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GILEAD | Medical Information

TRODELVY® (sacituzumab govitecan-hziy)

Can TRODELVY be used in HR+/HER2- metastatic breast cancer?

This information is provided in response to your question. It is not treatment advice on how to use TRODELVY. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the TRODELVY Patient Information for more details, including approved use(s) and important warnings. https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_patient_pi.pdf

The short answer[1,2]

In the TROPiCS-02 clinical trial, 543 people with a type of breast cancer, that was hormone receptor-positive (HR+), and human epidermal growth factor receptor 2-negative (HER2-), that had spread to nearby tissue (locally advanced) or other parts of the body (metastatic) and could not be removed by surgery, were treated with either TRODELVY or traditional chemotherapy (a treatment that kills cancer cells or stops them from dividing).

Results of the trial showed that patients lived with no sign of cancer progression, known as progression-free survival, for a median of **5.5 months** when treated with TRODELVY, and **4 months** when treated with chemotherapy. Median progression-free survival is how long half of the people were alive without their cancer getting worse.

Results of the trial also showed that patients lived, with or without their cancer getting worse, known as overall survival, for a median of **14.4 months** when treated with TRODELVY, and **11.2 months** when treated with chemotherapy. Median overall survival is the time at which half of the people were still alive after starting treatment.

The 3 most commonly reported side effects in people treated with TRODELVY in the trial were:

- low levels of white blood cells, also known as **neutropenia**, in 71 out of 100 people who received TRODELVY and in 55 out of 100 people who received chemotherapy.
- loose or watery stools, also known as **diarrhea**, in 62 out of 100 people who received TRODELVY and in 23 out of 100 people who received chemotherapy.
- Feeling sick, also known as **nausea**, in 59 out of 100 people who received TRODELVY and in 35 out of 100 people who received chemotherapy.

What is the most important information I should know about TRODELVY?[1]

Some medicines have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medicine.

TRODELVY has an important warning for: Severe diarrhea and severe, life-threatening, or low white blood cell count (neutropenia) that can cause death, as early as the first treatment cycle.

Your healthcare provider should check your blood cell counts during treatment with TRODELVY and may give a medicine to help prevent low white blood cell count starting in the first cycle of treatment if you have an increased risk for developing low white blood cell count with a fever, also known as febrile neutropenia.

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 fluid, your healthcare provider may need to give you fluids and electrolytes to replace body salts. If you develop diarrhea during treatment with TRODELVY, your healthcare provider should check to see if diarrhea may be caused by an infection.

If you develop serious side effects, your healthcare provider may treat you with certain medicines, delay treatment, lower your dose, or permanently stop treatment with TRODELVY.

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Who is TRODELVY for?[1]

TRODELVY is a prescription medicine used in adults to treat:

- a type of cancer called **hormone receptor (HR) positive and human epidermal growth factor receptor 2 (HER2) negative breast cancer** that has spread to nearby tissues (locally advanced) or to other parts of the body (metastatic)
    - when your HR-positive, HER2-negative breast cancer cannot be removed by surgery and you have received hormonal-based therapy and at least 2 more therapies throughout the body (systemic) for metastatic breast cancer

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

What is HR+/HER2- metastatic breast cancer?[2]

Metastatic breast cancer is where breast cells do not grow normally and form a mass, also called a tumor, that has spread to other parts of the body. A common type of breast cancer, known as being hormone receptor-positive (HR+), has one or two types of hormone receptors on the cell surface, these are estrogen and progesterone receptors. When the same cancer cells lack, or have a low amount of, the human epidermal growth factor 2 (HER2) protein they are also known as being human epidermal growth factor 2-negative (HER2-).

The HR and HER2 receptors can affect how breast cancer cells grow and what treatments may be helpful.

What did the TROPiCS-02 clinical trial tell us?[1,2]

In TROPiCS-02, 543 people with HR+/HER2- breast cancer which was locally advanced, metastatic or could not be removed by surgery were given either TRODELVY or chemotherapy (eribulin, vinorelbine, capecitabine or gemcitabine). A total of 272 people received TRODELVY and 271 people received chemotherapy.

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Everyone in the trial had previously been given, at any point in their disease, at least 1 hormone therapy, at least 1 targeted therapy known as a cyclin-dependent kinase 4/6 inhibitor, and at least 1 chemotherapy known as a taxane. Everyone had already received 2 to 4 chemotherapies for metastatic breast cancer but they did not work well or had stopped working.

TRODELVY was given by infusion into a vein, this is called intravenous or IV therapy, on **day 1** and **day 8** of a 21-day treatment cycle.

People could leave the trial for any reason, including: the tumor grew or spread, they could not handle side effects, decision to stop treatment, or the person died.

How long did people live without their disease getting worse?

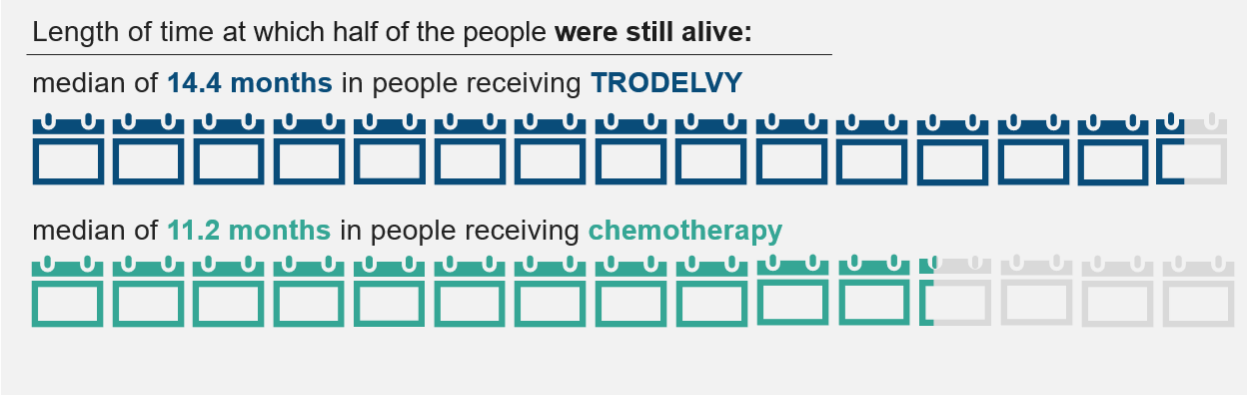
The trial showed that some people who were given TRODELVY lived longer without their disease getting worse, known as progression-free survival, compared to those who were given chemotherapy.



How long did people live with or without their cancer getting worse?

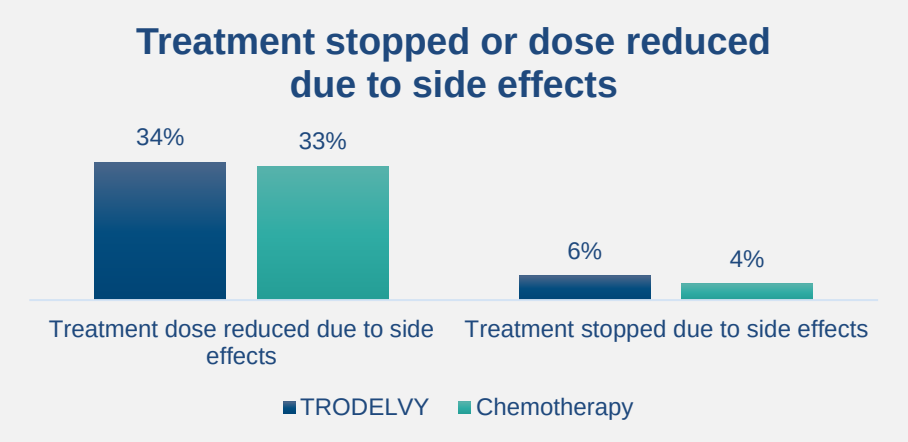
The trial also showed that some people who were given TRODELVY lived longer, with or without their cancer getting worse, known as overall survival.

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What side effects were reported in this trial?

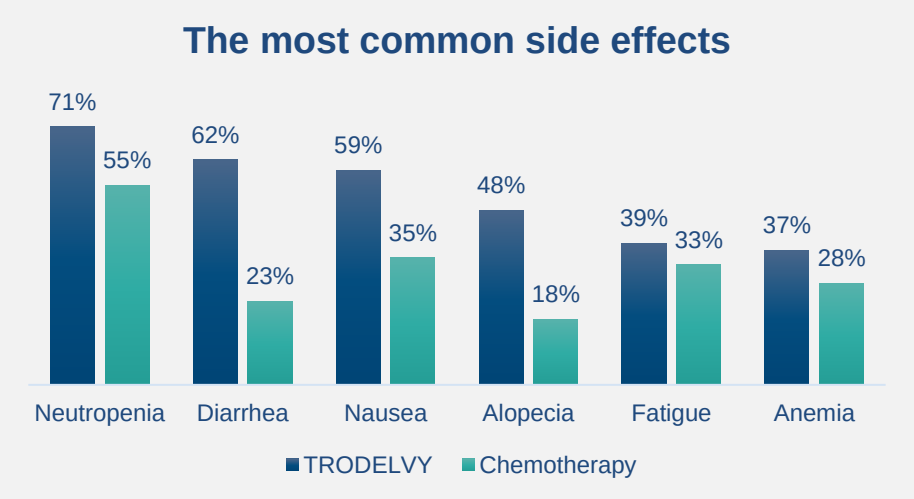
In general, people treated with TRODELVY experienced more side effects than those treated with chemotherapy in the clinical trial. However, the number of people who had their treatment dose reduced or stopped because of side effects was similar in both groups. This means that, while treatment with TRODELVY caused more side effects than treatment with chemotherapy, most people still received their full dose of TRODELVY as planned.



What were the most common side effects in this trial?

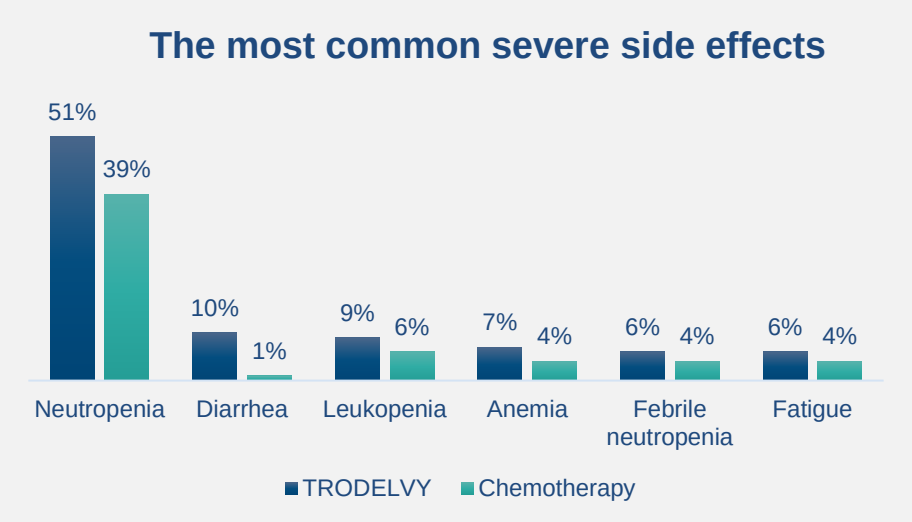
The most common side effects in the clinical trial are summarized below:

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What were the most common severe side effects in this trial?

The most common severe side effects in people who received TRODELVY are summarized below:



What serious side effects have been reported across TRODELVY clinical trials?[1]

The serious side effects listed below are based on what people experienced across several TRODELVY clinical trials. Side effects and their severity can be different for everyone. These are not all of the possible side effects of TRODELVY. Tell your healthcare provider about any side effects you may experience.

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If you develop serious side effects, your healthcare provider may treat you with certain medicines, delay treatment, lower your dose, or permanently stop treatment with TRODELVY.

Low white blood cell count (neutropenia)



Low white blood cell counts can 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 with TRODELVY and may give a medicine to help prevent low white blood cell count 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).



Tell 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

Loose or watery stools (diarrhea)



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 your diarrhea. 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 treatment with TRODELVY, your healthcare provider should check to see if diarrhea may be caused by an infection.



Tell your healthcare provider right away:

- The first time that you get diarrhea during treatment with TRODELVY
- If you develop black or bloody stools
- If you develop symptoms of losing too much body fluid and body salts, such as lightheadedness, dizziness or faintness
- If you cannot take fluids by mouth due to nausea or vomiting
- If you cannot get your diarrhea under control within 24 hours

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Allergic and infusion-related reactions



TRODELVY can cause serious or life-threatening allergic and infusion-related reactions. These reactions are more common within 24 hours of receiving TRODELVY.

Tell your healthcare provider right away if you get any of the following symptoms of an allergic or infusion-related reaction during or at any time after your TRODELVY infusion:



- 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 passing out
- Chills or shaking chills (rigors)
- Chest pain

Nausea and vomiting



Nausea and vomiting can 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.

Tell your healthcare provider right away if you develop nausea or vomiting that is not controlled with the medicines prescribed for you.

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Glossary

- **Allergic reaction:** happens when your body's immune system overreacts to something and causes symptoms such as rash, hives, swelling, and trouble breathing.
- **Alopecia:** hair loss.
- **Anemia:** condition where your body does not have enough healthy blood cells, resulting in less oxygen being carried to your cells.
- **Clinical trial**: a study in people that may help to find out how well a medicine works or how safe it is.
- **Dehydration:** occurs when you use or lose more fluid than you take in, and your body doesn't have enough water and other fluids to carry out its normal functions.
- **Diarrhea**: loose or watery stools.
- **Fatigue**: extreme tiredness and inability to function due to lack of energy.
- **Febrile neutropenia**: a fever while a person has low levels of neutrophils, which may indicate an infection.
- **Hormonal-based therapy**: a type of medicine that works by blocking or changing hormones in your body. It is often used to treat certain cancers, like some breast cancers, that rely on hormones to grow.
- **Hormone Receptor**: a hormone is a substance made by a gland in your body. A receptor is a protein found inside or on the surface of a cell. When hormones attach, or bind, to specific receptors, it causes changes within the cell. There are 2 types of hormone receptors, estrogen, and progesterone.
- **Human epidermal growth factor (HER2) receptor**: HER2 is a protein that can affect cell growth. A receptor is a protein found inside or on the surface of a cell. When proteins attach to specific receptors, it causes changes within the cell.
- **Leukopenia**: a low white blood cell count.
- **Locally advanced**: cancer that has spread to nearby tissues.
- **Median progression-free survival**: how long half of the people were alive without their cancer getting worse.
- **Median overall survival**: the time at which half of the people were still alive after starting treatment.
- **Metastatic**: spread of cancer from the place where it started to other parts of the body.
- **Neutropenia**: low levels of neutrophils, a type of white blood cell.
- **White blood cells**: part of your immune system that help protect you from infections, germs, and other harmful invaders. A low number can reduce your ability to fight infections.

References

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Patient Information. Foster City, CA.
2. Rugo HS, Bardia A, Marmé F, et al. A plain language summary of the TROPiCS-02 study in patients with breast cancer (HR-positive/HER2-negative). *Future Oncol.* 2024;20(11):635-651.

More information about TRODELVY

If you would like more detailed information about TRODELVY, please visit:
https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.pdf

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for TRODELVY. It will tell you about the uses, warnings, and other important safety information about TRODELVY.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for TRODELVY. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of TRODELVY in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:
☎1-866-MEDI-GSI (1-866-633-4474) or https://www.patient.askgileadmedical.com/

Reporting side effects

Please report all adverse events to:
Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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