TRODELVY™

sacituzumab govitecan-hziy

180 mg for injection

SIDE EFFECT MANAGEMENT GUIDE

Monitoring Patients and Management of Possible Side Effects

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

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

Please see additional Important Safety Information, including boxed Warning, on page 4.

COUNSEL PATIENTS ON THE POSSIBLE SIDE EFFECTS OF TRODELVY

Advise patients on the risk of the following serious side effects:

Neutropenia (low white blood cell count)

TRODELVY can cause severe or life-threatening neutropenia.

Advise patients that if their white blood cell count is too low, their healthcare provider may need to lower their dose of TRODELVY, give a medicine to help prevent low blood cell count with future doses of TRODELVY, or in some cases may stop TRODELVY. The healthcare provider may need to give antibiotic medicines if a fever develops while their white blood cell count is low.

Instruct patients to immediately contact their healthcare provider if they experience:

- Fever
- Chills
- Cough
- Shortness of breath
- Burning or pain during urination

Diarrhea

TRODELVY can cause severe 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.

Instruct patients to immediately contact their healthcare provider if they experience:

- Diarrhea for the first time during treatment
- 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 get diarrhea under control within 24 hours

Serious infusion reactions and anaphylaxis

TRODELVY can cause severe and life-threatening hypersensitivity. Anaphylactic reactions have been observed in clinical trials with TRODELVY.

Instruct patients to immediately contact their healthcare provider if they experience any of the following either during or within 24 hours following the infusion:

- Facial, lip, tongue, or throat swelling
- Urticaria
- Difficulty breathing
- Lightheadedness
- Dizziness
- Chills
- Rigors
- Wheezing
- Pruritus
- Flushing
- Rash
- Hypotension
- Fever

Nausea and vomiting

Instruct patients to immediately contact their healthcare provider if they experience uncontrolled nausea or vomiting.

Premedicate with a 2- or 3-drug combination regimen for prevention of chemotherapy-induced nausea and vomiting (CINV).

- Additional antiemetics, sedatives, and other supportive measures may also be employed as clinically indicated
- All patients should receive take-home medications with clear instructions for preventing and treating nausea and vomiting

Please see additional Important Safety Information, including boxed Warning, on page 4.

The most common side effects (incidence >25%) of TRODELVY include:

- **Nausea (69%)**
- **Low white blood cell count (64%)**
- **Diarrhea (63%)**
- **Feeling tired (57%)**
- **Low red blood cell count (52%)**
- **Vomiting (49%)**
- **Hair loss (38%)**
- **Constipation (34%)**
- **Rash (31%)**
- **Decreased appetite (30%)**
- **Abdominal pain (26%)**
- **Respiratory infection (26%)**

Some adverse reactions may be managed with dose delays and dose reductions. Please refer to the full Prescribing Information or visit **TRODELVY.com/hcp/dosing** for the recommended dose reduction schedule for TRODELVY.

Remind your patients to tell their healthcare provider:

- If they have been told they carry a gene for uridine diphosphate-glucuronosyl transferase A1 (UGT1A1)*28. People who carry this gene have an increased risk of getting side effects with TRODELVY, especially neutropenia.
- If they have liver problems
- About all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements

Patients may report suspected adverse reactions to the FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**

Important information about pregnancy and lactation:

Advise female patients to contact their healthcare provider if they are pregnant or become pregnant. Inform female patients of the risk to a fetus and potential loss of the pregnancy

- Advise female patients of reproductive potential to use effective contraception during treatment and for 6 months after the last dose of TRODELVY
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of TRODELVY
- Advise women not to breastfeed during treatment and for 1 month after the last dose of TRODELVY

Use the patient handout to:

- Review the serious and most common side effects with your patients
- Discuss tips with your patients to help them manage the possible side effects they may experience while on TRODELVY

Please see additional Important Safety Information, including boxed Warning, on page 4.

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^3 on Day 1 of any cycle or ANC below 1000/mm^3 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.

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 patients, 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-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 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 click here to see accompanying full Prescribing Information, including boxed Warning.

Immunomedics

2020-US-TROT-00529

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

Side effects:

WHAT YOU MAY EXPECT

Not an actual patient.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

What is TRODELVY?

TRODELVY™ (sacituzumab govitecan-hziy) is a prescription medicine used to treat adults with a certain type of breast cancer known as triple-negative (HR and HER2 negative) that has spread to other parts of the body (metastatic) and who received at least two therapies for metastatic disease.

TRODELVY is approved based on medical studies that measured how many patients responded and how long they responded. Continued approval may depend on benefit demonstrated in additional medical studies.

It is not known if TRODELVY is safe and effective in people with moderate or severe liver problems or in children.

IMPORTANT SAFETY INFORMATION

TRODELVY can cause serious side effects, including:

- **Low white blood cell count (neutropenia).** Low white blood cell counts are common with TRODELVY and can sometimes be severe and lead to infections that can be life-threatening. Your healthcare provider should check your blood cell counts during treatment with TRODELVY. If your white blood cell count is too low, your healthcare provider may need to lower your dose of TRODELVY, give you a medicine to help prevent low blood cell count with future doses of TRODELVY, or in some cases may stop TRODELVY. Your healthcare provider may need to give you antibiotic medicines if you develop fever while your white blood cell count is low. **Call your healthcare provider right away if you develop any of the following signs of infection during treatment with TRODELVY:** fever, chills, cough, shortness of breath, or burning or pain when you urinate.
- **Severe diarrhea.** Diarrhea is common with TRODELVY and can also be severe. Your healthcare provider should monitor you for diarrhea and give you medicine as needed to help control your diarrhea. If you lose too much body fluids (dehydration), your healthcare provider may need to give you fluids and electrolytes to replace body salts. If diarrhea happens later in your treatment, your healthcare provider may check you to see if the diarrhea may be caused by an infection. Your healthcare provider may decrease your dose or stop TRODELVY if your diarrhea is severe and cannot be controlled with anti-diarrheal medicines.
- **Call your healthcare provider right away** the first time that you get diarrhea during treatment with TRODELVY; if you have black or bloody stools; if you have symptoms of losing too much body fluid (dehydration) and body salts, such as lightheadedness, dizziness, or faintness; if you are unable to take fluids by mouth due to nausea or vomiting; or if you are not able to get your diarrhea under control within 24 hours.

HER2=human epithelial growth factor receptor 2; HR=hormone receptor.

Please see full Prescribing Information and Patient Information, including boxed Warning.

TIPS THAT MAY HELP MANAGE POSSIBLE SIDE EFFECTS

TRODELVY can cause side effects, some of which can be serious. Your doctor may suggest ways to help manage some of these side effects. These tips may also help:

Low white blood cell count (neutropenia)

TRODELVY may lower your neutrophils, a type of white blood cell. This can put you at higher risk of infection. The following tips may help reduce the risk of infection:

- Contact your doctor immediately if you experience fever, chills, cough, shortness of breath, or burning or pain when you urinate.
- Wash your hands often with soap and warm water
- Avoid large crowds and stay away from people who are sick
- Thoroughly wash raw fruits and vegetables before eating them

Diarrhea

Antidiarrheal medications may be given to you by your doctor. Contact your doctor immediately if you are unable to get your diarrhea under control within 24 hours after infusion. The following tips may help control diarrhea:

- Slowly sip cool, clear liquids throughout the day to stay hydrated
- Eat frequent, small meals that are bland and low-fiber such as bananas, white rice, and toast
- Avoid alcohol, caffeine, greasy or spicy foods, and limit dairy products and raw vegetables

Low red blood cell count (anemia)

A low red blood cell count can be common with treatment. This can leave you feeling weak and tired. Following these tips may help:

- Limit activities and get plenty of rest
- Take short naps, and try to get 7 to 8 hours of sleep each night
- Eat a well-balanced diet that includes proteins (such as meat, fish, eggs, dairy, and nuts), and drink plenty of water

Feeling tired (fatigue)

It's common for treatment to leave you feeling weak and tired. Help manage your fatigue using the following tips:

- Plan time to relax and rest, and create a schedule that works for you
- Take short naps, and try to get 7 to 8 hours of sleep each night
- Try to stay active, but talk with your doctor before starting a new exercise routine
- Drink plenty of water and eat well
- Reduce stress by trying meditation, yoga, reading, or keeping a diary

Nausea and vomiting

Your doctor may provide medications to help prevent nausea and vomiting. Follow the directions he or she gives you. These tips may also help:

- Eat 5 to 6 small meals or snacks a day rather than 3 large meals
- Eat bland foods, such as toast and crackers
- Try eating small amounts of foods that are high in calories
- Slowly sip cool, clear liquids such as ginger ale, apple juice, broth, or tea throughout the day to stay hydrated
- Try to take deep, slow breaths or get fresh air when you begin to feel sick
- If you are vomiting, ice chips or frozen juice chips may help you take in fluids more easily

Hair loss (alopecia)

Hair loss is common with treatment, but these tips may help.

- If you are considering a wig, buying it before treatment begins can help you match it to the color and style of your hair
- Check to see if your insurance company will cover the cost for a wig
- Wear a hair net at night or sleep on a satin pillowcase to keep hair from coming out in clumps
- Protect your scalp from the sun by using sunscreen, and wear a hat or scarf outside
- The effectiveness and safety of cooling caps is still being researched. If you are curious about this option, talk to your doctor. Also, ask if the treatment center has experience in using cooling caps and how successful they have been

IMPORTANT SAFETY INFORMATION *(cont'd)*

Do not receive TRODELVY if you have had a severe allergic reaction to TRODELVY. Ask your healthcare provider if you are not sure. TRODELVY can cause severe and life-threatening allergic reactions during infusion (infusion-related reactions). Tell your healthcare provider or nurse right away if you get any of the following symptoms of an allergic reaction during an infusion of TRODELVY or within 24 hours after you receive a dose of TRODELVY: swelling of your face, lips, tongue, or throat; hives; skin rash or flushing of your skin; difficulty breathing or wheezing; lightheadedness, dizziness, feeling faint, or pass out; chills or shaking chills (rigors); or fever.

Nausea and vomiting. Nausea and vomiting are common with TRODELVY and can sometimes be severe. Before each dose of TRODELVY, you will receive medicines to help prevent nausea and vomiting. You should be given medicines to take home with you, along with instructions about how to take them to help prevent and treat any nausea and vomiting after you receive TRODELVY. Call your healthcare provider right away if you have nausea or vomiting that is not controlled with the medicines prescribed for you. Your healthcare provider may decide to decrease your dose or stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see full Prescribing Information and Patient Information, including boxed Warning.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

IMPORTANT SAFETY INFORMATION *(cont'd)*

Before receiving TRODELVY, tell your healthcare provider about all of your medical conditions, including if you:

- have been told that you carry a gene for uridine diphosphate-glucuronosyl transferase A1 (UGT1A1)*28. People who carry this gene have an increased risk of getting side effects with TRODELVY, especially low white blood cell counts.
- have liver problems.
- are pregnant or plan to become pregnant. TRODELVY can harm your unborn baby. Your healthcare provider should check to see if you are pregnant before you start receiving TRODELVY. TRODELVY may cause fertility problems in females, which could affect your ability to have a baby. Talk to your healthcare provider if fertility is a concern for you.
  - Females who can become pregnant should use effective birth control during treatment and for 6 months after your last dose of TRODELVY. Talk to your healthcare provider about birth control choices that may be right for you during this time.
  - Males with a female partner who can become pregnant should use effective birth control during treatment and for 3 months after your last dose of TRODELVY.
  - Tell your healthcare provider right away if you or your partner become pregnant during treatment with TRODELVY.
- are breastfeeding or plan to breastfeed. It is not known if TRODELVY passes into your breastmilk and can harm your baby. Do not breastfeed during treatment and for 1 month after your last dose of TRODELVY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the way TRODELVY works.

The most common side effects of TRODELVY include nausea, low white blood cells (neutropenia), diarrhea, tiredness, decreased red blood cell count, vomiting, hair loss, constipation, rash, decreased appetite, stomach-area (abdomen) pain and respiratory infections.

These are not all of the possible side effects of TRODELVY. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information and Patient Information, including boxed Warning.

Immunomedics

2020-US-00442

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection