TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

A guide to help you support your patients during treatment

Review the management strategies for TRODELVY-associated neutropenia and diarrhea

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.**

Please see full Important Safety Information on pages 8-9 and click to see full Prescribing Information, including BOXED WARNING.

TRODELVY has a **well-characterized safety profile across indications**[1-3,a]

Adverse reactions in ≥10% of patients in two Phase 3, randomized, active-controlled, open-label studies[1,b,c]

ADVERSE REACTION	HR+/HER2- mBC in TROPiCS-02		mTNBC (HR-/HER2-) in ASCENT	
	TRODELVY (n=268) All grades % (Grade 3–4%)	Single-agent chemo[b] (n=249) All grades % (Grade 3–4%)	TRODELVY (n=258) All grades % (Grade 3–4%)	Single-agent chemoc (n=224) All grades % (Grade 3–4%)
GASTROINTESTINAL DISORDERS				
Diarrhea	62 (10)	23 (1)	59 (11)	17 (1)
Nausea	59 (1)	35 (3)	57 (3)	26 (0.4)
Vomiting	23 (1)	16 (2)	33 (2)	16 (1)
Constipation	34 (1)	25 (0)	37 (0.4)	23 (0)
Abdominal pain	20 (0)	14 (0)	30 (3)	12 (1)
Stomatitis[d]	–	–	17 (2)	13 (1)
Dyspepsia[e]	11 (0)	6 (0)	–	–
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
Fatigue[f]	60 (8)	51 (4)	65 (6)	50 (9)
Pyrexia	–	–	15 (0.4)	14 (2)
INFECTIONS AND INFESTATION				
Urinary tract infection	–	–	13 (0.4)	8 (0.4)
Upper respiratory tract infection	–	–	12 (0)	3 (0)
METABOLISM AND NUTRITION DISORDERS				
Decreased appetite	21 (2)	21 (0)	28 (2)	21 (1)
Hypokalemia	10 (2)	4 (0)	–	–
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
Back pain	–	–	16 (1)	14 (2)
Arthralgia	15 (0)	12 (0)	12 (0.4)	7 (0)
NERVOUS SYSTEM DISORDERS				
Headache	16 (1)	15 (1)	18 (0.8)	13 (0.4)
Dizziness	–	–	10 (0)	7 (0)
PSYCHIATRIC DISORDERS				
Insomnia	–	–	11 (0)	5 (0)
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS				
Cough	12 (0)	7 (0)	24 (0)	18 (0.4)
Dyspnea[g]	20 (0)	17 (0)	–	–
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
Alopecia	48 (0)	19 (0)	47 (0)	16 (0)
Rash	–	–	12 (0.4)	5 (0.4)
Pruritus	12 (0)	2 (0)	10 (0)	3 (0)

Other clinically significant adverse reactions (≤10%) in TROPiCS-02 included hypotension (5%), pain (5%), rhinorrhea (5%), hypocalcemia (3%), nasal congestion (3%), skin hyperpigmentation (3%), colitis or neutropenic colitis (2%), hyponatremia (2%), pneumonia (2%), proteinuria (1%), and enteritis (0.4%).[1]

Graded per NCI CTCAE v.5.0.[1]

[a]The discontinuation rate in TROPiCS-02 was 6%, and in ASCENT it was 5%, demonstrating that a majority of patients were able to continue TRODELVY with proper management of adverse reactions.[1,3] [b]Single-agent chemotherapy included one of the following single agents: eribulin (n=130), vinorelbine (n=63), gemcitabine (n=56), or capecitabine (n=22).[1] [c]Single-agent chemotherapy included one of the following single agents: eribulin (n=139), capecitabine (n=33), gemcitabine (n=38), or vinorelbine (except if patient had ≥Grade 2 neuropathy, n=52).[1] [d]Including stomatitis, glossitis, mouth ulceration, and mucosal inflammation.[1] [e]Including dyspepsia and gastroesophageal reflux disease.[1] [f]Including fatigue and asthenia.[1] [g]Including dyspnea and exertional dyspnea.[1]

Chemo=chemotherapy; HER2-=human epidermal growth factor receptor 2-negative; HR-=hormone receptor-negative; HR+=hormone receptor-positive; mBC=metastatic breast cancer; mTNBC=metastatic triple-negative breast cancer; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

TROPiCS-02: (N=543) 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[a]

ASCENT: (N=529) 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[a]

Rates of serious adverse reactions with TRODELVY[1]

TROPiCS-02

Serious adverse reactions: 28%

In >1% of patients: diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting (each 2%)

ASCENT

Serious adverse reactions: 27%

In >1% of patients: neutropenia (7%), diarrhea (4%), and pneumonia (3%)

Rates of adverse reactions leading to treatment discontinuation, reduction, and interruption of TRODELVY[1,2]

LOW DISCONTINUATION RATES DUE TO ADVERSE REACTIONS WITH TRODELVY

TROPiCS-02

Discontinuation: 6%

Most frequent (≥0.5%): asthenia, general physical health deterioration, and neutropenia (each 0.7%)

Dose reduction: 33%

Most frequent (>5%): neutropenia (16%) and diarrhea (8%)

Dose interruption: 66%

Most frequent (≥5%): neutropenia (50%)

G-CSF use: 54% of patients who received TRODELVY

ASCENT

Discontinuation: 5%

In ≥1% of patients: pneumonia (1%) and fatigue (1%)

Dose reduction: 22%

Most frequent (>4%): neutropenia (11%) and diarrhea (5%)

Dose interruption: 63%

Most frequent (≥5%): neutropenia (47%), diarrhea (5%), respiratory infection (5%), and leukopenia (5%)

G-CSF use: 44% of patients who received TRODELVY

Rates of most common (≥25%) adverse reactions, including lab abnormalities, with TRODELVY[1]

TROPiCS-02

The most common (≥25%) adverse reactions, including lab abnormalities, with TRODELVY were leukocytes decreased (88%), neutrophils decreased (83%), hemoglobin decreased (73%), lymphocytes decreased (65%), diarrhea (62%), fatigue (60%), nausea (59%), alopecia (48%), glucose increased (37%), constipation (34%), and albumin decreased (32%).

ASCENT

The most common (≥25%) adverse reactions, including lab abnormalities, were hemoglobin decreased (94%), lymphocyte count decreased (88%), leukocyte count decreased (86%), neutrophil count decreased (78%), fatigue (65%), diarrhea (59%), nausea (57%), glucose increased (49%), alopecia (47%), constipation (37%), calcium decreased (36%), vomiting (33%), magnesium decreased (33%), potassium decreased (33%), albumin increased (32%), abdominal pain (30%), appetite decreased (28%), aspartate aminotransferase increased (27%), alanine aminotransferase increased (26%), alkaline phosphatase increased (26%), and phosphate decreased (26%).

ILD is not listed as a warning in the TRODELVY PI, and there are no specific recommedations for monitoring for ILD[1]

For information on lab abnormalities, see tables 4 and 8 of the Full Prescribing Information

[a]Patients were treated until disease progression or unacceptable toxicity.[1]

CDK4/6i=cyclin-dependent kinase 4/6 inhibitor.

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What to know before you start

PREPARE

- Discussing potential adverse reactions with patients early on can help them feel prepared to continue treatment as appropriate
- Prior to each dose of TRODELVY, premedication for certain adverse reactions is recommended[1]

NEUTROPENIA

- **Primary prophylaxis with G-CSF is recommended as early as 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[1]

DIARRHEA

- 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[1]

INFUSION-RELATED REACTIONS

- Premedicate with antipyretics AND H1 and H2 blockers[1]
- Consider corticosteroids for patients who had prior infusion reactions[1]

NAUSEA AND VOMITING

- Premedicate with a 2- or 3-drug combination, such as dexamethasone with either a 5-HT3 receptor antagonist OR an NK_1 receptor antagonist, as well as other drugs as indicated[1]

INITIATE

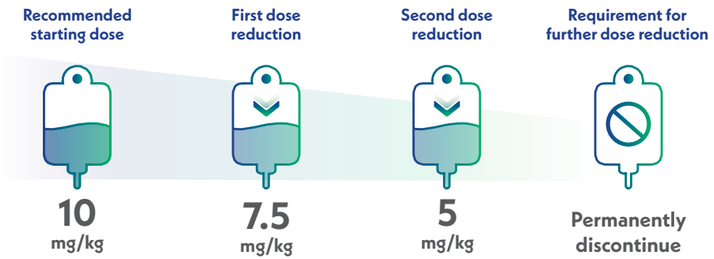
Start TRODELVY at 10 mg/kg[1,a]

- The recommended dosage of TRODELVY is 10 mg/kg intravenously on Days 1 and 8 of 21-day continuous treatment cycles until disease progression or unacceptable toxicity (see Section 2 of the USPI for more information on dosing)

MANAGE

- Management of adverse reactions may require temporary interruption, dose reduction, or treatment discontinuation of TRODELVY as described below and on subsequent pages. See Table 2 in USPI for full dose modifications for adverse reactions[1]

Dose Reduction Levels



Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made[1]

[a]Do not administer TRODELVY at doses greater than 10 mg/kg. Do NOT substitute TRODELVY for or use with other drugs containing irinotecan or its active metabolite SN-38.[1]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for assessing risk for febrile neutropenia[4]

NCCN Guidelines® classify sacituzumab govitecan-hziy (TRODELVY) as **intermediate risk (10%–20%)**[4]:

- Prophylactic G-CSF may be considered for patients with ≥1 risk factors for febrile neutropenia (shown below)
- If no risk factors, observe

Consider prophylaxis with G-CSF for patients with ≥1 risk factors[4,a,b]

- Prior chemotherapy or radiation therapy
- Persistent neutropenia
- Recent surgery and/or open wounds
- Age >65 years receiving full chemotherapy dose intensity
- Bone marrow involvement by tumor
- Liver dysfunction (ie, bilirubin >2.0 mg/dL)
- Renal dysfunction (ie, creatinine clearance <50 mL/min)

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

There is currently no consensus nomogram for FN risk assessment. While the NCCN Panel outlines criteria to aid in the assessment of FN risk, independent clinical judgment should be exercised based on the individual patient's situation.

- Febrile neutropenia occurred in 6% of patients receiving TRODELVY[1]

[a]Other possible patient risk factors for febrile neutropenia may include poor performance status or HIV infection (in particular, patients with low CD4 counts). The listed patient risk factors are based on a multivariable risk model using a prospective cohort study of several thousand ambulatory patients with cancer receiving chemotherapy. This cohort did not include patients with HIV, acute leukemia, or hematopoietic cell transplant.[4]

[b]Other factors may warrant the use of G-CSF (eg, chronic immunosuppression in the posttransplant setting, including organ transplant).[4]

Don't delay a prior authorization request for your patient, as it may be required for G-CSF

CD4=cluster of differentiation 4; CINV=chemotherapy-induced nausea and vomiting; FN=febrile neutropenia; G-CSF=granulocyte colony-stimulating factor; NCCN=National Comprehensive Cancer Network.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Neutropenia

Rates and time to onset and duration

- 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[1]
- The median time to first onset of neutropenia (including febrile neutropenia) was 16 days (range: 1 to 435 days). Neutropenia occurred earlier in patients with reduced UGT1A1 activity[1,a]

Median time to onset and duration of neutropenia[b]

TROPiCS-02: HR+/HER2- mBC[5]
(prespecified descriptive analysis)

ASCENT: 2L+ mTNBC (HR-/HER2-)[3]
(post hoc descriptive analysis)

[a] Includes patients from IMMU-132-01, a phase 2 trial in another tumor type, ASCENT, and TROPiCS-02 studies.[1]
[b] Any-grade events of "neutropenia" related to TRODELVY included the preferred terms "neutropenia" and "neutrophil count decreased" in both studies, as well as "febrile neutropenia" in TROPiCS-02.[3,5]

Management strategies

PREPARE

- Primary prophylaxis with G-CSF is recommended starting in the first cycle for all patients at increased risk of febrile neutropenia, including[1]:
  - Older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities
- Prior to initiating sacituzumab govitecan-hziy (TRODELVY), determine your patient's risk of developing febrile neutropenia. Also see NCCN Guidelines for febrile neutropenia risk factors on page 5
- Withhold TRODELVY for neutropenic fever[1]

MONITOR

Monitor absolute neutrophil count (ANC) during treatment[1]

MANAGE

To manage Grade 3-4 neutropenia (ANC <1000/mm³) or febrile neutropenia[1]

Withold TRODELVY until ANC ≥1500/mm³ for Day 1 dose or ANC ≥1000/mm³ for Day 8 dose

Administer G-CSF during treatment as clinically indcated

Reduce 1 dose level for each occurrence of febrile neutropenia or prolonged Grade 3–4 neutropenia, or discontinue according to Dose Reduction Levels on page 4

Please see full Important Safety Information on pages 8-9 and click to see full Prescribing Information, including BOXED WARNING.

Diarrhea

Rates and time to onset and duration

- 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[1]
- One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients[1]

Median time to onset and duration of diarrhea[a]

TROPiCS-02: HR+/HER2- mBC[5]
(prespecified descriptive analysis)

ASCENT: 2L+ mTNBC (HR-/HER2-)[3]
(post hoc descriptive analysis)

[a] Any-grade events of diarrhea related to TRODELVY.[3,5]

Management strategies

INITIATE

- Initiate loperamide at the onset of diarrhea unless an infectious cause is identified[1]
  - 4 mg initially followed by 2 mg with every episode of diarrhea for maximum of 16 mg daily or at HCP's direction
  - Discontinue loperamide 12 hours after diarrhea resolves
- Initiate other supportive measures, such as fluids or electrolytes, as clinically appropriate[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

MANAGE

To manage Grade 3-4 diarrhea that is not controlled with antidiarrheal agents[1]

Withold TRODELVY until resolved to ≤ Grade 1

Reduce 1 dose level for each occurrence or discontinue according to Dose Reduction Levels on page 4

ANC=absolute neutrophil count; CINV=chemotherapy-induced nausea and vomiting; G-CSF=granulocyte colony-stimulating factor; HER2-=human epidermal growth factor receptor 2-negative; HR+=hormone receptor-positive; HR-=hormone receptor-negative; mBC=metastatic breast cancer; mTNBC=metastatic triple-negative breast cancer; NCCN=National Comprehensive Cancer Network.

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INDICATIONS

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- **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/mm³ on Day 1 of any cycle or below 1000/mm³ 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.

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.

IMPORTANT SAFETY INFORMATION (cont'd)

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 REACTIONS

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.

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TRODELVY has a **well-characterized safety profile across indications**[1-3]

Established management strategies in the TRODELVY PI may help appropriate patients continue therapy[1]

Initiate TRODELVY at the recommended starting dose of 10 mg/kg[1,a]

Dose reduction, interruption, or discontinuation are options if necessary[1]

TRODELVY has been used to **treat an estimated 25,000 patients in the US**[6,b]

[a] The recommended dose is a 10 mg/kg IV infusion on Days 1 and 8 of 21-day treatment cycles until disease progression or unacceptable toxicity. See Section 2 of the USPI for more information on dosing.[1]

[b] Estimate as of October 2024 was based on assumptions including the number of vials sold.[6]

G-CSF=granulocyte colony-stimulating factor.

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- **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.**

Please see full Important Safety Information on pages 8-9 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, Marme 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. **3.** 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. **4.** Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Growth Factors V.1.2025. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 27, 2025. To view the most recent and complete version of the guidelines, go online to NCCN.org. **5.** Data on file. Gilead Sciences, Inc. July 2022. **6.** Data on file. Gilead Sciences, Inc. March 2025.

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TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection