyte-colony stimulating factor.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Diarrhea: Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: TRODELVY can cause serious hypersensitivity reactions including life-threatening anaphylactic reactions. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 35% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

Nausea and Vomiting: TRODELVY is emetogenic and can cause severe nausea and vomiting. Nausea occurred in 64% of all patients treated with TRODELVY and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 35% of patients and Grade 3-4 vomiting occurred in 2% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of Grade 3-4 neutropenia was 58% in patients homozygous for the UGT1A1*28, 49% in patients heterozygous for the UGT1A1*28 allele, and 43% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 21% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 9% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

ADVERSE REACTIONS

In the pooled safety population, the most common (≥25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (84%), decreased neutrophil count (75%), decreased hemoglobin (69%), diarrhea (64%), nausea (64%), decreased lymphocyte count (63%), fatigue (51%), alopecia (45%), constipation (37%), increased glucose (37%), decreased albumin (35%), vomiting (35%), decreased appetite (30%), decreased creatinine clearance (28%), increased alkaline phosphatase (28%), decreased magnesium (27%), decreased potassium (26%), and decreased sodium (26%).

In the ASCENT study (locally advanced or metastatic triple-negative breast cancer), the most common adverse reactions (incidence ≥25%) were fatigue, diarrhea, nausea, alopecia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent serious adverse reactions (SAR) (>1%) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR were reported in 27% of patients, and 5% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.

In the TROPiCS-02 study (locally advanced or metastatic HR-positive, HER2-negative breast cancer), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, alopecia, and constipation. The most frequent serious adverse reactions (SAR) (>1%) were diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting (each 2%). SAR were reported in 28% of patients, and 6% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPiCS-02 study were reduced neutrophils and leukocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

Please see full Important Safety Information throughout, and click to see full Prescribing Information, including BOXED WARNING.

References: 1. Trodelvy. Prescribing Information. Gilead Sciences, Inc; March 2025. **2.** Rugo HS, Bardia A, Marmé F, et al. Sacituzumab govitecan in hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer. *J Clin Oncol.* 2022;40(29):3365-3376. doi: 10.1200/JCO.22.01002 **3.** Bardia A, Hurvitz SA, Tolaney SM, et al. Sacituzumab govitecan in metastatic triple-negative breast cancer. *N Engl J Med.* 2021;384(16):1529-1541. doi:10.1056/NEJMoa2028485 **4.** Data on file. Gilead Sciences, Inc.; June 2022. **5.** Rugo HS, Tolaney SM, Loirat D, et al. Safety analyses from the phase 3 ASCENT trial of sacituzumab govitecan in metastatic triple-negative breast cancer. *NPJ Breast Cancer.* 2022;8(1):98. doi:10.1038/s41523-022-00467-1 **6.** Aghedo BO, Gupta V. Filgrastim. In: *StatPearls.* StatPearls Publishing; 2025. Accessed April 22, 2025. https://www.ncbi.nlm.nih.gov/books/NBK559282/ **7.** National Cancer Institute. Pegfilgrastim. National Institutes of Health. Accessed April 22, 2025. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pegfilgrastim **8.** National Cancer Institute, Division of Cancer Treatment & Diagnosis (DCTD). *Common Terminology Criteria for Adverse Events (CTCAE).* Version 5.0. National Institutes of Health. Published November 27, 2017. Accessed April 22, 2025.

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