TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

GETTING STARTED
WITH TRODELVY

Please see Important Safety Information on pages 14-15.
Please see Important Facts, including Important Warning.

WHAT IS TRODELVY?

TRODELVY® (sacituzumab govitecan-hziy) is a prescription medicine used to treat adults with hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic) or cannot be removed by surgery, and who previously received endocrine therapy and at least two additional treatments for metastatic disease.

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 and diarrhea:

- **Low white blood cell count (neutropenia)** is common and can sometimes be severe and lead to infections that can be life-threatening or cause death as early as the first cycle of treatment. Your healthcare provider should check your blood cell counts during treatment and may give a medicine to help prevent neutropenia starting in the first cycle of treatment if you have an increased risk for developing low white blood cell count with a fever (febrile neutropenia). If your white blood cell count is too low, your healthcare provider may need to delay treatment or lower your dose, give you a medicine to treat low blood cell count, or in some cases may permanently 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:** fever, chills, cough, shortness of breath, or burning or pain when you urinate.
- **Severe diarrhea.** Diarrhea is common and can be severe. Severe diarrhea can lead to loss of too much body fluid (dehydration) and kidney problems. Your healthcare provider should monitor you for diarrhea and give you medicine as needed to help control it. If you lose too much body fluid, your healthcare provider may need to give you fluids and electrolytes to replace body salts. If you develop diarrhea during your treatment with TRODELVY, your healthcare provider should check to see if it may be caused by an infection. Your healthcare provider may decrease your dose, delay treatment, or permanently 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 dehydration, 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.

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

Allergic and infusion-related reactions can be serious and life-threatening. Tell your healthcare provider or nurse right away if you get any of the following symptoms during your infusion of TRODELVY or within 24 hours after: swelling of your face, lips, tongue, or throat; hives; skin rash, itching, or flushing of your skin; fever; difficulty breathing or wheezing; lightheadedness, dizziness, feeling faint, or pass out; or chills or shaking chills (rigors).

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A LOOK INSIDE

Select a section to jump ahead

Ready to discuss TRODELVY with your healthcare provider?

Create your own discussion guide

Download Guide →

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Actor portrayals.

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What is TRODELVY?

TRODELVY may be an option for certain adults with pretreated HR+/HER2- metastatic breast cancer (mBC)

TRODELVY is for certain adults with metastatic breast cancer who meet the following requirements:

HR+ AND **HER2-**

This means at least **1 out of every 100 cancer cells** has **estrogen** and/or **progesterone** receptors

This means **low amounts or no HER2** is detected in tests

In addition to an HR+/HER2- diagnosis, you must have also been treated with:

1 (OR MORE) Hormone-based therapy

AND

2 (OR MORE) Additional treatments for metastatic breast cancer

What if my cancer is HR+ and HER2-low?

TRODELVY can be used in certain adults whose cancer is HR+ and HER2-negative, which includes cancer that is HER2-low.

Abbreviations: HER2- = human epidermal growth factor receptor 2-negative; HR+ = hormone receptor-positive; mBC = metastatic breast cancer

IMPORTANT SAFETY INFORMATION (cont'd)

Nausea and vomiting are common and can sometimes be severe. Before each dose of TRODELVY, you will receive medicines to help prevent nausea and vomiting along with medicines to take home with instructions about how to take them. 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, delay treatment, or permanently stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

How it works

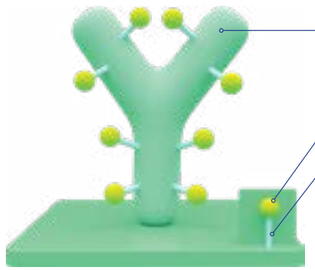
TRODELVY is designed to seek out and destroy cells with Trop-2

TRODELVY is a type of treatment called an antibody-drug conjugate (ADC), given as an intravenous (IV) infusion. It is designed to deliver medicine differently than traditional chemotherapy by binding to a specific protein called Trop-2 found on the surface of certain cells. Once TRODELVY binds with these cells, it delivers a powerful anticancer medicine to help destroy them.

Information from laboratory studies suggests that this is how TRODELVY works. The clinical benefit of these observations is unknown.

Testing for Trop-2 is not required.

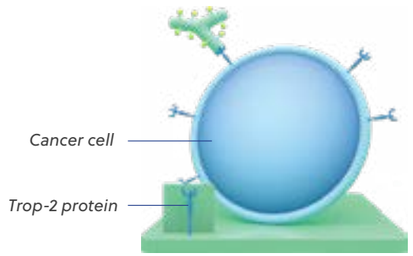
TRODELVY is made up of 3 parts



1. A Y-shaped antibody that targets Trop-2 proteins
2. An anticancer drug
3. A linker that connects the antibody to the drug

TRODELVY targets cells with Trop-2

Scientists discovered that adults with certain types of cancer have tumor cells that often contain more Trop-2 proteins than normal cells (or noncancerous cells). TRODELVY binds to cells with Trop-2.



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 UGT1A1*28, which can increase your risk of getting side effects with TRODELVY, especially low white blood cell counts, with or without a fever, and low red blood cell counts.
- have liver problems.

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When TRODELVY finds a cell with Trop-2, it then:

SEEKS OUT

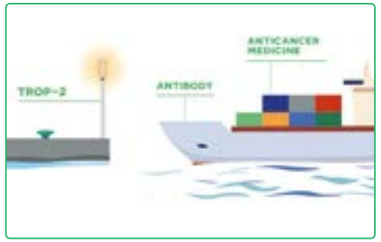
TRODELVY attaches to Trop-2

BREAKS IN

Once attached, TRODELVY enters the cancer cell

DESTROYS

Once TRODELVY enters, the anticancer medicine is released, killing the cell



Trop-2 acts like a beacon, guiding the TRODELVY ship to that specific cell.

Breaking down the science behind TRODELVY

In this video, you'll join Crystal, a woman curious about TRODELVY and how it works, as she gets advice from a healthcare provider and some unexpected guests. You and Crystal will learn how TRODELVY is designed to work kind of like a cargo ship.

Click to watch a video about how TRODELVY is designed to work.

Diving into the HR+/HER2- mBC Clinical Trial

TRODELVY was tested in a phase 3 clinical trial against traditional chemo

Researchers studied TRODELVY in 543 adults with HR+/HER2- breast cancer that had spread to other parts of the body (metastatic) or could not be removed by surgery, and received previous treatments.*

Phase 3 clinical trials test how safe a medicine is and how well a medicine works, compared to a standard treatment.

543 adults in the trial

272 received TRODELVY

10 mg/kg as an intravenous infusion on day 1 and day 8 of a 21-day treatment cycle

271 received traditional chemo

Researchers selected the type of single-agent chemotherapy (traditional chemo) given: eribulin, capecitabine, gemcitabine, or vinorelbine

** All adults had received:*

- *Endocrine therapy*
- *CDK4/6 inhibitor (a type of targeted therapy)*
- *Taxane (a type of chemo)*
- ***At least 2 and no more than 4** prior chemotherapies for metastatic breast cancer. One of the chemotherapies could have been given as a neoadjuvant or adjuvant treatment if recurrence occurred within 12 months*

Endocrine therapy, CDK4/6 inhibitor, and taxane treatments were administered in a neoadjuvant, adjuvant, or metastatic setting.

Neoadjuvant: The first treatment given to shrink a tumor before surgery or after another primary treatment.

Adjuvant: A secondary cancer treatment given after the primary treatment to help lessen the chances of cancer returning.

Abbreviations: HER2- = human epidermal growth factor receptor 2-negative; HR+ = hormone receptor-positive; mBC = metastatic breast cancer

IMPORTANT SAFETY INFORMATION (cont'd)

Before receiving TRODELVY, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- 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.

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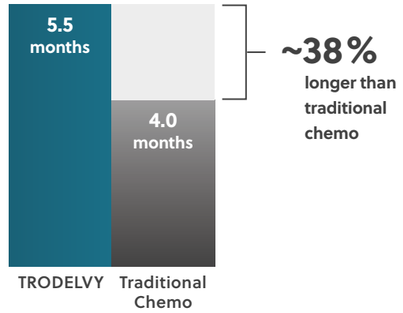
TRODELVY helped adults live longer than traditional chemo:

Lived longer without cancer progression

Median Progression-Free Survival



TRODELVY = 272 adults
Traditional chemo = 271 adults

TRODELVY

Half of those who received TRODELVY lived with **no sign of cancer progression for 5.5 months.**

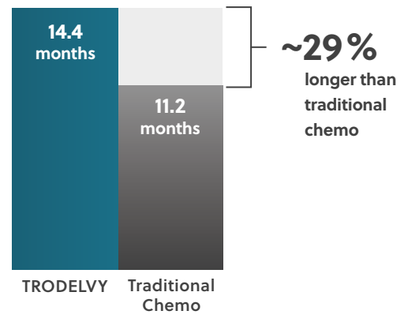
Traditional chemo

Half of those who received traditional chemo (eribulin, capecitabine, gemcitabine, or vinorelbine) lived with **no sign of cancer progression for 4 months.**

Median progression-free survival: How long a treatment stops the growth or spread of HR+/HER2- mBC in half of the adults who take it.

Lived longer overall

Median Overall Survival



TRODELVY = 272 adults
Traditional chemo = 271 adults

TRODELVY

Half of those who received TRODELVY **lived for more than 1 year (14.4 months).**

Traditional chemo

Half of those receiving traditional chemo (eribulin, capecitabine, gemcitabine, or vinorelbine) **lived for 11.2 months.**

Median overall survival: How long half of the adults are alive after starting treatment.

Side effects with TRODELVY

In the phase 3 clinical trials, TRODELVY caused **serious side effects**, including low white blood cell count, severe diarrhea, serious infusion-related reactions and severe allergic reactions, which could be life-threatening, as well as nausea and vomiting.

For those receiving TRODELVY in the HR+/HER2- mBC clinical trial:

- Serious adverse reactions occurred in **28%** of adults
- Serious adverse reactions in **>1%** of adults included diarrhea **(5%)**, neutropenia with fever **(4%)**, neutropenia **(3%)**, abdominal pain **(2%)**, colitis **(2%)**, neutropenic colitis **(2%)**, pneumonia **(2%)**, and vomiting **(2%)**
- **6%** of adults stopped treatment due to side effects
- Side effects leading to a treatment interruption of TRODELVY occurred in **66%** of adults
- Doses were reduced for **33%** of adults to help manage side effects

The most common side effects experienced by adults in the TRODELVY clinical trials include decreased white blood cell (leukocyte, neutrophil*, and lymphocyte) and red blood cell counts, diarrhea, nausea, feeling tired or weak, hair loss, constipation, increased sugar levels in the blood, decreased protein levels (albumin) in the blood, vomiting, decreased appetite, changes in kidney function test, increased levels of enzymes called alkaline phosphatase in the blood (test for liver or bone problems), and decreased levels of magnesium, potassium, and sodium in the blood.

These are not all of the possible side effects of TRODELVY. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Addressing side effects

While some side effects may be immediate, others may develop over time. Your healthcare team may be able to help you manage certain side effects by prescribing other medicines. It can be common for your doctor to modify your TRODELVY dose. Your healthcare provider may need to decrease your dose, delay treatment, or permanently stop your TRODELVY treatment.

**A decreased neutrophil count is called neutropenia.*

IMPORTANT SAFETY INFORMATION (cont'd)

Before receiving TRODELVY, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- 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. Tell your healthcare provider right away if you become pregnant during treatment with TRODELVY.
- 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.

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Actor portrayals.

Difficult but necessary conversations about side effects

Your healthcare provider (HCP) may be able to help manage some side effects of TRODELVY. It's critical to communicate with them early and often if side effects occur. It is common to discuss side effects with your HCP. Ask them any questions you have. Here's are some helpful questions you may want to ask, and why they matter.

Based on your experience, what side effects should I expect?

Some side effects of TRODELVY may be similar to side effect of traditional chemo. The severity of side effects is different for everyone. Ask your HCP about possible side effects of TRODELVY. They may be able to give you a clearer picture of what to expect.

What should I be sharing with you about side effects? How often should I check in?

Talk to your HCP as soon as you experience any side effects while receiving TRODELVY. They may decrease your dose in order to find what works best for you. This may help to manage certain side effects and may assist you to continue treatment if appropriate for you. Some side effects may require your HCP to delay treatment or permanently stop TRODELVY. Do not make any changes to your treatment plan or usage of medicines prescribed to you without being instructed to do so by your HCP.

What steps do you usually recommend for dealing with side effects?

Your HCP is the best resource you have. They may know of medication you can receive, and lifestyle changes you can make to help manage some side effects.

See what other TRODELVY patients have to say

Hear patient stories →

IMPORTANT SAFETY INFORMATION (cont'd)

Before receiving TRODELVY, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- 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.

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Take a self-care break

Thinking about possible side effects and how to potentially manage them isn't fun, but it's an important part of any treatment. Follow the steps below to pause and show yourself some loving kindness.

1

Just close your eyes and place your hands over your heart.

2

When you're ready, take 3 full, deep breaths, letting your chest and belly expand and contract.

3

Continue your breathing, and when you are ready, repeat these phrases:

"I love and accept myself."

"I honor and support myself."

"I practice peace and patience."

"I am worthy of my own compassion and kindness."

IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of TRODELVY include decreased white blood cell (leukocyte and lymphocyte) and red blood cell counts, feeling tired or weak, hair loss, constipation, increased sugar levels in the blood, decreased protein levels (albumin) in the blood, decreased appetite, changes in kidney function test, increased levels of enzyme called alkaline phosphatase in the blood (test for liver or bone problems), and decreased levels of magnesium, potassium, and sodium in the blood.

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- 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.
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GILEAD | Oncology Support

Cost and coverage information for your TRODELVY prescription

Gilead Oncology Support is a patient support program that can provide information and resources to help patients understand coverage and financial options for their prescribed Gilead medication. This includes offering benefit investigations, information on the prior authorization and appeals process, and researching financial support options for eligible patients (such as the co-pay program for commercially insured eligible patients and the patient assistance program [PAP] for eligible uninsured patients).

For additional information, contact a Gilead Oncology Support program specialist.

Monday through Friday, 9 AM to 7 PM ET at 1-844-TRODELVY (1-844-876-3358).
You can also visit **www.gileadoncologysupport.com** for more information.

Have more questions about TRODELVY?
Talk to your healthcare provider, and **review the FAQs**.

Please see Important Safety Information throughout and on pages 14-15.

Please see Important Facts, including Important Warning for low white blood cell count and diarrhea.

GILEAD