

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 to 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 additional Important Safety Information, including boxed Warning, on pages 10-11.

UNDERSTANDING DIFFERENT **BREAST CANCER TYPES**

One of the ways breast cancers are classified is by proteins called receptors. There are thousands of different types of receptors on cells in the body. Some receptors are found on the cancer cell surface. Knowing which receptors are present helps your doctor choose a treatment that your type of cancer is most likely to respond to.

HR+ breast cancer

Cancers are called hormone receptor-positive (HR+) if they have estrogen or progesterone receptors. When the estrogen or progesterone attach to these receptors, they fuel the cancer growth. Breast cancers that have estrogen receptors are called estrogen receptor-positive (ER+). Breast cancers that have progesterone receptors are called progesterone receptor-positive (PR+).

Treatment for HR+ breast cancers may include medicines that block the effect of estrogen or progesterone.

HER2+ breast cancer

Some breast cancers are fueled by a different receptor called HER2. Both normal cells and cancer cells have HER2 receptors. In HER2+ breast cancer, cancer cells have more HER2 receptors than normal cells. This makes the cancer grow faster than normal cells.

Treatments for HER2+ breast cancer target and block the HER2 receptor.

Triple-negative breast cancer

Some breast cancers do not have estrogen or progesterone receptors (ER- or PR-). They also do not have too much HER2 (HER2-). This is called triple-negative breast cancer (TNBC).

Hormone therapy is typically not helpful in TNBC because the cancer cells do not have hormone receptors. Drugs that target HER2 are not helpful because the cancer cells do not have enough HER2 receptors.

MORE ABOUT TNBC

- When comparing age groups, the majority of TNBC cases are diagnosed in women 51-60 years old
- However, when women under 40 are diagnosed with breast cancer, it is more likely to be TNBC than if they are diagnosed over 40
- More commonly affects African American and Hispanic women
- In addition, breast cancers associated with a BRCA mutation (either BRCA-1 or BRCA-2) are often, but not always, triple negative

BRCA=BReast CAncer susceptibility gene.

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HOW TRODELVY IS THOUGHT TO WORK

WHAT TRODELVY IS MADE OF

TRODELVY is a type of drug called an antibody-drug conjugate, or ADC for short. ADCs contain 3 parts: an antibody, a linker, and an anti-cancer drug.

Looks for a specific protein, in this case Trop-2, which can be found in high levels on cancer cells

B. Anti-cancer drug

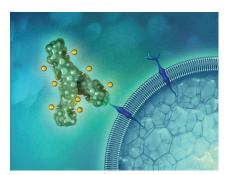
Kills cancer cells once they're found

C. Linker

Connects the anti-cancer drug to the antibody

How TRODELVY is thought to attack TNBC tumors

Scientists discovered that patients with TNBC have tumor cells that contain a higher-than-normal level of Trop-2 protein. TRODELVY binds to cancer cells with Trop-2.



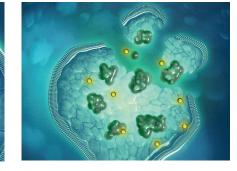
1. Attaches

The antibody in TRODELVY finds and sticks to the Trop-2 protein on cancer cells.



2. Penetrates

Once attached, TRODELVY delivers an anti-cancer drug **directly** into the TNBC cells.



3. Destroys

TRODELVY kills the TNBC cells from within.

This is how TRODELVY was shown to work in laboratory studies. The clinical benefit of these observations is unknown.

> TRODELVY IS THE FIRST AND ONLY BREAST CANCER TREATMENT TO TARGET THE TROP-2 PROTEIN

IMPORTANT SAFETY INFORMATION (cont'd)

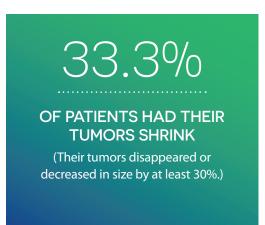
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ONE-THIRD OF PATIENTS HAD THEIR TUMORS SHRINK

TRODELVY was studied in 108 patients with mTNBC who had at least 2 prior treatments for their metastatic disease.

- -Patients with bulky disease, defined as a mass >7 cm, were not eligible
- -Patients with treated brain metastases not receiving a high dose of steroids (>20 mg prednisone or equivalent) for at least 4 weeks were eligible
- -Patients with known Gilbert's disease were excluded





TRODELVY was studied across a range of patients:

- The median age was 55 years (range 31-80); 87% of patients were younger than 65 years
- The majority of patients were female (99%) and White (76%)
- The median number of prior metastatic therapies was 3. The range was 2-10



Not an actual patient.

SIDE EFFECTS: WHAT TO EXPECT

It's important to understand what side effects may be expected with TRODELVY, including serious side effects. Contact your doctor immediately if you experience any side effects. Some side effects may require medical attention and, for some side effects, your doctor may have tips to help you manage or cope with them.

The most common side effects seen during the study were:

Nausea

Vomiting

 Low white blood cells (neutropenia) Hair lossConstipation

Diarrhea

Decreased appetite

Fatique

Rash

· Low red blood cells (anemia)

- Abdominal pain
- Respiratory infection

2% of patients stopped treatment due to side effects

Doses were reduced for 33% of patients to help manage side effects

TRODELVY can also cause serious side effects, including serious infusion-related reactions and severe allergic reactions, lack of a white blood cell type called neutrophils, nausea and vomiting, and diarrhea.

Be sure to tell your doctor about any side effects you have while on TRODELVY. They may be able to help by:

- Recommending medications that support your treatment
- Reducing your dose
- Discontinuing your treatment with TRODELVY

These are not all of the possible side effects of TRODELVY.

Tell your doctor about any side effects that bother you or do not go away. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Ask your doctor if TRODELVY is right for you

If you have tried 2 or more other treatments, but your metastatic TNBC hasn't responded to treatment (refractory) or has come back (relapsed), talk to your doctor to see if TRODELVY is right for you.



HOW TRODELVY IS GIVEN



TRODELVY is an intravenous (IV) infusion



Each treatment cycle is **21 days** (3 weeks)



Doses are given once a week for 2 weeks (Day 1 and Day 8), followed by 1 week off



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.

WHAT TO EXPECT ON TREATMENT DAYS

Your doctor may recommend the following on treatment days:

- · Your height and weight measured to find the right dosage
- · A short physical exam to check your blood pressure, pulse, breathing, and temperature
- An IV tube put in your arm
- A blood sample taken

On treatment days, you can also expect to go through these 3 steps:

1. PRE-INFUSION

You may be given medicines before your infusion to help prevent infusion reactions, including a fever reducer, antihistamines, or corticosteroids. Your doctor may also give you medicine to help reduce or prevent nausea or vomiting.

2. INFUSION

Your first infusion will take approximately 3 hours. Your doctor will observe you during the infusion.

After that, if prior treatment was well tolerated, your infusions with TRODELVY will take 1 to 2 hours.

3. OBSERVATION

After each infusion, your doctor will watch for reactions for at least 30 minutes.

If you experience any side effects while taking TRODELVY, tell your doctor right away. Please read the Important Safety Information on pages 10-11 and the information on side effects on page 5.

Your doctor may give you medicines to take home that can help you manage the side effects of TRODELVY. Keep track of when and how often side effects occur, as well as their severity, so your doctor can best support you.



Before starting TRODELVY, tell your doctor about any medicines you are taking. Be sure to include prescription and over-the-counter medicines, vitamins, and herbal supplements.

Not an actual patient.



PATIENT ACCESS AND REIMBURSEMENT SUPPORT PROGRAM



TRODELVY ACCESS SERVICES is a patient access and reimbursement support program. It will help you understand specific coverage and reimbursement guidelines for TRODELVY.

REIMBURSEMENT SUPPORT SERVICES INCLUDE:

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



The TRODELVY Savings Program can provide financial assistance toward the cost of TRODELVY.

For more information, please contact

TRODELVY ACCESS SERVICES:

Phone: 1-844-TRODELVY (1-844-876-3358)

Monday – Friday, 9 AM – 7 PM ET | **Fax:** 1-833-851-4344

Terms and conditions apply. Please visit **TRODELVY.com/access** for more information.

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.

QUESTIONS TO ASK YOUR DOCTOR

Be sure to ask your doctor any questions you have. This list can help.

What treatment options are available for mTNBC patients who have received previous treatments?

How is TRODELVY different from other treatments?

How is mTNBC different from other breast cancers?

Why are you recommending TRODELVY?

If my tumor has mutated to mTNBC, can I take TRODELVY?

What side effects could I have with TRODELVY?

What tests need to be done before I am given TRODELVY?

How should I get ready for my first TRODELVY infusion?

How often will I receive TRODELVY?

How long will I be on TRODELVY?

How will I know if TRODELVY is working?

What if I need help paying for TRODELVY?





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- 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.
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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, including boxed Warning, in pocket.





Not an actual patient.

Resources

There are additional resources that may be helpful to patients, families, and caregivers dealing with breast cancer. The following resources are not controlled or owned by Immunomedics, and Immunomedics is not responsible for their content.

Breastcancer.org: A complete resource for patients with breast cancer.

breastcancer.org

Living Beyond Breast Cancer®: Information, community, and support for people whose lives have been impacted by breast cancer.

lbbc.org

Metavivor: Dedicated to increasing awareness of advanced breast cancer and equity in research and patient support.

metavivor.org

Share Cancer Support: A supportive community of women affected by breast or ovarian cancer.

sharecancersupport.org

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Sharsheret®: A Jewish breast cancer organization that helps women and their families face breast cancer.

sharsheret.org

Sisters Network® Inc: Committed to increasing local and national attention to the devastating impact that breast cancer has in the African American community.

sistersnetworkinc.org

Triple Negative Breast Cancer Foundation®: Dedicated to raising awareness of triple-negative breast cancer. **tnbcfoundation.org**

Young Survival Coalition®: Dedicated to the critical issues unique to young women who are diagnosed with breast cancer.

youngsurvival.org

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Patient Brochure: Version for Breast Cancer Awareness Month US-TROT-00033

Line:

Recognizing Your Unique Story

During Breast Cancer Awareness Month



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 $\label{eq:HER2-human epithelial growth factor receptor 2; HR-hormone receptor.}$

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