

# 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

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm<sup>3</sup> or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **Severe diarrhea may occur. 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 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%. Withhold TRODELVY for absolute neutrophil count below 1500/mm<sup>3</sup> on Day 1 of any cycle or neutrophil count below 1000/mm<sup>3</sup> on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Administer G-CSF as clinically indicated or indicated in Table 1 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<sup>1</sup>

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
<ul style="list-style-type: none"> <li>• Fever</li> <li>• Chills</li> <li>• Cough</li> <li>• Shortness of breath</li> <li>• Burning or pain when they urinate</li> </ul>	<ul style="list-style-type: none"> <li>• Patients should contact their healthcare provider the first time they experience diarrhea during treatment with TRODELVY</li> <li>• Black or bloody stools</li> <li>• Symptoms of dehydration, such as lightheadedness, dizziness, or faintness</li> <li>• Inability to take fluids by mouth due to nausea or vomiting</li> <li>• Diarrhea that is not under control within 24 hours</li> </ul>	<p><b>If they experience the following symptoms during their infusion or within 24 hours afterward:</b></p> <ul style="list-style-type: none"> <li>• Swelling of face, lips, tongue, or throat</li> <li>• Hives</li> <li>• Skin rash, itching, or flushing of their skin</li> <li>• Fever</li> <li>• Difficulty breathing or wheezing</li> <li>• Hypotension</li> <li>• Chills or shaking chills (rigors)</li> </ul>	<ul style="list-style-type: none"> <li>• Nausea or vomiting that is not controlled with the medicines prescribed for them</li> </ul>

 **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.



Encourage your patients to communicate with you and other healthcare providers to proactively manage potential side effects.



On the following pages, some side effects from the TROPiCS-02 and ASCENT trials will be discussed. TROPiCS-02 was a phase 3 study of TRODELVY in pretreated HR+/HER2- metastatic breast cancer. ASCENT was a phase 3 study of TRODELVY in pretreated metastatic triple-negative breast cancer.

**Abbreviations:** HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive

### 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.

Please see full Important Safety Information throughout, and click to see full [Prescribing Information](#), including **BOXED WARNING**.

Develop a side effect management plan to help support your patients.

#### 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.

##### MONITOR

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

##### MANAGE

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

#### After administering TRODELVY

### Dose modifications<sup>1</sup>

- Modify, withhold, or discontinue TRODELVY to manage adverse reactions as described below
- Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made
- Slow or interrupt the infusion rate of TRODELVY if the patient develops an infusion-related reaction
- Permanently discontinue TRODELVY for life-threatening infusion-related reactions

#### Severe neutropenia

Adverse reactions	Occurrence	Dose modification
<ul style="list-style-type: none"> <li>• <b>Grade 3-4 neutropenia that lasts ≥7 days,</b></li> <li><b>OR</b></li> <li>• <b>Grade 3 febrile neutropenia,</b></li> <li><b>OR</b></li> <li>• <b>At time of scheduled treatment, Grade 3-4 neutropenia which delays dosing by 2 or 3 weeks for recovery to ≤Grade 1</b></li> </ul>	First	25% dose reduction from the original dose and administer G-CSF
	Second	50% dose reduction from the original dose and administer G-CSF
	Third	Discontinue treatment and administer G-CSF
<ul style="list-style-type: none"> <li>• <b>At time of scheduled treatment, Grade 3-4 neutropenia which delays dosing beyond 3 weeks for recovery to ≤Grade 1</b></li> </ul>	First	Discontinue treatment and administer G-CSF

#### Severe non-neutropenic toxicity

Adverse reactions	Occurrence	Dose modification
<ul style="list-style-type: none"> <li>• <b>Grade 4 non-hematologic toxicity of any duration,</b></li> <li><b>OR</b></li> <li>• <b>Any Grade 3-4 nausea, vomiting or diarrhea due to treatment that is not controlled with antiemetics and antidiarrheal agents,</b></li> <li><b>OR</b></li> <li>• <b>Other Grade 3-4 non-hematologic toxicity persisting for &gt;48 hours despite optimal medical management,</b></li> <li><b>OR</b></li> <li>• <b>Grade 3-4 non-neutropenic hematologic or non-hematologic toxicity at the time of a scheduled treatment that delays dosing by 2 or 3 weeks to achieve recovery to ≤Grade 1</b></li> </ul>	First	25% dose reduction from the original dose
	Second	50% dose reduction from the original dose
	Third	Discontinue treatment
<ul style="list-style-type: none"> <li>• <b>Grade 3-4 non-neutropenic hematologic or non-hematologic toxicity which does not recover to ≤Grade 1 within 3 weeks</b></li> </ul>	First	Discontinue treatment

**Abbreviation:** G-CSF, granulocyte-colony stimulating factor

# Neutropenia side effect management plan

## BE AWARE



### Severe, life-threatening, or fatal neutropenia can occur in patients treated with TRODELVY.<sup>1</sup>

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.

- The median time to first onset of neutropenia (including febrile neutropenia) in patients receiving TRODELVY was 16 days, but it has occurred earlier in some patient populations<sup>1,a</sup>
- In a prespecified descriptive analysis of the TROPiCS-02 study, median time to onset for any grade neutropenia<sup>b</sup> related to TRODELVY was 20 days, and the median duration was 8 days<sup>2</sup>
- In a post hoc descriptive analysis of the ASCENT study, median time to onset for any grade neutropenia related to TRODELVY was 20 days, and the median duration was 7 days<sup>3</sup>

## PREPARE



It is important to develop a proactive plan for neutropenia management. As you start a patient on TRODELVY, ensure that you take the appropriate steps so that you can help manage with G-CSF if needed.

### Considerations for management with G-CSF<sup>1</sup>

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?

## MONITOR



### Important patient counseling information<sup>1</sup>

Advise patients of the risk of neutropenia. Instruct and remind patients to contact their healthcare provider immediately if they experience fever, chills, or other signs of infection.

#### Neutropenia grade scale<sup>4</sup>

<b>Grade 0</b>	ANC $\geq$ 2000/mm <sup>3</sup>
<b>Grade 1</b>	ANC $\geq$ 1500 to $<$ 2000/mm <sup>3</sup>
<b>Grade 2</b>	ANC $\geq$ 1000 to $<$ 1500/mm <sup>3</sup>
<b>Grade 3</b>	ANC $\geq$ 500 to $<$ 1000/mm <sup>3</sup>
<b>Grade 4</b>	ANC $<$ 500/mm <sup>3</sup>

#### Febrile neutropenia grade scale<sup>5</sup>

<b>Grade 1</b>	-
<b>Grade 2</b>	-
<b>Grade 3</b>	ANC $<$ 1000/mm <sup>3</sup> with a single temperature of $>$ 38.3 °C (101 °F) or a sustained temperature of $\geq$ 38 °C (100.4 °F) for more than 1 hour
<b>Grade 4</b>	Life-threatening consequences; urgent intervention indicated
<b>Grade 5</b>	Death

## MANAGE



### Dose modification<sup>1</sup>

TRODELVY should be withheld if ANC is below 1500/mm<sup>3</sup> on day 1 of any cycle, the neutrophil count is below 1000/mm<sup>3</sup> on day 8 of any cycle, or the patient develops neutropenic fever.



If patients experience neutropenia, be ready with G-CSF prophylaxis or support to help patients stay on therapy if clinically indicated or appropriate.

There are different types of G-CSF, including various formulations of<sup>6,7</sup>

- Filgrastim
- Pegfilgrastim (a longer-acting formulation)

Longer-acting G-CSF may require treatment less frequently than shorter-acting G-CSF.<sup>7</sup>

**Please see page 3 for specific dose modifications for severe neutropenia.**



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

# Diarrhea side effect management plan

## BE AWARE



### TRODELVY can cause severe diarrhea.<sup>1</sup>

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<sup>2</sup>
- 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<sup>3</sup>

## PREPARE



### Important patient counseling information<sup>1</sup>

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

## MANAGE



### Premedication<sup>1</sup>

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.



### Ongoing supportive care<sup>1</sup>

- Should diarrhea occur, evaluate for infectious causes. If no infectious cause is found, 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. Additional supportive measures such as fluid and electrolyte support may be added as needed



### Dose modification<sup>1</sup>

- Doses of TRODELVY can be withheld or modified to help manage adverse reactions
- For patients who experience Grade 3-4 diarrhea at the time of scheduled treatment, withhold the dose of TRODELVY, resume when  $\leq$ Grade 1 diarrhea is achieved, and reduce subsequent doses

**Please see page 3 for specific dose modifications for severe non-neutropenic toxicity.**



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

## MONITOR

#### Diarrhea grade scale<sup>5</sup>

<b>Grade 1</b>	Increase of $<$ 4 stools per day over baseline; mild increase in ostomy output compared to baseline
<b>Grade 2</b>	Increase of 4 to 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental activities of daily living
<b>Grade 3</b>	Increase of $\geq$ 7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care activities of daily living
<b>Grade 4</b>	Life-threatening consequences; urgent intervention indicated
<b>Grade 5</b>	Death

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<sup>a</sup> Includes patients from 4 trials (IMMU-132-01, TROPiCS-01, ASCENT, and TROPiCS-02).<sup>1, b</sup> Events of neutropenia included the preferred terms neutropenia, neutrophil count decreased, and febrile neutropenia.<sup>2</sup>  
**Abbreviations:** ANC, absolute neutrophil count; G-CSF, granulocyte-colony stimulating factor

## Hypersensitivity and infusion-related reactions side effect management plan

### BE AWARE



#### Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY.<sup>1</sup>

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

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%.

In a prespecified descriptive analysis of the TROPiCS-02 study, median time to onset for any grade hypersensitivity and infusion-related reactions related to TRODELVY was 29 days, and the median duration was 15 days.<sup>2</sup>

### PREPARE



#### Premedication<sup>1</sup>

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.

### MONITOR



Closely monitor patients for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after the infusion is complete.<sup>1</sup>



#### Important patient counseling information<sup>1</sup>

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

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

### MANAGE



#### Dose modification<sup>1</sup>

- Infusion of TRODELVY may be modified or withheld to help infusion-related reactions
- Slow or interrupt the infusion rate of TRODELVY if the patient develops an infusion-related reaction
- Permanently discontinue TRODELVY for Grade 4 infusion-related reactions



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

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

## Nausea and vomiting side effect management plan

### BE AWARE



#### TRODELVY is emetogenic, or a substance that may cause vomiting in some patients.<sup>1,8</sup>

Nausea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 nausea occurred in 3% of patients. Vomiting occurred in 35% of all patients treated with TRODELVY. Grade 3-4 vomiting occurred in 2% of these patients.

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.<sup>3</sup>

### PREPARE



#### Premedication<sup>1</sup>

- 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-HT<sub>3</sub> receptor antagonist or an NK<sub>1</sub> receptor antagonist, as well as other drugs as needed)
- Additional antiemetics, sedatives, 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 delayed nausea and vomiting

### MONITOR



#### Important patient counseling information<sup>1</sup>

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.

#### Nausea and vomiting grade scales<sup>5</sup>

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

### MANAGE



#### Dose modification<sup>1</sup>

- Doses of TRODELVY can be withheld or modified to help manage adverse reactions
- Doses of TRODELVY should be withheld for Grade 3 nausea or Grade 3-4 vomiting at the time of scheduled treatment administration and resume with additional supportive measures when resolution to ≤Grade 1 is achieved

**Please see page 3 for specific dose modifications for severe non-neutropenic toxicity.**



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

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## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### **Hypersensitivity and Infusion-Related Reactions:**

Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY. 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 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:** 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-HT<sub>3</sub> receptor antagonist or an NK<sub>1</sub> 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. Package insert. Gilead Sciences, Inc; February 2023. 2. Data on file. Gilead Sciences, Inc.; June 2022. 3. Ruغو HS, Tolaney SM, Lohr 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 4. Lyman GH. Neutropenia. In: Schwab M, ed. *Encyclopedia of Cancer*. Springer; 2011:2506-2509. 5. 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 November 28, 2022. 6. National Cancer Institute. Granulocyte colony-stimulating factor. National Institutes of Health. Accessed April 12, 2022. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/granulocyte-colony-stimulating-factor> 7. National Cancer Institute. Pegfilgrastim. National Institutes of Health. Accessed April 12, 2022. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pegfilgrastim> 8. National Cancer Institute. Emetogenic. National Institutes of Health. Accessed April 12, 2022. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/emetogenic>



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sacituzumab govitecan-hziy  
180 mg for injection