



TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

GETTING STARTED WITH TRODELVY



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

Actor portrayal.

WHAT IS TRODELVY?

TRODELVY® (sacituzumab govitecan-hziy) is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract that have spread (metastatic) or cannot be removed by surgery, and who have received a platinum-containing chemotherapy medicine and also received an immunotherapy medicine.

This indication 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 and diarrhea:

- **Low white blood cell count (neutropenia)** which is common and can sometimes be severe and lead to infections that can be life-threatening or cause death. Your healthcare provider should check your blood cell counts during treatment. If your white blood cell count is too low, your healthcare provider may need to lower your dose, 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:** 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 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 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 which 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).

TRODELVY is for people with advanced bladder cancer

As you take this next step, remember that you're not alone. Your healthcare team is with you. While there may be times when discussing pain or side effects is the last thing you want to do, it's important for your healthcare team to know how you're feeling. This guide may help you organize your thoughts and questions.

Please see full Important Safety Information on pages 14-15.
Please see [Important Facts](#) about TRODELVY, including Important Warning.

STEP 1

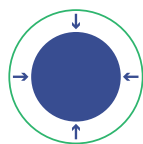
Let the facts guide you

Begin with the clinical trial

- TRODELVY was studied in a phase 2 clinical trial that included 112 adults
- Participants had bladder cancer and cancers of the urinary tract that spread (metastatic) or could not be removed by surgery
- Participants had previously received a platinum-containing chemotherapy and an immunotherapy medicine
- A dose of 10 mg/kg of TRODELVY was given as an intravenous infusion on Days 1 and 8 of a 21-day treatment cycle

TRODELVY may help tumors shrink or disappear

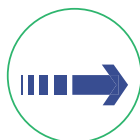
27.7% of patients (31 out of 112) responded to TRODELVY in the clinical trial



22.3% (25 out of 112) saw their tumors **DECREASE IN SIZE** by at least 30%



5.4% (6 out of 112) saw their tumors **DISAPPEAR**



The median* length of response to treatment was **7.2 MONTHS**[†] (for 31 out of 112)

*The median is the middle number in a list of numbers sorted from lowest to highest.

[†]The range of response was 1.4+ months to 13.7. The + indicates that the response is ongoing.

TRODELVY may not work for everyone. Individual results may vary.

IMPORTANT SAFETY INFORMATION (cont'd)

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 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 or stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

STEP 2

Plan for possibilities

The most common side effects seen in at least 25% of patients were:

- Decreased white blood cell (leukocyte, lymphocyte, and neutrophil) and red blood cell counts
- Diarrhea
- Feeling tired or weak (fatigue)
- Nausea
- Increased sugar levels in the blood
- Decreased protein levels (albumin) in the blood
- Hair loss (alopecia)
- Any infection
- Decreased levels of calcium, sodium, phosphate, magnesium, and potassium in the blood
- Decreased appetite
- Increased levels of enzyme called alkaline phosphatase in the blood (test for liver or bone problems)
- Constipation
- Vomiting
- Changes in the ability of blood to clot
- Rash
- Changes in kidney function
- Abdominal pain
- Increased liver enzyme tests (for liver problems)
- Increased levels of enzyme called lactate dehydrogenase
- Decreased platelet counts in blood

TRODELVY can also cause serious side effects, including neutropenia, severe diarrhea, serious infusion-related reactions and severe allergic reactions, which could be life-threatening, as well as nausea and vomiting. Some side effects can be managed before, during, and after treatment.

For those who took TRODELVY in the clinical trial:

- Serious side effects occurred in 44% of patients. The most common serious side effects in ≥5% of patients were infection (18%), low white blood cell counts (neutropenia) (12%), acute kidney injury (6%), urinary tract infections (6%), and blood infections (5%)
- 12% reported mild (did not affect daily activities) to moderate (affected daily activities) symptoms of peripheral neuropathy (damage to the nerves outside of the brain and spinal cord). There were no reports of severe (required hospitalization) to life-threatening peripheral neuropathy
- 10% of patients stopped treatment due to side effects
- 52% of patients had treatment interrupted due to side effects
- Doses were reduced for 42% of patients to help manage side effects

These are not all of the possible side effects of TRODELVY. Tell your healthcare provider about any side effects that bother you or do not go away. Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

STEP 3

Know what to expect on treatment days

When you arrive for your treatment infusion, your healthcare team will:

- Measure your weight
- Take a blood sample
- Perform a short physical
- Put an IV in your arm (unless you already have a port that can be used for the infusion)



Your first infusion of TRODELVY will take about 3 hours. You will be observed during the infusion. If you tolerate the treatment well, the next infusion may only take 1 to 2 hours.



Before each dose, you may be given medicines to help prevent infusion-related reactions, nausea and vomiting, or to help treat diarrhea. These medicines might include fever reducers, antihistamines, and corticosteroids.



After each dose, you will be monitored for side effects for at least 30 minutes. You may be given medicines to take home that can help you manage possible side effects.

Before starting TRODELVY to treat advanced bladder cancer, tell your healthcare provider about any medicines you are taking. Be sure to include prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the way TRODELVY works.

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.

How TRODELVY is given

Treatment cycles repeat every 21 days

You and your healthcare provider will decide how many treatment cycles you receive. This may be based on factors like how well your tumor responds and your ability to tolerate treatment.

This is what a typical dosing schedule will look like:



A TRODELVY dose of **10 mg/kg** is given as an IV



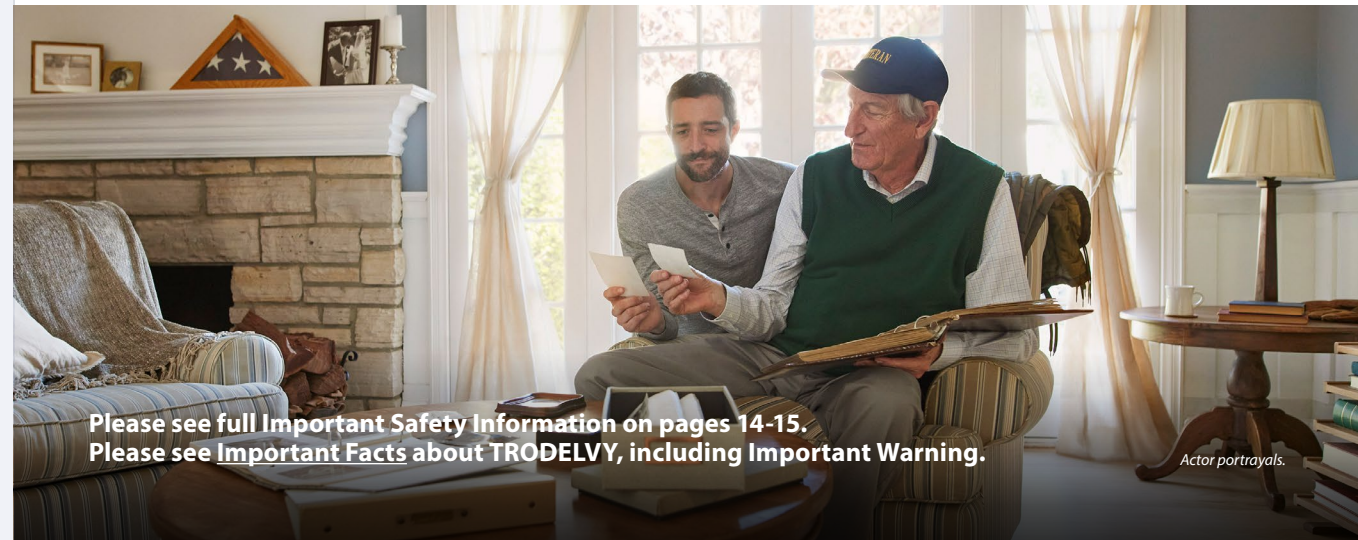
Doses are given once a week for **2 weeks (Day 1 and Day 8)** of 21-day treatment cycles



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

You may be given medicines to take home that can help you manage possible side effects of TRODELVY. When side effects occur, tell your healthcare provider, even if it's something you consider to be minor or personal. It may require medical attention.

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.



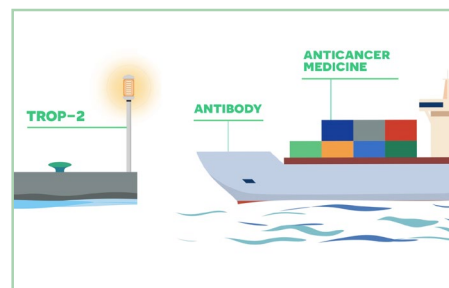
Please see full Important Safety Information on pages 14-15.
Please see Important Facts about TRODELVY, including Important Warning.

STEP 4

Learn how TRODELVY is designed to work

TRODELVY is like a cargo ship

TRODELVY is designed to work differently than traditional chemotherapy. Think of TRODELVY as a cargo ship carrying anticancer medicine.



Every ship needs a dock

Trop-2 is a specific kind of protein found in cells throughout the body. With certain types of cancer, like advanced bladder cancer, tumor cells have a higher amount of Trop-2 than noncancer cells. Trop-2 acts like a beacon, telling the TRODELVY ship to enter the docking area of that specific cell.

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

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.
 - 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.
- 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.

TRODELVY seeks out, breaks in, and destroys

TRODELVY is a type of treatment called an antibody-drug conjugate that is designed to deliver powerful anticancer medicine directly into cells with Trop-2 proteins. Advanced bladder cancer is one type of cancer with tumor cells that contain more Trop-2.



Watch to learn more about 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 like a cargo ship.



STEP 5

Connect with the community around you

Learn from others or share your experience

Whether you're living with advanced bladder cancer or supporting someone who is, you may be taking on responsibilities that each have their own challenges. There may be help for these challenges within your community.

Advanced bladder cancer support groups may provide insight on important questions. How do you bring up difficult topics with a healthcare provider? How can you stay positive when treatment seems overwhelming?

Support groups may help you get started

You don't have to go through this alone

Looking to talk with someone who is also living with advanced bladder cancer? Just want to listen? Willing to share your experience with others? No matter your reason for joining a support group, there is always something to be gained. Take it at your own pace and see what helps you.

Consider the following resources as a place to start:

- **Bladder Cancer Advocacy Network (BCAN):** Advancing bladder cancer research and supporting those impacted by the disease. **Here, you can find:** support line and local support groups
> [bcan.org](https://www.bcan.org)
- **Bladder Cancer Support Line: 833-275-4222.** Connecting those affected by bladder cancer with professional oncology social workers who have specific expertise on emotional, practical, and informational needs of living with bladder cancer. **Here, you can find:** professional oncology social workers, psychosocial support, and free resources for patients and loved ones
> [bcan.org/free-support-line-for-bladder-cancer-patients-and-loved-ones](https://www.bcan.org/free-support-line-for-bladder-cancer-patients-and-loved-ones)
- **Bladder Cancer Matters Podcast:** Getting different perspectives on advanced bladder cancer, host Rick Bangs chats with guests about research, treatment, caregiving, and survivorship. **Here, you can find:** treatment information, interviews with doctors, and real stories
> [bcan.org/bladder-cancer-podcast](https://www.bcan.org/bladder-cancer-podcast)
- **Cancer Care:** Providing free, professional support services for caregivers and loved ones, as well as caregiving information and additional resources. **Here, you can find:** online support groups, books and podcasts, and educational workshops
> [cancercareservices.org](https://www.cancercareservices.org)
- **Cancer Support Community:** Ensuring that all people impacted by cancer are empowered by knowledge, strengthened by action, and sustained by community. **Here, you can find:** local support groups, discussion forums, and private communities
> [cancersupportcommunity.org](https://www.cancersupportcommunity.org) or call 888-793-9355
- **Inspire Online Community:** Connecting patients, families, friends, and caregivers with support and inspiration through online discussion forums. **Here, you can find:** treatment choices, self-advocacy, and metastatic bladder cancer information
> [inspire.com](https://www.inspire.com)

These groups are not controlled or owned by Gilead, and Gilead is not responsible for their content.

Please see full Important Safety Information on pages 14-15.
Please see [Important Facts](#) about TRODELVY, including Important Warning.



Actor portrayals.

STEP

6

Consider your next steps

What's important to you?

No matter what direction you take on your path, think about what you want out of a treatment. If you feel like you aren't getting enough information, say so. Your personal goals and treatment expectations are important to your healthcare team.

Living with other conditions?

Let your healthcare provider know about other conditions you may be managing, medicines you've tried, and any side effects you've experienced. Sharing this information can help you and your healthcare team make decisions throughout your treatment.

FAQs

Have more questions about TRODELVY?

[Click](#) to read some of the most common questions about treating with TRODELVY.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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 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.

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.



This is what
it's all about

Please see full Important Safety Information on pages 14-15.
Please see [Important Facts](#) about TRODELVY, including Important Warning.

WHAT IS TRODELVY?

TRODELVY® (sacituzumab govitecan-hziy) is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract that have spread (metastatic) or cannot be removed by surgery, and who have received a platinum-containing chemotherapy medicine and also received an immunotherapy medicine.

This indication 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 and diarrhea:

- **Low white blood cell count (neutropenia)** which is common and can sometimes be severe and lead to infections that can be life-threatening or cause death. Your healthcare provider should check your blood cell counts during treatment. If your white blood cell count is too low, your healthcare provider may need to lower your dose, 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:** 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 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 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 which 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).

IMPORTANT SAFETY INFORMATION (cont'd)

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 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 or stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

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.
- 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. 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.
- 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 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.

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.

Please see [Important Facts about TRODELVY, including Important Warning](#).



Actor portrayal.



TRODELVY, the TRODELVY logo, GILEAD, and the GILEAD logo are trademarks of Gilead Sciences, Inc., or its related companies. All other marks are the property of their respective owners.

© 2024 Gilead Sciences, Inc. All rights reserved. US-TROC-0412 02/24