



# TRODELVY™

sacituzumab govitecan-hziy

180 mg for injection

## RECONSTITUTION AND ADMINISTRATION GUIDE

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

### INDICATION

TRODELVY™ (sacituzumab govitecan-hziy) is indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least 2 prior therapies for metastatic disease.

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

#### WARNING: NEUTROPENIA AND DIARRHEA

**TRODELVY can cause severe or life-threatening neutropenia. Withhold TRODELVY for absolute neutrophil count (ANC) below 1500/mm<sup>3</sup> on Day 1 of any cycle or ANC below 1000/mm<sup>3</sup> on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.**

**Monitor blood cell counts periodically during treatment. Consider Granulocyte Colony-Stimulating Factor (G-CSF) for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**

- Dose modifications may be required due to neutropenia. Febrile neutropenia occurred in 6% (24/408) of patients treated with TRODELVY, including 8% (9/108) of patients with mTNBC after at least 2 prior therapies. Less than 1% (1/408) of patients had febrile neutropenia leading to permanent discontinuation. The incidence of Grade 1-4 neutropenia was 64% in patients with mTNBC (n=108). In all patients treated with TRODELVY (n=408), the incidence of Grade 1-4 neutropenia

was 54%; Grade 4 neutropenia occurred in 13%. Less than 1% (2/408) of patients permanently discontinued treatment due to neutropenia.

**Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late 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.**

- Diarrhea occurred in 63% (68/108) of patients with mTNBC and 62% (254/408) of all patients treated with TRODELVY. In each population, events of Grade 3-4 occurred in 9% (10/108) of mTNBC patients and 9% (36/408) of all patients treated with TRODELVY. Four out of 408 patients (<1%) discontinued treatment because of diarrhea. Neutropenic colitis was observed in 2% (2/108) of patients in the mTNBC cohort and 1% of all patients treated with TRODELVY.

**Please see additional Important Safety Information, including boxed Warning, on back cover.**

TRODELVY: PREPARATION AND ADMINISTRATION

DOSING

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

- 1 The recommended dose of TRODELVY is 10 mg/kg administered as an intravenous infusion once weekly on Days 1 and 8 of 21-day treatment cycles.
- 2 Continue treatment until disease progression or unacceptable toxicity.
- 3 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.

Please see full Prescribing Information for dose modifications for adverse reactions.

RECONSTITUTION

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

- 4 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). 10 mg/kg
- 5 Allow the required number of vials to warm to room temperature.
- 6 Using a sterile syringe, slowly inject 20 mL of 0.9% Sodium Chloride Injection, USP, into each 180 mg TRODELVY vial. The resulting concentration is 10 mg/mL. 1 vial + 20 mL saline (0.9% Sodium Chloride) = 10 mg/mL

Please note, the target fill amount of drug product is 200 mg per each TRODELVY vial. The amount of drug indicated on the FDA-approved label (180 mg/vial) represents the minimum amount of drug possibly contained in the vial based on filling and extraction variability. Based on the target fill amount of 200 mg per vial, upon reconstitution with 20 mL of Sodium Chloride Injection, USP, following labeled instructions contained in the TRODELVY Prescribing Information, the resulting target concentration is 10 mg/mL.

- 7 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.
- 8 Use immediately to prepare a diluted TRODELVY infusion solution.

Please see Important Safety Information, including boxed Warning, on back cover.

DILUTION

- 9 Calculate the required volume of the reconstituted TRODELVY solution needed to obtain the appropriate dose according to patient’s body weight. Withdraw this amount. Discard any unused portion remaining in the vial(s).
- 10 Adjust the volume in the infusion bag as needed with 0.9% Sodium Chloride Injection, USP, to obtain a concentration of 1.1 mg/mL to 3.4 mg/mL (total volume should not exceed 500 mL).
- 11 Slowly inject the required volume of reconstituted TRODELVY solution into a polypropylene (PP) infusion bag, to minimize foaming. Do not shake the contents.



For patients whose body weight exceeds 170 kg, divide the total dosage of TRODELVY equally between two 500 mL infusion bags and infuse sequentially via slow infusion.

- 12 Only normal saline (0.9% Sodium Chloride Injection, USP) should be used.
- 13 Use the diluted solution in the infusion bag immediately.

If not used immediately:

Refrigerate between 2°C to 8°C (36°F to 46°F) for up to 4 hours

After refrigeration, administer diluted solution within 4 hours (including infusion time).

Do Not Freeze or Shake. Protect from Light.

ADMINISTRATION

- 14 Administer TRODELVY as an intravenous infusion. Protect infusion bag from light. An infusion pump may be used.
- 15 Do not mix TRODELVY, or administer as an infusion, with other medicinal products.
- 16 Upon completion of the infusion, flush the intravenous line with 20 mL 0.9% Sodium Chloride Injection, USP.

See accompanying Prescribing Information for additional information about first and subsequent infusions, premedication requirements, and dose reductions for adverse reactions.



## IMPORTANT SAFETY INFORMATION (cont'd)

**Contraindications:** Severe hypersensitivity reaction to TRODELVY.

### Hypersensitivity

- TRODELVY can cause severe and life-threatening hypersensitivity, including anaphylactic reactions. Hypersensitivity reactions occurred within 24 hours of dosing in 37% (151/408) and Grade 3-4 hypersensitivity occurred in 1% (6/408) of all patients treated with TRODELVY (n=408). The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 1% (3/408).
- Pre-infusion medication for patients receiving TRODELVY is recommended. Observe patients closely for infusion-related reactions during each TRODELVY infusion and for at least 30 minutes after completion of each infusion. Medication to treat such reactions, as well as emergency equipment, should be available for immediate use.

### Nausea and Vomiting

- TRODELVY is emetogenic. Nausea occurred in 69% (74/108) of patients with mTNBC and 69% (281/408) of all patients treated with TRODELVY. Grade 3 nausea occurred in 6% (7/108) and 5% (22/408) of these populations, respectively. Vomiting occurred in 49% (53/108) of patients with mTNBC and 45% (183/408) of all patients treated with TRODELVY. Grade 3 vomiting occurred in 6% (7/108) and 4% (16/408) of these patients, respectively.
- Premedicate with a 2- or 3-drug combination regimen (e.g., dexamethasone with either a 5-HT<sub>3</sub> 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 at the time of scheduled treatment administration 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.

### Use in Patients with Reduced UGT1A1 Activity

- Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)\*28 allele are at increased risk for

neutropenia and may be at increased risk for other adverse events following initiation of TRODELVY treatment. Closely monitor patients with reduced UGT1A1 activity for severe neutropenia. The appropriate dose for patients who are homozygous for UGT1A1\*28 is not known and should be considered based on individual patient tolerance to treatment.

- In 84% (343/408) of patients who received TRODELVY (up to 10 mg/kg on Days 1 and 8 of a 21-day cycle) and had retrospective UGT1A1 genotype results available, the incidence of Grade 4 neutropenia was 26% (10/39) in patients homozygous for the UGT1A1\*28 allele, 13% (20/155) in patients heterozygous for the UGT1A1\*28 allele, and 11% (16/149) in patients homozygous for the wild-type allele.

### Embryo-Fetal Toxicity

- TRODELVY contains a genotoxic component and can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. 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 following 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.

### Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 1 month after the last dose of TRODELVY.

### Adverse Reactions

Most common adverse reactions (incidence >25%) in patients with mTNBC are nausea (69%), neutropenia (64%), diarrhea (63%), fatigue (57%), anemia (52%), vomiting (49%), alopecia (38%), constipation (34%), rash (31%), decreased appetite (30%), abdominal pain (26%), and respiratory infection (26%).

**Please see full Prescribing Information, including boxed Warning, in pocket.**

