Patient Information

TRODELVY™ (troh-DELL-vee)

(sacituzumab govitecan-hziy) injection

What is the most important information I should know about TRODELVY?

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
  - 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
  - if you are not able to get your diarrhea under control within 24 hours

What is TRODELVY?

TRODELVY is a prescription medicine used to treat adults with breast cancer that is:

- estrogen and progesterone hormone receptor (HR) negative, and human epidermal growth factor receptor 2 (HER2)-negative (also called triple-negative breast cancer), **and**
- that has spread to other parts of the body metastatic, **and**
- who previously received at least two therapies for metastatic disease

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

It is not known if TRODELVY is safe and effective in children.

Do not receive TRODELVY if you have had a severe allergic reaction to TRODELVY. Ask your healthcare provider if you are not sure.

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. **See "What is the most important information I should know about TRODELVY?"**
- 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.
  - 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.

How will I receive TRODELVY?

- Your healthcare provider will give you TRODELVY into your vein through an intravenous (IV) line.
- TRODELVY is given 1 time each week, on Day 1 and on Day 8 of a 21-day treatment cycle.
- You will receive the first dose of TRODELVY over 3 hours. If you tolerate the first dose well, future doses may be given over 1 to 2 hours.
- Before each dose of TRODELVY, you will receive medicines to help prevent infusion reactions, and nausea and vomiting.
- You will be monitored for side effects during and for at least 30 minutes after you receive each infusion of TRODELVY.
- Your healthcare provider may slow down or temporarily stop your infusion of TRODELVY if you have an infusion-related reaction, or permanently stop TRODELVY if you have a life-threatening infusion-related reaction.
- Your healthcare provider will decide how long you will continue to receive TRODELVY.

What are the possible side effects of TRODELVY?

TRODELVY can cause serious side effects, including:

- **See "What is the most important information I should know about TRODELVY?"**
- **Severe and life-threatening allergic reactions**. 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:
  - o swelling of your face, lips, tongue, or throat
  - o hives
  - o skin rash or flushing of your skin
  - o difficulty breathing or wheezing
  - o lightheadedness, dizziness, feeling faint or pass out
  - o chills or shaking chills (rigors)
  - o 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.

The most common side effects of TRODELVY include:

- tiredness
- decreased red blood cell count
- hair loss
- constipation
- rash. **See "Severe and life-threatening allergic reactions" above.**
- decreased appetite
- stomach-area (abdomen) pain

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.

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.

General information about the safe and effective use of TRODELVY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about TRODELVY that is written for health professionals.

What are the ingredients in TRODELVY?

Active ingredient: sacituzumab govitecan-hziy

Inactive ingredients: 2-(N-morpholino) ethane sulfonic acid (MES), polysorbate 80 and trehalose dihydrate

Manufactured by: Immunomedics, Inc., 300 The American Road, Morris Plains, NJ 07950, USA
U.S. License No. 1737
For more information about TRODELVY, go to www.TRODELVY.com or call 1-888-983-4668.
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