DOSING, RECONSTITUTION, AND ADMINISTRATION GUIDE

180 mg off-white to yellowish lyophilized powder in a single-dose vial

ADC=antibody-drug conjugate.

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.
- Locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 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.**

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

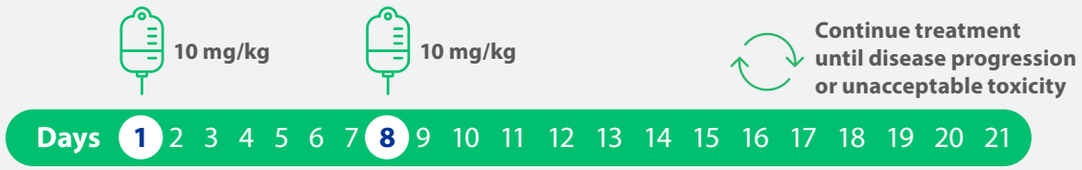
TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

Start TRODELVY at 10 mg/kg

The recommended dosage of TRODELVY is 10 mg/kg intravenously on Days 1 and 8 of 21-day continuous treatment cycles

- Continue treatment until disease progression or unacceptable toxicity
- 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**
- Do not mix TRODELVY, or administer as an infusion, with other medicinal products
- Protect infusion bag from light

21-day treatment cycles



First infusion

- Administer infusion over 3 hours
- Observe patients during the infusion and for at least 30 minutes following the initial dose for signs or symptoms of infusion-related reactions

Subsequent infusions

- Administer infusion over 1 to 2 hours if prior infusions were tolerated
- Observe patients during the infusion and for at least 30 minutes after the infusion

Premedication recommended prior to each dose of TRODELVY for the following:

To prevent chemotherapy-induced nausea and vomiting (CINV), premedicate with:	To prevent infusion reactions, premedicate with:	In patients with a prior excessive cholinergic reaction,* premedicate with:
• Dexamethasone **AND**	• Antipyretics	• Atropine or other appropriate premedication
• 5-HT3 receptor antagonist **OR** NK_1 receptor antagonist	• H1 and H2 blockers	
• Other drugs as indicated	• Corticosteroids (may be used for patients with a prior infusion reaction)	

Medication to treat infusion-related reactions, as well as emergency equipment, should be available for immediate use.

*Eg, abdominal cramping, diarrhea, salivation, etc.

This information does not constitute the provision of medical advice and should not substitute for clinical decision making.

IMPORTANT SAFETY INFORMATION *(cont'd)*

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^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Administer G-CSF as clinically indicated or indicated in Table 1 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.

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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 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: 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.

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After initiation on starting dose, doses can be modified as needed to help manage adverse reactions

Dose modifications for adverse reactions

Severe Neutropenia

Adverse Reaction	Occurrence	Dose Modification
Grade 4 neutropenia ≥7 days **OR** Grade 3–4 febrile neutropenia **OR** At time of scheduled treatment, Grade 3–4 neutropenia, which delays dosing by 2 or 3 weeks for recovery to ≤Grade 1	First	25% dose reduction and administer granulocyte colony-stimulating factor (G-CSF)
	Second	50% dose reduction and administer G-CSF
	Third	Discontinue treatment and administer G-CSF
At time of scheduled treatment, Grade 3–4 neutropenia, which delays dosing beyond 3 weeks for recovery to ≤Grade 1	First	Discontinue treatment and administer G-CSF

Severe Non-Neutropenic Toxicity

Adverse Reaction	Occurrence	Dose Modification
Grade 4 non-hematologic toxicity of any duration, OR Any Grade 3–4 nausea, vomiting, or diarrhea due to treatment that is not controlled with antiemetics and antidiarrheal agents, OR Other Grade 3–4 non-hematologic toxicity persisting >48 hours despite optimal medical management, OR At time of scheduled treatment, Grade 3–4 non-neutropenic hematologic or non-hematologic toxicity, which delays dose by 2 or 3 weeks for recovery to ≤Grade 1	First	25% dose reduction
	Second	50% dose reduction
	Third	Discontinue treatment
In the event of Grade 3–4 non-neutropenic hematologic or non-hematologic toxicity, which does not recover to ≤Grade 1 within 3 weeks	First	Discontinue treatment

- Withhold or discontinue TRODELVY to manage adverse reactions as described here
- Do not re-escalate 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

Scan to learn about the dosing and safety of* TRODELVY *with Sara Tolaney, MD, MPH

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS *(cont'd)*

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.

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IMPORTANT SAFETY INFORMATION *(cont'd)*

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.

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Recommended preparation for TRODELVY

Reconstitution

TRODELVY is a hazardous drug. Follow applicable special handling and disposal procedures.

1. Calculate the required dose (mg) of TRODELVY based on the patient's body weight at the beginning of each treatment cycle (or more frequently if the patient's body weight changed by more than 10% since previous administration).
2. Allow the required number of vials to warm to room temperature.
3. Using a sterile syringe, slowly inject 20 mL of 0.9% Sodium Chloride Injection, USP, into each 180 mg TRODELVY vial. Each vial contains overfill to compensate for liquid loss during preparation and after reconstitution, the total resulting volume delivers a **concentration of 10 mg/mL**.
4. Gently swirl vials and allow to dissolve for up to 15 minutes. Do not shake. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be free of visible particulates, clear and yellow. Do not use the reconstituted solution if it is cloudy or discolored.
5. Use immediately to prepare a diluted TRODELVY infusion solution.

Dilution

6. Calculate the required amount of the reconstituted TRODELVY solution needed to obtain the appropriate dose according to the patient's body weight.
7. Determine the final volume of the infusion solution to deliver the appropriate dose at a TRODELVY concentration range of 1.1 mg/mL to 3.4 mg/mL.
8. Use 0.9% Sodium Chloride Injection, USP, only since the stability of the reconstituted TRODELVY solution has not been determined with other infusion-based solutions. Use a polyvinyl chloride, polypropylene/polyethylene, polyolefin, or ethylene vinyl acetate infusion bag.
9. Withdraw and discard the volume of 0.9% Sodium Chloride Injection, USP, from the final infusion bag that is necessary to achieve the indicated TRODELVY concentration following the addition of the calculated amount of reconstituted TRODELVY solution.
10. Withdraw the calculated amount of the reconstituted TRODELVY solution from the vial(s) using a syringe. Discard any unused portion remaining in the vial(s).
11. To minimize foaming, slowly inject the calculated amount of reconstituted TRODELVY solution into the infusion bag. Do not shake the contents.

Administration

- Administer TRODELVY as an intravenous infusion. Protect infusion bag from light. The infusion bag should be covered during administration to the patient until dosing is complete. It is not necessary to cover the infusion tubing or to use light-protective tubing during the infusion
- An infusion pump may be used
- Do not mix TRODELVY, or administer as an infusion, with other medicinal products
- Upon completion of the infusion, flush the intravenous line with 20 mL 0.9% Sodium Chloride Injection, USP

If not used immediately

The infusion bag containing TRODELVY solution can be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours protected from light

After refrigeration, administer diluted solution at room temperature up to 25°C (77°F) within 8 hours (including infusion time). Protect from light

Do not freeze or shake

Administer solution within 8 hours after refrigeration (including infusion time)

IMPORTANT SAFETY INFORMATION *(cont'd)*

ADVERSE REACTIONS *(cont'd)*

In the TROPHY study (locally advanced or metastatic urothelial cancer), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, any infection, alopecia, decreased appetite, constipation, vomiting, rash, and abdominal pain. The most frequent serious adverse reactions (SAR) (≥5%) were infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), and sepsis or bacteremia (5%). SAR were reported in 44% of patients, and 10% discontinued due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPHY study were reduced neutrophils, leukocytes, and lymphocytes.

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.

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TRODELVY® ACCESS SUPPORT

TRODELVY ACCESS SUPPORT is a patient access and reimbursement support program. It will help you and your patients understand specific coverage and reimbursement guidelines for TRODELVY 180-mg single-dose vial.

Reimbursement support services include:

- Coverage verification
- Prior Authorization information
- Claims status information
- Billing and coding information
- Alternate assistance options

Patient access support includes:

- TRODELVY Savings Program[a]
- Gilead Patient Assistance Program (PAP)[b]
- Referrals to independent third-party assistance organizations[c]

TRODELVY ACCESS SUPPORT can help your patients determine their benefits and coverage.

To enroll a patient into **TRODELVY ACCESS SUPPORT,** please complete the Enrollment Form with your patient and fax to 1-833-851-4344.

For more information on the **TRODELVY Savings Program,** visit **TRODELVYHCP.com/support/access**, or call **1-844-TRODELVY** (1-844-876-3358) Monday-Friday, 9 AM-7 PM ET.

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TRODELVY support may vary based on application criteria and is subject to change or discontinuation. Physician office must submit prior authorizations and appeals.

[a]The TRODELVY Savings Program is not available to patients with any form of government insurance. Patients must meet certain eligibility criteria to qualify for this program. Once enrolled the patient pays as little as $0 out-of-pocket for TRODELVY, with maximum benefit of $25,000 per year.

[b]Gilead PAP provides TRODELVY free of charge for eligible patients who are uninsured or underinsured. To qualify for assistance, patients must meet certain eligibility criteria.

[c]Patients with Medicare or other government insurance who need assistance with cost-share requirements for TRODELVY may be eligible for co-pay or co-insurance assistance through an independent co-pay assistance foundation. Case managers can help patients assess their high-level eligibility for possible coverage for TRODELVY through an independent co-pay assistance foundation. If co-pay assistance needs are identified, the case managers can provide information about any available foundations. The foundation will determine the patient's eligibility for co-pay or co-insurance assistance based on their own criteria and, completely independent of Gilead and its agents, will contact the patient directly.

Reference: TRODELVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; February 2023.

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