FOR ONCOLOGY NURSE EDUCATOR USE

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

Dosing, Administration, and Adverse Reaction Management Guide

INDICATIONS

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2–directed antibody and topoisomerase inhibitor conjugate indicated in adult patients:

Locally Advanced or Metastatic Triple-Negative Breast Cancer

First Line

- As a single agent for the first-line treatment of unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who are not candidates for PD-1 or PD-L1 inhibitor-based therapy
- In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of unresectable locally advanced or mTNBC whose tumors express PD-L1 [Combined Positive Score (CPS ≥10)] as determined by an FDA-authorized test

Second Line or Later

- For the treatment of unresectable locally advanced or mTNBC who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Locally Advanced or Metastatic HR-positive, HER2-negative Breast Cancer

- For the treatment of unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

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

CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

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

Dosing

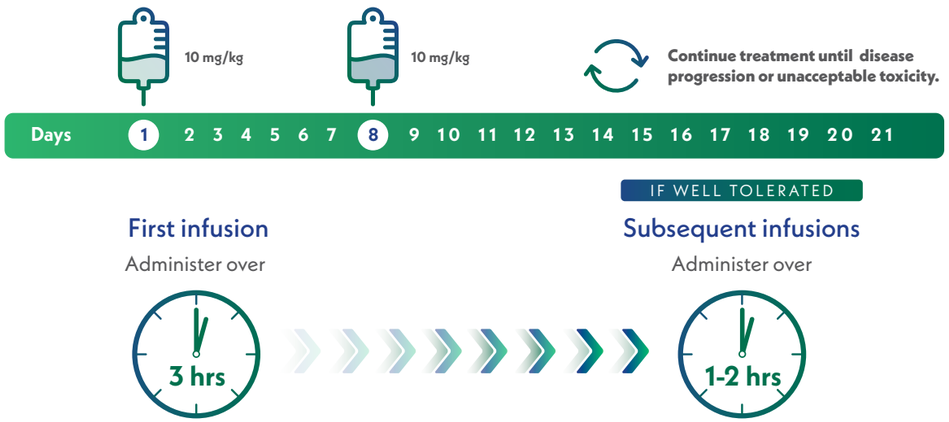
Dosing and infusion schedule[1]

Start TRODELVY at 10 mg/kg

The recommended dosage of TRODELVY as single agent or in combination with pembrolizumab is 10 mg/kg intravenously on Days 1 and 8 of 21-day cycles.

- Do not administer TRODELVY at doses greater than 10 mg/kg
- Administer TRODELVY as an intravenous infusion

Note: Do NOT substitute TRODELVY for or use with other drugs containing irinotecan or its active metabolite, SN-38.



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

Patient Selection for Combination Therapy

Select patients for treatment of unresectable locally advanced or metastatic TNBC with TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, based on the tumor expression of PD-L1 as confirmed by an FDA-authorized test.[a]

When TRODELVY is administered in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, discontinue pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph after approximately 24 months.

- Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the recommended dosing information.

Prepare with premedications and additional supportive measures based on your patients' needs. See page 8 for more information.

[a]Information on FDA-authorized tests is available at http://www.fda.gov/companiondiagnostics.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

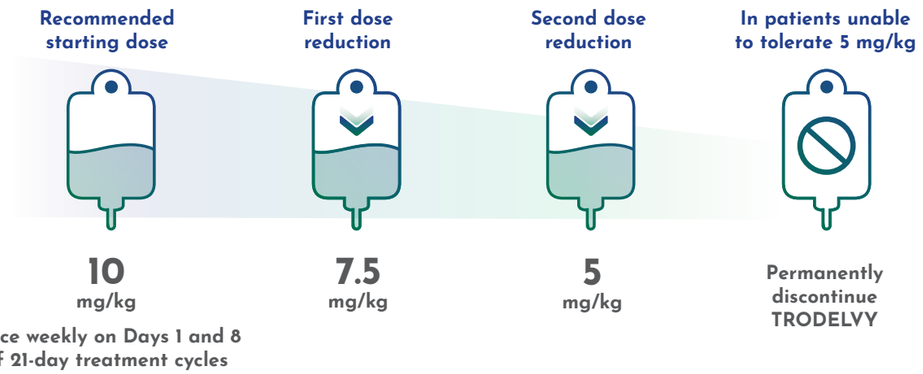
Neutropenia: Severe, life-threatening, or fatal neutropenia can occur as early as the first cycle of treatment and may require dose modification. Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 48% of patients. Febrile neutropenia occurred in 6%. Neutropenic 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.

Dose modifications for adverse reactions[1]

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

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

Dosage reduction levels for TRODELVY



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

When administering TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, interrupt or discontinue one or both drugs of the combination or reduce the dose of TRODELVY to manage adverse reactions as appropriate. Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for recommendations on dosage interruption or discontinuation due to adverse reactions.

ANC=absolute neutrophil count; FDA=US Food and Drug Administration; G-CSF=granulocyte colony-stimulating factor; PD-L1=programmed death ligand 1.

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Recommended preparation for TRODELVY[1]

The recommended dosage of TRODELVY as a single agent or in combination with pembrolizumab is a 10 mg/kg intravenous infusion on Days 1 and 8 of 21-day cycles until disease progression or unacceptable toxicity. Do not administer TRODELVY at doses greater than 10 mg/kg

Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the recommended dosing information of pembrolizumab.

All handling, use, and storage of TRODELVY should comply with institutional guidelines and follow the clinical judgment of the managing healthcare professional. Clinical professional judgment and local practices/institutional guidelines regarding safety precautions should be used.

Reconstitution[1]

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

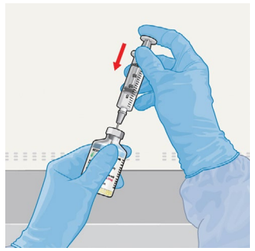
1

Calculate the required dose of TRODELVY

a. **Calculate the required dose (mg) of TRODELVY** based on the patient's current body weight.
   - Ensure the patient's body weight is in kg for calculations (1 kg = 2.205 lb)

b. Determine the number of vials needed. Each vial contains 180 mg.

2



Reconstitute the vials

a. 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

b. **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**

c. **Use reconstituted TRODELVY immediately to prepare a diluted TRODELVY infusion solution.**

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

Dilution[1]

3

Calculate the required amount of reconstituted TRODELVY and infusion solution needed for dilution

a. **Calculate the required amount of the reconstituted TRODELVY** solution needed to obtain the appropriate dose according to the patient's body weight.
   - After reconstitution in step 2, each vial has a concentration of 10 mg/mL

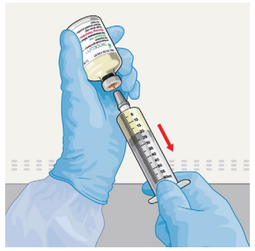
b. **Determine the final volume of the infusion solution** to deliver the appropriate dose at a TRODELVY concentration range of 1.1 mg/mL to 3.4 mg/mL.
   - For the infusion solution, only use 0.9% Sodium Chloride Injection, USP, since the stability of the reconstituted TRODELVY solution has not been determined with other infusion-based solutions
   - Use a polyvinyl chloride, polypropylene/polyethylene, polyolefin, or ethylene vinyl acetate infusion bag

4

Prepare the infusion bag

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.

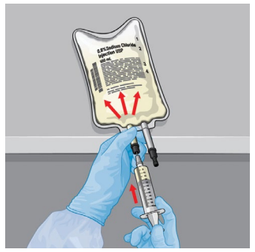
5



Withdraw the required dose of reconstituted TRODELVY

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).

6



Add the reconstituted solution to the final infusion bag

a. **Slowly inject** the calculated amount of reconstituted TRODELVY solution **into the infusion bag** to minimize foaming. **Do not shake the contents.**

b. Verify final concentration is within range of 1.1 mg/mL to 3.4 mg/mL.

USP=United States Pharmacopeia.

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Recommended preparation for TRODELVY (CONT'D)[1]

Administration[1]

- 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 in the same intravenous line, with other medicinal products
- Upon completion of the infusion, flush the intravenous line with 20 mL of 0.9% Sodium Chloride Injection, USP

If not used immediately[1]

- 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 infusion bag from light until dosing is complete
- Do not freeze or shake

USP=United States Pharmacopeia.

Example TRODELVY calculations[1]

The sample calculations are based on a 154-lb (70-kg) patient prescribed TRODELVY at the recommended dose of 10 mg/kg.

	Action	Example	Result
Reconstitution			
Step 1a	Calculate the total dose of TRODELVY based on the patient's weight in kg (1 kg = 2.205 lb)	154 lb ÷ 2.205 ≈ 70 kg 70 kg x 10 mg/kg = 700 mg	700 mg of TRODELVY
Step 1b	Determine the number of vials needed. Each vial contains 180 mg of TRODELVY	700 mg ÷ 180 mg per vial	4 vials needed
Step 2	Reconstitute the vials by slowly adding 20 mL of 0.9% Sodium Chloride Injection, USP into each vial	Add 20 mL to each of the 4 vials	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
Dilution			
Step 3a	Calculate the required volume (number of mL needed) of reconstituted TRODELVY solution for the required dose calculated in step 1a	700 mg ÷ 10 mg/mL	70 mL of reconstituted TRODELVY solution
Step 3b	Select an infusion bag with the appropriate volume to deliver the required dose at a concentration of 1.1 mg/mL to 3.4 mg/mL	700 mg ÷ 250 mL 0.9% Sodium Chloride Injection, USP = 2.8 mg/mL (within 1.1–3.4 mg/mL concentration range)	250-mL infusion bag selected
Step 4	Withdraw volume from the infusion bag equivalent to the volume of reconstituted TRODELVY solution to be added calculated in step 3a	250 mL – 70 mL	180 mL 0.9% Sodium Chloride Injection, USP remaining in the infusion bag
Step 5	Withdraw the calculated dose of reconstituted TRODELVY from the vials	Withdraw 70 mL of reconstituted TRODELVY	–
Step 6a	Slowly transfer the TRODELVY solution into the infusion bag	70 mL TRODELVY solution + 180 mL 0.9% Sodium Chloride Injection, USP	250 mL total volume in infusion bag
Step 6b	Verify the final concentration is within the range of 1.1 mg/mL to 3.4 mg/mL	700 mg ÷ 250 mL = 2.8 mg/mL	Final concentration of reconstituted TRODELVY solution is within the range

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Diarrhea: Diarrhea occurred in 62% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 10% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.6% 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 (eg, fluid and electrolyte replacement) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (eg, 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, and skin reactions. Hypersensitivity reactions occurred in 28% of patients with 13% occurring within 24 hours of dosage. Grade 3-4 hypersensitivity occurred in 1.5% of patients with 0.4% of these occurring within 24 hours of dosage. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.4%. The incidence of anaphylactic reaction was <0.1%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Closely monitor patients 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.

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

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Nausea and Vomiting: TRODELVY is emetogenic and can cause severe nausea and vomiting. Nausea occurred in 63% of all patients treated with TRODELVY, and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 33% of patients, and Grade 3-4 vomiting occurred in 2% of these patients. Premedicate with a two- or three-drug combination regimen (eg, 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. 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.

Premedication and additional supportive measures

Neutropenia

Primary prophylaxis with G-CSF is recommended in the TRODELVY USPI starting in the first cycle of treatment 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**

Prophylactic G-CSF is supported by NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).[2]

- Prior to initiating TRODELVY, determine your patient's risk of developing febrile neutropenia. See NCCN Guidelines® for febrile neutropenia risk factors on page 9

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

- For the prevention of infusion reactions, premedication with antipyretics and H1 and H2 blockers is recommended[1]
- For patients who had prior infusion reactions, consider corticosteroids[1]
- **Have medications and emergency equipment to treat infusion-related reactions, including anaphylaxis, available for immediate use when administering TRODELVY[1]**

Nausea and vomiting

Prevention of chemotherapy-induced nausea and vomiting is recommended and can include premedication with a 2- or 3-drug combination regimen. For example, dexamethasone can be administered with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as outlined below, as well as other drugs as indicated.[1]

Examples of 5-HT3 receptor antagonists[3]

dolasetron	granisetron	ondansetron	palonosetron

Examples of NK_1 receptor antagonists[4]

aprepitant	fosnetupitant	fosaprepitant	netupitant	rolapitant

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 57% in patients homozygous for the UGT1A1*28 allele, 48% in patients heterozygous for the UGT1A1*28 allele, and 41% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 17% in patients homozygous for the UGT1A1*28 allele, 9% in patients heterozygous for the UGT1A1*28 allele, and 8% 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.

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NCCN Guidelines for assessing risk for febrile neutropenia[2]

The NCCN Guidelines classify sacituzumab govitecan-hziy (TRODELVY®) as intermediate risk (10%–20%) for febrile neutropenia.[2]

- 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[2,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)

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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.

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

[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.[2]
[b]Other factors may warrant the use of G-CSF (eg, chronic immunosuppression in the posttransplant setting, including organ transplant).[2]

5-HT3=5-hydroxytryptamine type 3 receptor; CD4=cluster of differentiation 4; FN=febrile neutropenia; G-CSF=granulocyte colony-stimulating factor; H1=histamine receptor 1; H2=histamine receptor 2; NCCN=National Comprehensive Cancer Network; NK_1=neurokinin-1; USPI=United States Prescribing Information.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

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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Adverse reactions and management strategies

Adverse reactions may occur during treatment with TRODELVY[1]

In the pooled safety population with TRODELVY as a monotherapy (N=1354), the most common (≥25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (83%), decreased neutrophil count (77%), decreased hemoglobin (71%), nausea (63%), diarrhea (62%), decreased lymphocyte count (60%), fatigue (59%), alopecia (47%), increased glucose (40%), constipation (37%), vomiting (33%), decreased albumin (32%), increased alkaline phosphatase (30%), decreased appetite (28%), abdominal pain (27%), decreased creatinine clearance (27%), decreased magnesium (26%), and decreased potassium (26%).

Among the 221 patients who received TRODELVY in combination with intravenous pembrolizumab, the most common (≥25%) adverse reactions including laboratory abnormalities were decreased neutrophil count and decreased hemoglobin (86% each), decreased leukocyte count (84%), diarrhea (72%), nausea (68%), decreased lymphocyte count (61%), fatigue (58%), alopecia (52%), increased alkaline phosphatase and increased glucose (50% each), increased alanine aminotransferase (47%), constipation (41%), increased aspartate aminotransferase (40%), rash (37%), decreased potassium (35%), increased lactate dehydrogenase (34%), vomiting (29%), abdominal pain, headache, increased eosinophils (26% each), and decreased albumin (25%).

Note: Information provided does not constitute the provision of medical advice and should not substitute for clinical decision-making.

Establish an open dialogue with your patients from the start of treatment

Before starting patients with TRODELVY, have a conversation to set expectations:

- ☐ Discuss the efficacy and safety results from the clinical trials
- ☐ Review the mechanism of action of TRODELVY and how it is different from previous treatments they may have received
- ☐ Share available resources, including information about psychosocial support throughout treatment (ie, social worker, behavioral health, pastoral care, advocacy groups, etc)
- ☐ Review their medical history and any previous treatments or adverse reactions they may have experienced

Some patients may be hesitant to report adverse reactions, so it is important to talk about:

- ☐ Any adverse reactions they may have experienced with previous doses of TRODELVY, if applicable
- ☐ Potential serious and common adverse reactions, including signs and symptoms, when to expect onset, and how long symptoms may last
- ☐ When to contact you or another healthcare provider if the patient experiences adverse reactions
- ☐ Medications that may be prescribed for use before or during treatment to help manage certain adverse reactions
- ☐ Roles and expectations for patients and caregivers, including the importance of open and honest communication

Proactively monitor for adverse reactions and educate patients about the importance of reporting certain symptoms promptly

Develop an adverse reaction management plan to help support your patients

Before administering TRODELVY

BE AWARE

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

PREPARE

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

After administering TRODELVY

MONITOR

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

MANAGE

Help manage certain adverse reactions with appropriate medication and/or by interrupting, reducing, or permanently discontinuing doses of TRODELVY.

More information about select adverse reaction management strategies for:

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

In the pooled safety population of TRODELVY as a single agent, the most common (≥25%) adverse reactions, including laboratory abnormalities, were decreased leukocyte count (83%), decreased neutrophil count (77%), decreased hemoglobin (71%), nausea (63%), diarrhea (62%), decreased lymphocyte count (60%), fatigue (59%), alopecia (47%), increased glucose (40%), constipation (37%), vomiting (33%), decreased albumin (32%), increased alkaline phosphatase (30%), decreased appetite (28%), abdominal pain (27%), decreased creatinine clearance (27%), decreased magnesium and potassium (26% each).

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Neutropenia management plan

BE AWARE

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

In TRODELVY monotherapy studies (pooled safety data)

- Neutropenia occurred in 64% of patients
- Grade 3-4 neutropenia occurred in 48% of patients
- Neutropenic colitis occurred in 1.4% of patients
- Febrile neutropenia occurred in 6% of patients
- The median time to first onset of neutropenia (including febrile neutropenia) was 19 days (range: 1 to 1022 days). Neutropenia occurred earlier in patients with reduced UGT1A1 activity

TRODELVY as a combination therapy with pembrolizumab (safety data)

- Any grade decreased neutrophil count occurred in 86% of patients
- Grade 3-4 decreased neutrophil count occurred in 50% of patients

Refer to page 15 for additional onset and duration information.

PREPARE

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

Withhold TRODELVY for neutropenic fever[1]

Plan for G-CSF prophylaxis and support

- Primary prophylaxis with G-CSF is recommended in the TRODELVY USPI starting in the first cycle of treatment for all patients at increased risk of febrile neutropenia, including older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities[1]
- Prophylactic G-CSF is supported by NCCN Guidelines[2]
- If patients do not receive primary prophylaxis with G-CSF and experience neutropenia, be ready with G-CSF support to help patients continue therapy, if clinically indicated[1]

Considerations for management with G-CSF:

There are different types of G-CSF, including various formulations of[5,6]

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

Longer-acting G-CSF may be given less frequently than shorter-acting G-CSF.[6]

Ask:

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

Important patient counseling information[1]

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

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MONITOR

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

Inform patients about the lab work they may expect.

NCI CTCAE Version 5.0 neutropenia grade scale[7]	
Grade 1	ANC <LLN to 1500/mm^3
Grade 2	ANC <1500 to 1000/mm^3
Grade 3	ANC <1000 to 500/mm^3
Grade 4	ANC <500/mm^3

NCI CTCAE Version 5.0 febrile neutropenia grade scale[7]	
Grade 1	–
Grade 2	–
Grade 3	ANC <1000/mm^3 with a single temperature of >38.3 °C (101 °F) or a sustained temperature of ≥38 °C (100.4 °F) for more than 1 hour
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death

MANAGE

Doses of TRODELVY can be interrupted, reduced, or permanently discontinued to help manage neutropenia[1]

To manage Grade 3-4 neutropenia (ANC <1000/mm^3) or febrile neutropenia

Withhold TRODELVY

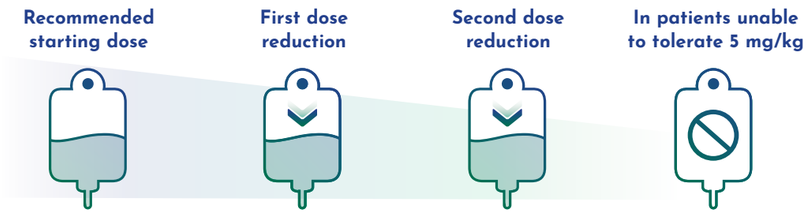
- Until ANC ≥1500/mm^3 for Day 1 dose or
- Until ANC ≥1000/mm^3 for Day 8 dose

Administer G-CSF during treatment as clinically indicated

If the patient experiences:

- Febrile neutropenia
- Prolonged Grade 3-4 neutropenia

Reduce 1 dose level for each occurrence.



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

When administering TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, interrupt or discontinue one or both drugs of the combination or reduce the dose of TRODELVY to manage adverse reactions as appropriate. Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for recommendations on dosage interruption or discontinuation due to adverse reactions.

ANC=absolute neutrophil count; G-CSF=granulocyte colony-stimulating factor; LLN=lower limit of normal; NCCN=National Comprehensive Cancer Network; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events; UGT1A1=uridine diphosphate-glucuronosyl transferase 1A1; USPI=United States Prescribing Information.

Additional data for onset and duration of select adverse reactions

Post hoc descriptive analyses of the Phase 3 studies ASCENT-04, ASCENT-03, and ASCENT

ASCENT-04 Study Design[1,8]

1L mTNBC in combination with pembrolizumab

A Phase 3, randomized, active-controlled, open-label study (N=443) evaluating TRODELVY in combination with pembrolizumab vs chemotherapy with pembrolizumab in patients with previously untreated, locally advanced unresectable, or mTNBC whose tumors express PD-L1 (CPS ≥10).[a,b]

ASCENT-03 Study Design[1,9]

1L mTNBC monotherapy

A Phase 3, randomized, active-controlled, open-label study (N=558) evaluating TRODELVY vs chemotherapy in patients with previously untreated, locally advanced unresectable, or mTNBC who were not candidates for PD-(L)1 inhibitor therapy.[b,c]

ASCENT Study Design[1,10]

2L+ mTNBC

A Phase 3, randomized, active-controlled, open-label trial (N=529) that assessed TRODELVY vs single-agent chemotherapy in patients with unresectable locally advanced or mTNBC who had relapsed after at least 2 prior chemotherapies, at least one of them for metastatic disease.[d,e]

A prespecified descriptive analysis of the Phase 3 TROPiCS-02 study

TROPiCS-02 Study Design[1,11]

Pretreated HR+/HER2– mBC

A Phase 3, randomized, active-controlled, open-label trial (N=543) that assessed patients with HR+/HER2– mBC who were previously treated with ≥1 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.[d,e]

[a]Patients were randomized (1:1) to receive TRODELVY 10 mg/kg as an IV infusion on Days 1 and 8 of a 21-day cycle and pembrolizumab 200 mg on Day 1 of 21-day cycles or pembrolizumab plus treatment of physician's choice, which included gemcitabine/carboplatin, nab-paclitaxel, and paclitaxel.[1]

[b]Patients were treated until BICR-verified disease progression, unacceptable toxicity, death, or consent withdrawal.[12,13]

[c]Patients were randomized (1:1) to receive TRODELVY 10 mg/kg as an intravenous infusion on Days 1 and 8 of a 21-day cycle or chemotherapy of investigator's choice, which included gemcitabine and carboplatin, paclitaxel, or nab-paclitaxel.[1]

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

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

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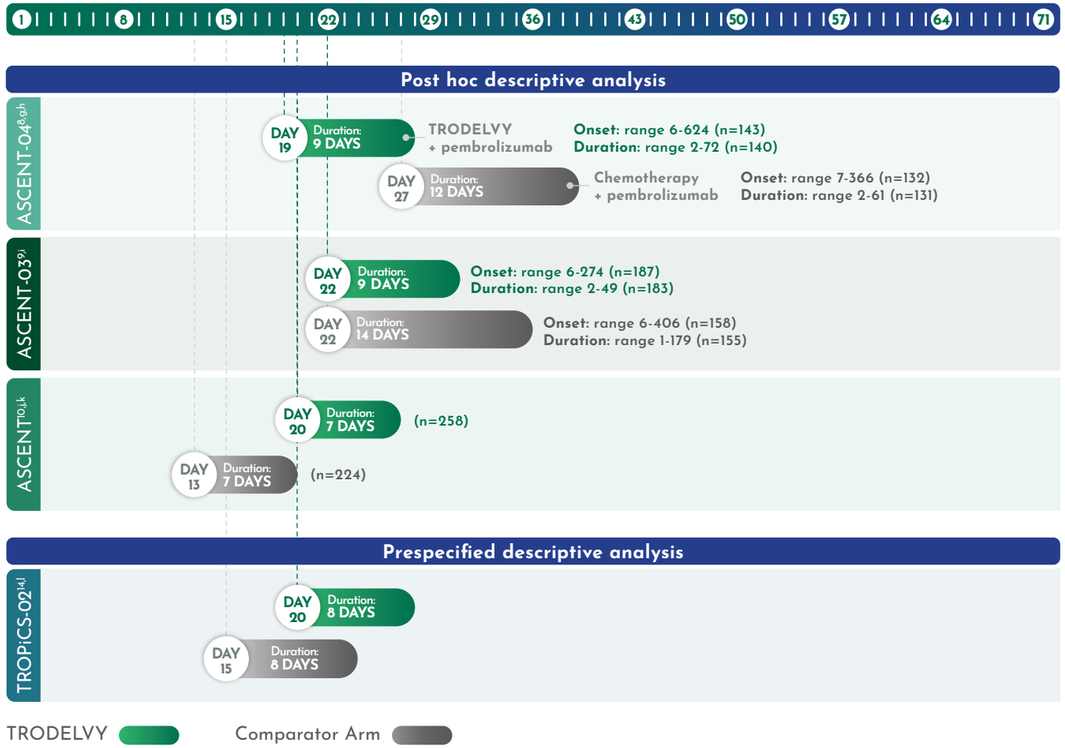
Neutropenia

Median time to first onset and duration of neutropenia (any grade)

In the pooled safety population with TRODELVY as a monotherapy (N=1354), the median time to first onset of neutropenia (including febrile neutropenia) was 19 days (range: 1 to 1022 days). Neutropenia occurred earlier in patients with reduced UGT1A1 activity.[1,f]

[f]Includes patients from 5 trials (IMMU-132-01, ASCENT, TROPiCS-02, ASCENT-03, and a phase 2 trial in another tumor type).[1]



Limitations: Results from ASCENT-04, ASCENT-03, and ASCENT are from post hoc descriptive analyses. Results from TROPiCS-02 were from a prespecified descriptive analysis. These were not powered for statistical analysis and should be considered descriptive only. Therefore the results require cautious interpretation and could represent chance findings.

[g]Number of participants may differ between time to onset and duration data due to events with no recorded end date or ongoing events. Time to onset of first event is calculated as time from the first dose date of any study drug to the onset date of first event. Duration is the median duration among multiple episodes of any grade or among multiple episodes of Grade ≥3 (the end date of event of interest minus the onset date of event of interest plus 1 day for each episode).[8]

[h]Treatment-emergent neutropenia includes preferred terms of neutrophil count decreased, neutropenia, and febrile neutropenia.[8]

[i]Time to onset of first TEAE is defined as time from first dose date of study drug to onset date of first TEAE. Duration of TEAE is median duration among multiple preferred terms; within each preferred term, duration is median duration among multiple episodes (end date of TEAE minus onset date of TEAE plus 1 day for each episode).[9]

[j]Time to onset of first TRAEs was defined as time from first dosing date to the start date of the TRAE. Duration of an individual episode of TRAE was calculated as the TRAE end date minus the TRAE start date.[10]

[k]Treatment-related neutropenia includes preferred terms of neutropenia and neutrophil count decreased.[10]

[l]Treatment-related neutropenia includes preferred terms of neutrophil count decreased, neutropenia, and febrile neutropenia.[14]

1L=first line; 2L+=second line and later; AUC=area under the curve; BICR=blinded independent central review; CDK4/6i=cyclin-dependent kinase 4/6 inhibitor; HER2–=human epidermal growth factor receptor 2-negative; HR+=hormone receptor-positive; IV=intravenous; mBC=metastatic breast cancer; mTNBC=metastatic triple-negative breast cancer; PD-L1=programmed death ligand 1; PD-(L)1=PD-1 or PD-L1; TEAE=treatment-emergent adverse event; TRAE=treatment-related adverse event; UGT1A1=uridine diphosphate-glucuronosyl transferase 1A1.

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Diarrhea management plan

BE AWARE

TRODELVY can cause severe diarrhea[1]

In TRODELVY monotherapy studies (pooled safety data)

- Diarrhea occurred in 62% of patients
- Grade 3–4 diarrhea occurred in 10% of patients
- One patient had an intestinal perforation following diarrhea
- Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.6% of all patients

TRODELVY as a combination therapy with pembrolizumab (safety data)

- Diarrhea occurred in 72% of patients
- Grade 3–4 diarrhea occurred in 12% of patients

Refer to page 18 for onset and duration information.

PREPARE

Premedication[1]

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

Important patient counseling information[1]

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

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

MONITOR

NCI CTCAE Version 5.0 diarrhea grade scale[7]	
Grade 1	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
Grade 2	Increase of 4 to 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental activities of daily living
Grade 3	Increase of ≥7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care activities of daily living
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death

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

MANAGE

Evaluate for infectious causes[1]

At the onset of diarrhea, evaluate for infectious causes. If no infectious cause is found, promptly initiate loperamide.

Initiate loperamide[1]

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

Ongoing supportive care[1]

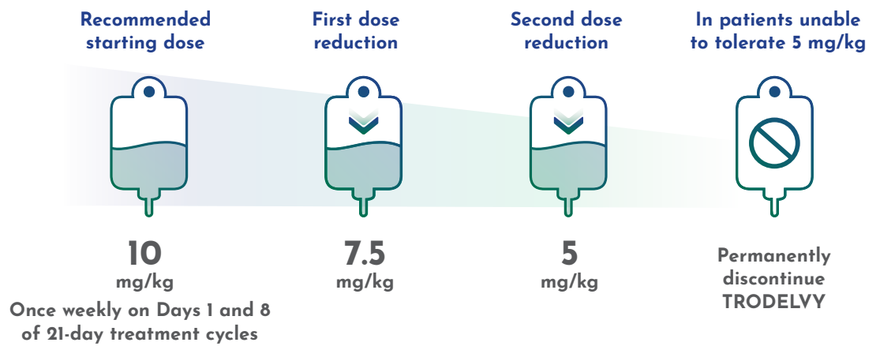
Additional supportive measures, such as fluid and electrolyte support, may be employed as clinically indicated.

Doses of TRODELVY can be interrupted, reduced, or permanently discontinued to help manage diarrhea[1]

To manage Grade 3-4 diarrhea that is not controlled with antidiarrheal agents,

Withhold TRODELVY until resolved to ≤Grade 1

Reduce 1 dose level for each occurrence



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

When administering TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, interrupt or discontinue one or both drugs of the combination or reduce the dose of TRODELVY to manage adverse reactions as appropriate. Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for recommendations on dosage interruption or discontinuation due to adverse reactions.

NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

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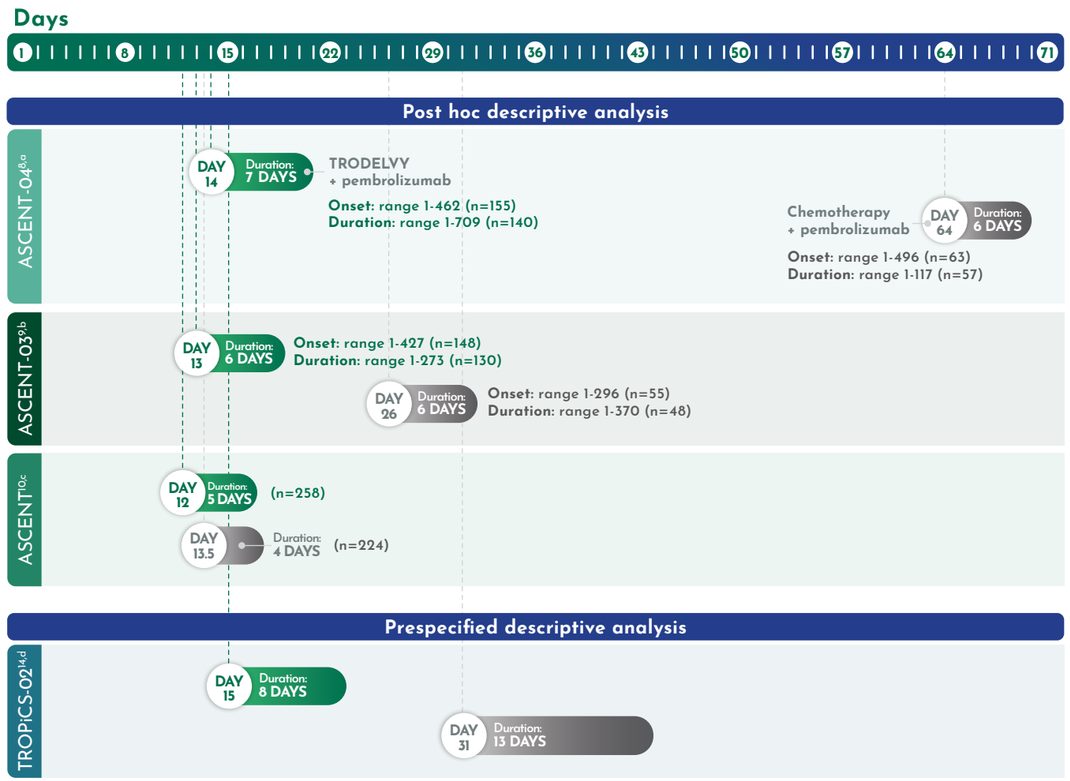
Diarrhea

Median time to first onset and duration of diarrhea (any grade)



Limitations: Results from ASCENT-04, ASCENT-03, and ASCENT are from post hoc descriptive analyses. Results from TROPiCS-02 were from a prespecified descriptive analysis. These were not powered for statistical analysis and should be considered descriptive only. Therefore the results require cautious interpretation and could represent chance findings.

[a]Number of participants may differ between time to onset and duration data due to events with no recorded end date or ongoing events. Time to onset of first event is calculated as time from the first dose date of any study drug to the onset date of first event. Duration is the median duration among multiple episodes of any grade or among multiple episodes of Grade ≥3 (the end date of event of interest minus the onset date of event of interest plus 1 day for each episode).[8]

[b]Time to onset of first TEAE is defined as time from first dose date of study drug to onset date of first TEAEs. Duration of TEAE is median duration among multiple preferred terms; within each preferred term, duration is median duration among multiple episodes (end date of TEAE minus onset date of TEAE plus 1 day for each episode).[9]

[c]Time to onset of first TRAEs was defined as time from first dosing date to the start date of the TRAE. Duration of an individual episode of TRAE was calculated as the TRAE end date minus the TRAE start date.[10]

[d]Time to first onset and duration of treatment-related diarrhea.[14]

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

Considerations for diarrhea with TRODELVY in combination with pembrolizumab[15]

Early identification and management of immune-mediated adverse reactions are essential for the use of PD-1/PD-L1 blocking antibodies.

BE AWARE

Pembrolizumab can cause immune-mediated colitis, which may be severe or fatal, and may present with diarrhea

Immune-mediated adverse reactions can occur at any time after starting treatment with a PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies.

PREPARE

Important patient counseling information

Inform patients of the risk of immune-mediated adverse reactions that may be severe or fatal, may occur after discontinuation of treatment, and may require corticosteroid treatment and interruption or discontinuation of pembrolizumab.

Advise patients to contact their healthcare provider immediately for diarrhea or severe abdominal pain.

MONITOR

Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions

Advise patients of the importance of keeping scheduled appointments for blood work or other laboratory tests.

MANAGE

In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection

Institute medical management promptly, including specialty consultation as appropriate.

For recommendations for management of adverse reactions of pembrolizumab, refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph.

PD-1=programmed cell death protein 1; PD-L1=programmed death ligand 1; TEAE=treatment-emergent adverse event; TRAE=treatment-related adverse event.

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Hypersensitivity and infusion-related reactions management plan

BE AWARE

TRODELVY can cause serious hypersensitivity reactions including life-threatening anaphylactic reactions.[1]

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

TRODELVY is contraindicated in patients who have experienced a severe hypersensitivity reaction to TRODELVY.[1]

In TRODELVY monotherapy studies (pooled safety data)[1]

- Hypersensitivity reactions in 28% of patients
  - Hypersensitivity reactions occurred within 24 hours of dosing in 13% of patients
- Grade 3-4 hypersensitivity occurred in 1.5% of patients
  - Grade 3-4 hypersensitivity occurred within 24 hours of dosing in 0.4% of patients
- Incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.4%
- Incidence of anaphylactic reactions was <0.1%

Median time to onset and duration for any grade hypersensitivity related to TRODELVY[14]

TROPiCS-02 study: HR+/HER2– mBC (prespecified descriptive analysis)

Limitation: These results are from a prespecified descriptive analysis of the Phase 3 TROPiCS-02 study. This analysis was not powered for statistical analysis and should be considered descriptive only. Therefore, the results require cautious interpretation and could represent chance findings.

PREPARE

Premedication[1]

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

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

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

Important patient counseling information[1]

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

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

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

MONITOR

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

NCI CTCAE Version 5.0 infusion-related reaction grade scale[7]	
Grade 1	Mild transient reaction; infusion interruption not indicated; intervention not indicated
Grade 2	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (eg, antihistamines, NSAIDS, narcotics, IV fluids); prophylactic medications indicated for ≤24 hours
Grade 3	Prolonged (eg, not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death

MANAGE

Doses of TRODELVY can be interrupted, reduced, or permanently discontinued to help manage infusion-related reactions[1]

To manage Grade 1-3 infusion-related reactions,
Slow or interrupt the infusion rate of TRODELVY.

To manage Grade 4 infusion-related reactions,
Permanently discontinue TRODELVY.

When administering TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, interrupt or discontinue one or both drugs of the combination or reduce the dose of TRODELVY to manage adverse reactions as appropriate. Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for recommendations on dosage interruption or discontinuation due to adverse reactions.

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

H1=histamine receptor 1; H2=histamine receptor 2; HER2–=human epidermal growth factor receptor 2-negative; HR+=hormone receptor-positive; mBC=metastatic breast cancer; IV=intravenous; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events; NSAID=nonsteroidal anti-inflammatory drug.

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS (CONT'D)

In the safety population of TRODELVY in combination with pembrolizumab, the most common (≥25%) adverse reactions, including laboratory abnormalities, were decreased neutrophil count and hemoglobin (86% each), decreased leukocyte count (84%), diarrhea (72%), nausea (68%), decreased lymphocyte count (61%), fatigue (58%), alopecia (52%), increased alkaline phosphatase and glucose (50% each), increased alanine aminotransferase (47%), constipation (41%), increased aspartate aminotransferase (40%), rash (37%), decreased potassium (35%), increased lactate dehydrogenase (34%), vomiting (29%), abdominal pain, headache, and increased eosinophils (26% each), and decreased albumin (25%).

In the ASCENT-03 study (single agent in previously untreated, unresectable locally advanced or mTNBC), the most common adverse reactions (incidence ≥25%) were nausea, diarrhea, alopecia, fatigue, constipation, and vomiting. The most frequent serious adverse reactions (SAR) (>2%) were diarrhea, febrile neutropenia, and neutropenia (3.6% each), and pneumonia (2.9%). SAR occurred in 26% of patients, and 3.6% permanently discontinued TRODELVY due to adverse reactions. Fatal adverse reactions occurred in 2.5% of patients and included sepsis (1.1%), and acute respiratory failure, neutropenic colitis, pneumonia, and septic shock (0.4% each). The most common Grade 3-4 lab abnormalities (incidence ≥25%) were decreased neutrophils and leukocytes.

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Nausea and vomiting management plan

BE AWARE

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

In TRODELVY monotherapy studies (pooled safety data)

- Nausea and vomiting occurred in 63% and 33% of patients, respectively
- Grade 3-4 nausea occurred in 3% of patients
- Grade 3-4 vomiting occurred in 2% of patients

TRODELVY as a combination therapy with pembrolizumab (safety data)

- Nausea occurred in 68% of patients
- Grade 3-4 nausea occurred in 3.2% of patients
- Vomiting occurred in 29% of patients
- Grade 3-4 vomiting occurred in 0.9% of patients

ASCENT study: 2L+ mTNBC (HR-/HER2-) (post hoc descriptive analysis)[10]

Median time to onset and duration for any grade nausea related to TRODELVY (n=258)

Median time to onset and duration for any grade vomiting related to TRODELVY (n=258)

Limitation: These results are from a post hoc analysis of the Phase 3 ASCENT study. This post hoc analysis was not powered for statistical analysis and should be considered descriptive only. Therefore, the results require cautious interpretation and could represent chance findings.

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

PREPARE

Premedication[1]

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

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

Ongoing supportive care[1]

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

Important patient counseling information[1]

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

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

MONITOR

NCI CTCAE Version 5.0 nausea and vomiting grade scales[7]		
	Nausea	**Vomiting**
Grade 1	Loss of appetite without alteration in eating habits	Intervention not indicated
Grade 2	Oral intake decreased without significant weight loss, dehydration, or malnutrition	Outpatient IV hydration; medical intervention indicated
Grade 3	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	Tube feeding, TPN, or hospitalization indicated
Grade 4	-	Life-threatening consequences
Grade 5	-	Death

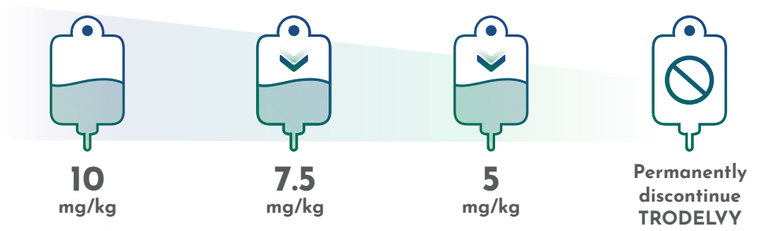
MANAGE

Doses of TRODELVY can be interrupted, reduced, or permanently discontinued to help manage nausea and vomiting[1]

To manage Grade 3-4 nausea or vomiting that is not controlled with antiemetics,

Withhold TRODELVY until resolved to ≤Grade 1

Reduce 1 dose level for each occurrence



Once weekly on Days 1 and 8 of 21-day treatment cycles

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

When administering TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, interrupt or discontinue one or both drugs of the combination or reduce the dose of TRODELVY to manage adverse reactions as appropriate. Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for recommendations on dosage interruption or discontinuation due to adverse reactions.

Ongoing supportive care[1]

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

2L+=second line and later; 5-HT3=5-hydroxytryptamine type 3 receptor; CINV=chemotherapy-induced nausea and vomiting; HER2-=human epidermal growth factor receptor 2-negative; HR-=hormone receptor-negative; IV=intravenous; mTNBC=metastatic triple-negative breast cancer; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events; NK_1=neurokinin-1; TPN=total parenteral nutrition.

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Drug interactions

Drug interactions with UGT1A1 inhibitors[1]

Avoid administering UGT1A1 inhibitors with TRODELVY. SN-38 is a UGT1A1 substrate. 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.

Examples of UGT1A1 inhibitors include[16,17]

- protease inhibitors (eg, atazanavir, ritonavir)
- tyrosine kinase inhibitors (eg, lapatinib, nilotinib, sorafenib)
- SGLT2 inhibitors (eg, canagliflozin, dapagliflozin)
- gemfibrozil
- levothyroxine
- ketoconazole
- diclofenac
- entacapone
- everolimus
- vitamin A
- zafirlukast

Note: This is not an inclusive list of all UGT1A1 inhibitors.

Drug interactions with UGT1A1 inducers[1]

Avoid administering UGT1A1 inducers with TRODELVY. SN-38 is a UGT1A1 substrate. Concomitant administration of TRODELVY with inducers of UGT1A1 may reduce exposure to SN-38.

Examples of UGT1A1 inducers include[18-20]

- carbamazepine
- phenobarbital
- rifampicin
- phenytoin

Note: This is not an inclusive list of all UGT1A1 inducers.

Important patient counseling information[1]

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 enzyme activity.

SGLT2=sodium-glucose cotransporter-2; UGT1A1=uridine diphosphate-glucuronosyl transferase 1A1.

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS (CONT'D)

In the ASCENT-04 study (in combination with pembrolizumab in previously untreated, unresectable locally advanced or mTNBC whose tumors express PD-L1), the most common adverse reactions (incidence ≥25%) were diarrhea, nausea, fatigue, alopecia, constipation, rash, vomiting, abdominal pain, and headache. The most frequent SAR (≥2%) were febrile neutropenia (7%), neutropenia (6%), diarrhea (5%), and fatigue and pneumonia (2.3% each). SAR occurred in 38% of patients, and 7% permanently discontinued TRODELVY due to adverse reactions. Fatal adverse reactions occurred in 3.2% of patients and included death (unknown cause) (0.9%) and completed suicide, neutropenic sepsis, sepsis, pneumonia, and pulmonary embolism (0.5% each). The most common Grade 3-4 lab abnormalities (incidence ≥25%) were decreased neutrophils and leukocytes.

In the ASCENT study (previously treated locally advanced or mTNBC), the most common adverse reactions (incidence ≥25%) were fatigue, diarrhea, nausea, alopecia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent SAR (>1%) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR occurred in 27% of patients, and 5% permanently discontinued TRODELVY due to adverse reactions. Fatal adverse reactions occurred in 1.2% of patients and included respiratory failure (0.8%) and pneumonia (0.4%). The most common Grade 3-4 lab abnormalities (incidence ≥25%) were decreased neutrophils, leukocytes, and lymphocytes.

In the TROPiCS-02 study (locally advanced or metastatic HR+/HER2– breast cancer), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, alopecia, and constipation. The most frequent SAR (>1%) were diarrhea (5%), febrile neutropenia (4.1%), neutropenia (3%), abdominal pain (2.2%), neutropenic colitis and vomiting (1.9% each), and colitis and pneumonia (1.5% each). SAR occurred in 28% of patients, and 6% permanently discontinued TRODELVY due to adverse reactions. Fatal adverse reactions occurred in 2.2% of patients and included arrhythmia, COVID-19 pneumonia, pneumonia, nervous system disorder, pulmonary embolism, and septic shock (0.4% each). The most common Grade 3-4 lab abnormalities (incidence ≥25%) were decreased neutrophils and leukocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Avoid administering UGT1A1 inhibitors with TRODELVY. SN-38 is a UGT1A1 substrate. 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.

UGT1A1 Inducers: Avoid administering UGT1A1 inducers with TRODELVY. SN-38 is a UGT1A1 substrate. Concomitant administration of TRODELVY with inducers of UGT1A1 may reduce exposure to SN-38.

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INDICATIONS

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2–directed antibody and topoisomerase inhibitor conjugate indicated in adult patients:

Locally Advanced or Metastatic Triple-Negative Breast Cancer

First Line

- As a single agent for the first-line treatment of unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who are not candidates for PD-1 or PD-L1 inhibitor-based therapy
- In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of unresectable locally advanced or mTNBC whose tumors express PD-L1 [Combined Positive Score (CPS ≥10)] as determined by an FDA-authorized test

Second Line or Later

- For the treatment of unresectable locally advanced or mTNBC who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Locally Advanced or Metastatic HR-positive, HER2-negative Breast Cancer

- For the treatment of 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 throughout, and click to see full Prescribing Information, including BOXED WARNING.

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sacituzumab govitecan-hziy
180 mg for injection