



3-step guide to dosing TRODELVY

- 1 **Start** TRODELVY at recommended dose¹
- 2 **Prepare** with recommended premedications based on your patients' needs¹
- 3 **Manage** certain adverse reactions with strategies to help appropriate patients stay on TRODELVY¹

Dosing, premedication, and dose modification guidance to help you support your patients

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/mm³ 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.

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



Start

Start TRODELVY (sacituzumab govitecan-hziy) at 10 mg/kg^{1,a}

The recommended dose of TRODELVY is 10 mg/kg intravenously on Days 1 and 8 of 21-day continuous treatment cycles.^{1,a,b}

- Do not administer TRODELVY at doses greater than 10 mg/kg
- Administer TRODELVY as an intravenous infusion only. Do not administer as an intravenous push or bolus
- **Do NOT substitute TRODELVY for or use with other drugs containing irinotecan or its active metabolite, SN-38**



10 mg/kg



10 mg/kg



^bContinue treatment until disease progression or unacceptable toxicity.¹



IF WELL TOLERATED

First infusion^{1,a}

Administer over



Subsequent infusions^{1,a}

Administer over



^aObserve patients during the infusion and for at least 30 minutes following the infusion for signs or symptoms of infusion-related reactions.¹

Scan or [click](#) for reconstitution and dilution steps



IMPORTANT SAFETY INFORMATION (cont'd)

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.

2

Prepare

Prepare with premedications and other supportive care medications based on your patients' needs¹

Prior to each dose of TRODELVY (sacituzumab govitecan-hziy), premedication for certain adverse reactions is recommended¹

- Discussing potential adverse reactions with patients early on can help them feel prepared to continue treatment as appropriate¹



NEUTROPENIA

Primary prophylaxis with G-CSF is recommended in the TRODELVY USPI 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 comorbidities¹



INFUSION-RELATED REACTIONS

- Premedicate with antipyretics **AND** H1 and H2 blockers¹
- Consider corticosteroids for patients who had prior infusion reactions¹



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 treatments¹



NAUSEA AND VOMITING (CINV)

Premedicate with a 2- or 3-drug combination, such as dexamethasone with either a 5-HT3 receptor antagonist **OR** an NK₁ receptor antagonist, as well as other drugs as indicated¹



PROPHYLACTIC G-CSF IS SUPPORTED BY NCCN CLINICAL PRACTICE GUIDELINES IN ONCOLOGY (NCCN GUIDELINES[®]) FOR GROWTH FACTORS²



Scan or [click](#) to review the NCCN Guidelines[®] when assessing risk for febrile neutropenia

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5-HT3=5-hydroxytryptamine 3 receptor; CINV=chemotherapy-induced nausea and vomiting; G-CSF=granulocyte colony-stimulating factor; H1=histamine receptor 1; H2=histamine receptor 2; NCCN=National Comprehensive Cancer Network; NK₁=neurokinin 1.

3

Manage

Manage certain adverse reactions with strategies to help appropriate patients stay on TRODELVY¹

Management of adverse reactions may require temporary interruption, dose reduction, or treatment discontinuation of TRODELVY (sacituzumab govitecan-hziy).¹

- Withhold TRODELVY for neutropenic fever¹

Adverse reactions	Severity	Dose modification
Neutropenia	Grade 3-4 neutropenia (absolute neutrophil count [ANC] <1000/mm ³) or febrile neutropenia	<ul style="list-style-type: none">Withhold TRODELVY until ANC \geq1500/mm³ for Day 1 dose or ANC \geq1000/mm³ for Day 8 doseAdminister G-CSF during treatment as clinically indicatedReduce 1 dosage level for each occurrence of febrile neutropenia or prolonged Grade 3-4 neutropenia, or discontinue according to the dose reduction levels information below
Nausea/Vomiting/ Diarrhea	Grade 3-4 nausea, vomiting or diarrhea that is not controlled with antiemetics or anti-diarrheal agents	<ul style="list-style-type: none">Withhold TRODELVY until resolved to \leqGrade 1Reduce 1 dose level with each occurrence, or discontinue according to the dose reduction levels 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	<ul style="list-style-type: none">Withhold TRODELVY until resolved to \leqGrade 1Reduce 1 dosage level with each occurrence or discontinue according to the dose reduction levels below

Dose reduction levels¹

Recommended starting dose	First dose reduction	Second dose reduction	Requirement for further dose reduction
 10 mg/kg Once weekly on Days 1 and 8 of 21-day treatment cycles	 7.5 mg/kg	 5 mg/kg	 Permanently discontinue

Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made¹

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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 NK₁ 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 \leq 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 (\geq 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 \geq 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 \geq 25%) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.



Gilead Oncology Support

Do your patients have questions about cost or coverage for their prescribed medication?
We can help your patients understand their options.^a

Support is available Monday through Friday, 9 AM to 7 PM ET



1-844-TRODELVY (1-844-876-3358)

^aSupport may vary based on application criteria and is subject to change or discontinuation.
Physician office must submit Prior Authorizations and appeals.

Scan the code or visit gileadoncologysupport.com



IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

In the TROPiCS-02 study (locally advanced or metastatic HR-positive, HER2-negative breast cancer), the most common adverse reactions (incidence $\geq 25\%$) 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 $\geq 25\%$) 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. Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Hematopoietic Growth Factors V1.2025. © 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.



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