

For 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. 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.

I'M CONTINUING TO STAND UP TO ADVANCED BLADDER CANCER



Not actual patients.

Ask your healthcare provider where
TRODELVY may fit into your plan



TRODELVY[™]
sacituzumab govitecan-hziy
180 mg for injection

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.

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IMPORTANT SAFETY INFORMATION

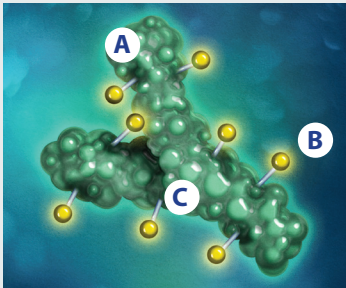
TRODELVY can cause serious side effects, including low white blood cell count and diarrhea:

- **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.

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Please see full Important Safety Information on pages 10-11. Please click to see [Important Facts](#) about TRODELVY, including Important Warning.

TRODELVY IS DESIGNED TO WORK DIFFERENTLY THAN TRADITIONAL CHEMOTHERAPIES



What TRODELVY is made of

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

A. Antibody

Looks for a specific protein, in this case Trop-2, which is found to be overexpressed in many cancers, including bladder cancer

B. Anti-cancer drug

Kills cancer cells once they're found

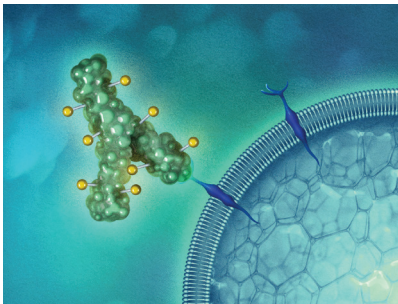
C. Linker

Connects the anti-cancer drug to the antibody

How TRODELVY is thought to attack bladder cancer tumors

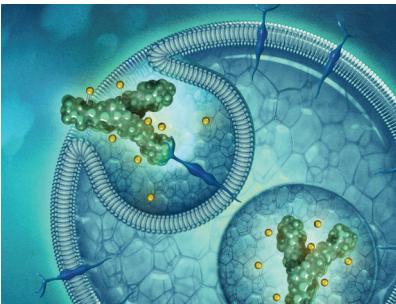
Scientists discovered that patients with advanced bladder cancer have tumor cells that more often contain the Trop-2 protein. TRODELVY binds to cells with Trop-2.

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



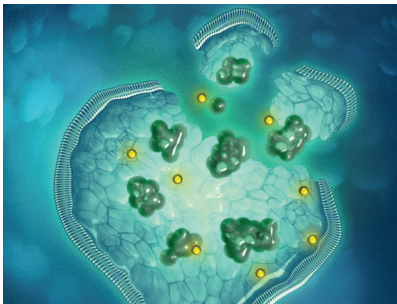
1. Attaches

The antibody in TRODELVY finds and sticks to the Trop-2 protein



2. Penetrates

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



3. Destroys

TRODELVY kills the bladder cancer cells from within

TRODELVY IS THE FIRST ADVANCED BLADDER CANCER TREATMENT TO **TARGET THE TROP-2 PROTEIN**

IMPORTANT SAFETY INFORMATION *(cont'd)*

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TRODELVY CAN HELP SHRINK YOUR TUMORS

- TRODELVY was studied in 112 adults with bladder cancer and cancers of the urinary tract that spread or could not be removed by surgery who had received a platinum-containing chemotherapy medicine and an immunotherapy medicine
- Patients were given TRODELVY 10 mg/kg as an intravenous infusion on Days 1 and 8 of a 21-day treatment cycle

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27.7%

31 OUT OF 112 PATIENTS

SAW THEIR TUMORS SHRINK OR DISAPPEAR

- 5.4% saw their tumors disappear (complete response)
- 22.3% saw their tumors decrease in size by at least 30% (partial response)

7.2 MONTHS

HOW LONG THE RESPONSE TO TREATMENT LASTED IN THOSE THAT RESPONDED

(Median length of response to TRODELVY. The range of response was 1.4+ months to 13.7 months)

+ means that response is ongoing.

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

TRODELVY was studied across a range of patients

- The median age was 66 years (range 33–90 years)
- The majority of patients were male (78%) and White (74%)
- 96% of patients had metastatic disease; 67% had visceral metastases, including 34% with liver metastases
- The median number of prior therapies for advanced cancer was 3 (range 1–8)

IMPORTANT SAFETY INFORMATION (cont'd)


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).

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.


SIDE EFFECTS: WHAT YOU MAY EXPECT

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


The **most common side effects** seen in ≥25% of all the patients were:




Nausea




Diarrhea




Feeling tired or weak




Decreased white blood cell count (neutropenia)




Hair loss




Decreased red blood cell count (anemia)




Vomiting




Constipation



Decreased appetite



Rash



Stomach-area (abdominal) pain or discomfort

TRODELVY can also cause **serious side effects**, including low white blood cell counts called neutrophils (neutropenia), severe diarrhea, serious infusion-related reactions and severe allergic reactions that can be life-threatening, and nausea and vomiting.

- Serious side effects occurred in 44% of patients receiving TRODELVY. The most common serious side effects in ≥5% of patients in the TRODELVY group were infection (18%), low white blood cell counts called neutrophils (12%), acute kidney injury (6%), urinary tract infections (6%), and blood infections (5%)

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

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

10% OF PATIENTS STOPPED TREATMENT DUE TO SIDE EFFECTS

DOSES WERE REDUCED FOR 42% OF PATIENTS TO HELP MANAGE SIDE EFFECTS

Adverse events leading to treatment interruption of TRODELVY occurred in 52% of patients

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.

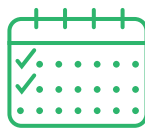
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HOW TRODELVY IS GIVEN



TRODELVY is an intravenous (IV) infusion (10 mg/kg)



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)

WHAT TO EXPECT ON TREATMENT DAYS

Your healthcare provider may recommend the following on treatment days:

- Your weight measured to find the right dose
- 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:

SAMPLE 21-DAY TREATMENT CYCLE

M	T	W	T	F	S	S
1 DOSE 1	2	3	4	5	6	7
8 DOSE 2	9	10	11	12	13	14
15	16	17	18	19	20	21

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 such as whether your tumor has responded to treatment or your body's ability to tolerate treatment.

1 PRE-INFUSION

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

2 INFUSION

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

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

3 OBSERVATION

After each infusion, your healthcare provider will watch you for reactions for at least 30 minutes.

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

Your healthcare provider 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 healthcare provider can best support you.

Before starting TRODELVY, 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.

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PATIENT ACCESS AND REIMBURSEMENT SUPPORT PROGRAM



TRODELVY ACCESS SUPPORT 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 SUPPORT:
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/bladder-cancer/access-support](https://trodelvy.com/bladder-cancer/access-support) for more information.

IMPORTANT SAFETY INFORMATION *(cont'd)*

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

- 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.

QUESTIONS TO ASK YOUR HEALTHCARE PROVIDER

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

- ☐ What is advanced bladder cancer?
- ☐ What treatment options are available for patients with advanced bladder cancer who have received previous treatment?
- ☐ How is TRODELVY different from other treatments?
- ☐ If my cancer has spread (metastatic) or has become advanced (has spread and cannot be removed by surgery), can I take TRODELVY?
- ☐ What side effects could I have with TRODELVY?
- ☐ What tests need to be done before I am given TRODELVY?
- ☐ Will TRODELVY affect other pre-existing health conditions I have?
- ☐ 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?

IMPORTANT SAFETY INFORMATION *(cont'd)*

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- **Severe diarrhea.** Diarrhea is common and can be severe. 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 (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 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).

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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.
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I'M TAKING ON ADVANCED BLADDER CANCER

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Not an
actual patient.

Advanced bladder cancer community support

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

Bladder Cancer Advocacy Network (BCAN): Connect with a community of patients, caregivers, survivors, advocates, and medical and research professionals dedicated to helping people with bladder cancer.
bcan.org

American Cancer Society: Find local cancer support programs and resources.
cancer.org/treatment/support-programs-and-services

Cancer Support Community: Access information, support, and other resources.
cancersupportcommunity.org/bladder-cancer

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MOST IMPORTANT INFORMATION ABOUT TRODELVY

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 - cough
 - burning or pain when you urinate
 - chills
 - shortness of breath
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- 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
 - if you are not able to get your diarrhea under control within 24 hours

ABOUT 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) that has spread to other parts of the body (metastatic) or cannot be removed by surgery, **and** who have previously received two or more prior treatments, including at least one treatment for metastatic disease.
- bladder cancer and cancers of the urinary tract that have spread or cannot be removed by surgery. TRODELVY may be used if you have received a platinum-containing chemotherapy medicine **and** also received an immunotherapy medicine.

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

POSSIBLE SIDE EFFECTS OF TRODELVY

TRODELVY can also cause serious side effects, including:

- **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 an infusion or within 24 hours after:

- swelling of your face, lips, tongue, or throat	- fever
- hives	- difficulty breathing or wheezing
- skin rash, itching, or flushing of your skin	- lightheadedness, dizziness, feeling faint or pass out
	- chills or shaking chills (rigors)

IMPORTANT FACTS

This is only a brief summary of important information about TRODELVY and does not replace talking to your healthcare provider about your condition and your treatment.

POSSIBLE SIDE EFFECTS OF TRODELVY (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.

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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. Before and during treatment with TRODELVY, your healthcare provider will need to do tests to monitor your health. Tell your healthcare provider right away if you have any new symptoms while taking TRODELVY.

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.

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.
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 - 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.
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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.

HOW TO 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 over 3 hours; if well-tolerated, future doses may be given over 1 to 2 hours.
- Before each dose, 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 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 stay on treatment.

GET MORE INFORMATION

This is only a brief summary of important information about TRODELVY. Talk to your healthcare provider or pharmacist to learn more.

To learn more, go to TRODELVY.com or call 1-844-TRODELVY (1-844-876-3358)