GILEAD | Medical Information

TRODELVY® (sacituzumab govitecan-hziy)

Can TRODELVY be used in mTNBC?

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 ASCENT clinical trial, 529 people had a type of breast cancer that was hormone receptor-negative (HR-) and human epidermal growth factor receptor 2-negative (HER2-), known as triple-negative breast cancer. The cancer had spread to other parts of the body, known as metastatic or could not be removed by surgery. They were given either TRODELVY or chemotherapy (a treatment that kills cancer cells or stops them from dividing).

Results of the trial showed that people lived with no sign of cancer progression, known as progression-free survival, for a median of **4.8 months** when treated with TRODELVY, and **1.7 months** when treated with chemotherapy.

Results of the trial also showed that people lived, with or without their cancer getting worse, known as overall survival, for a median of **11.8 months** when treated with TRODELVY, and **6.9 months** when treated with chemotherapy.

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 63 out of 100 people who were given TRODELVY and in 43 out of 100 people who were given chemotherapy.

- loose or watery stools, also known as **diarrhea**, in 59 out of 100 people who were given TRODELVY and in 12 out of 100 people who were given chemotherapy.
- feeling sick, also known as **nausea**, in 57 out of 100 people who were given TRODELVY and in 26 out of 100 people who were given 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 or life-threatening low white blood cell count (neutropenia) as early as the first treatment cycle. Your healthcare provider should check your blood cell counts during treatment. You may receive a medicine 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 during treatment with TRODELVY and check to see if it is caused by an infection. You may be given a medicine to help control your diarrhea.

If your white blood cell count is too low or your diarrhea is severe and cannot be controlled with medicines, your healthcare provider may lower your dose of TRODELVY, delay your treatment, or permanently stop treatment.

Who is TRODELVY for?[1]

TRODELVY is a prescription medication used to treat adults with:

- a type of breast cancer called **metastatic triple-negative breast cancer (mTNBC)**

  TRODELVY may be used:
  - when your breast cancer has spread to other parts of the body, known as metastatic, or cannot be removed by surgery, **and**
  - if you previously received two or more prior treatments, including at least one treatment for metastatic disease.

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

What is metastatic triple-negative breast cancer (mTNBC)?[1]

Metastatic breast cancer is a disease where breast cells do not grow normally and form a mass, or a tumor, that has spread to other parts of the body. Triple-negative breast cancer is cancer that starts forming in breast tissue and does not have estrogen receptors, progesterone receptors, or low to no HER2 protein on the surface of the cancer cells. All of these receptors can affect how breast cancer cells grow and what treatments may be helpful.

What did the ASCENT clinical trial tell us?[1,2]

In ASCENT, 529 people with TNBC that was metastatic or could not be removed by surgery were given either TRODELVY or chemotherapy, either eribulin, vinorelbine, capecitabine, or gemcitabine. There were 267 people who were given TRODELVY and 262 people that were given chemotherapy.

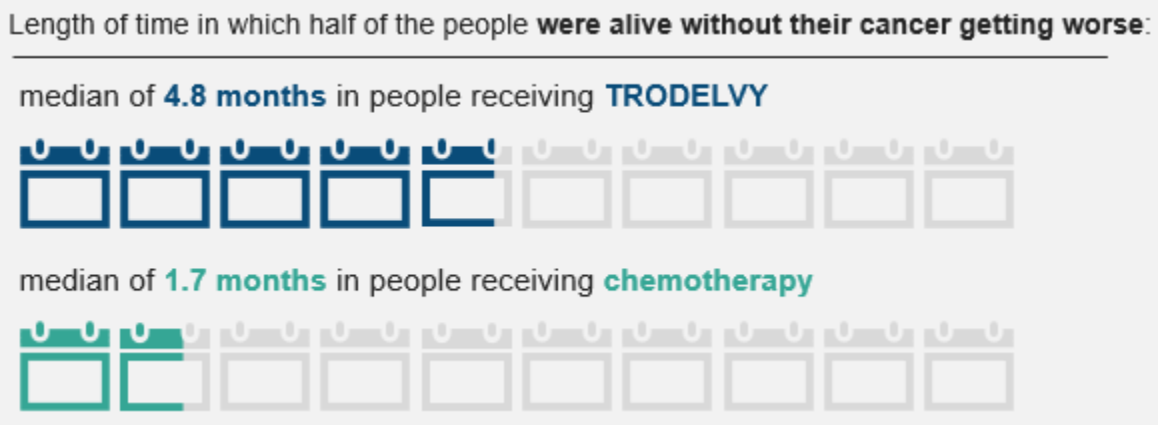
Everyone in the trial had previously been given at least 2 chemotherapies, one of them had to be a taxane. These treatments did not work well or had stopped working.

TRODELVY was given by infusion into the vein, also called intravenous or IV therapy, on **day 1 and day 8** every 21 days.

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

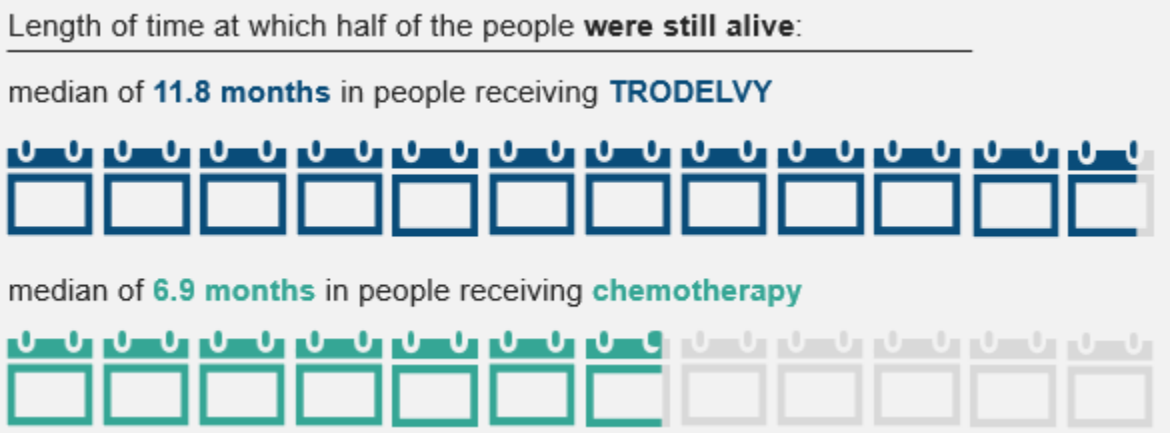
How long did people live without their cancer getting worse?

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



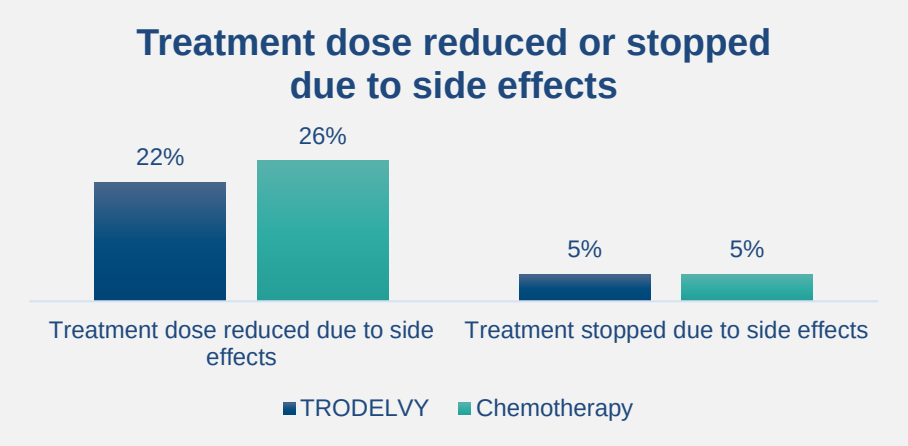
How long did people live with or without their cancer getting worse?

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



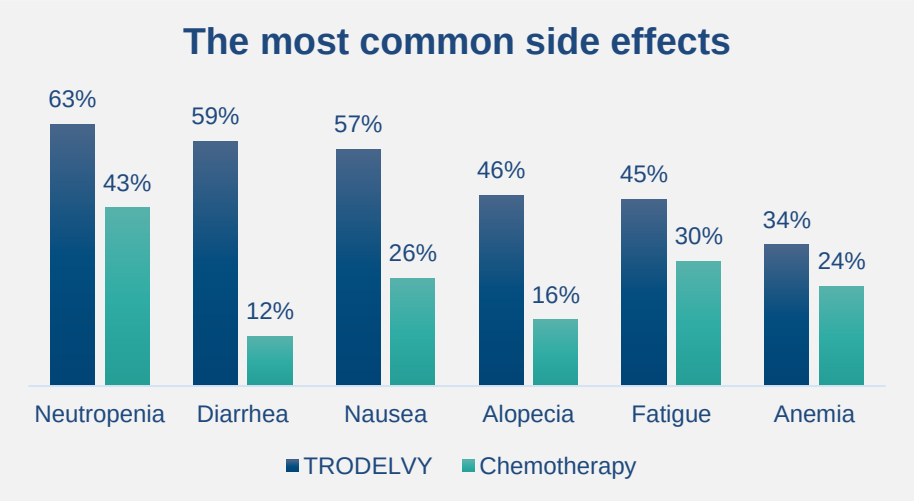
What side effects were reported in this trial?

Side effects were experienced in 98 out of 100 people who were given TRODELVY and in 86 out of 100 people who were given chemotherapy. 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.



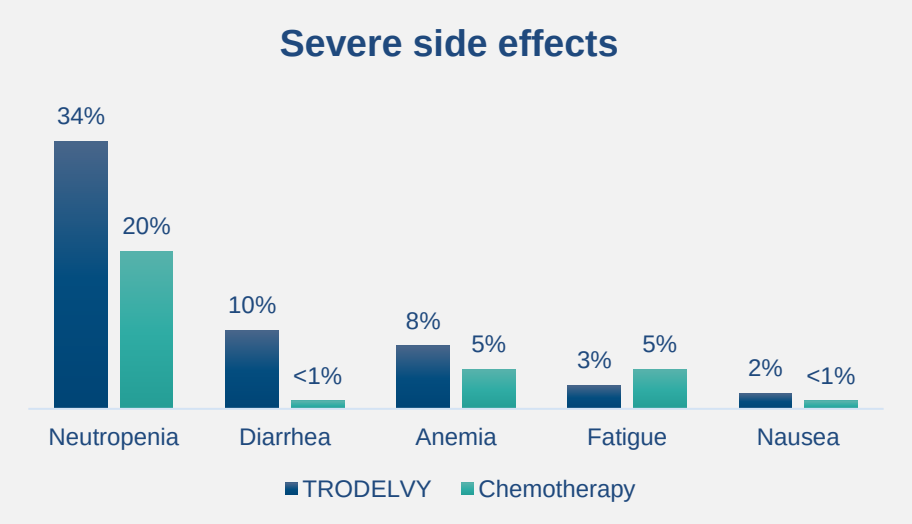
What were the most common side effects in this trial?

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



What were the severe side effects in this trial?

The severe side effects in people who were given 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.

Low white blood cell count (neutropenia)

Low levels of white blood cells are common with TRODELVY 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 with TRODELVY and may give you a medicine to help prevent low 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).

If your white blood cell count is too low, your healthcare provider may need to delay treatment or lower your dose of TRODELVY, give you a medicine called granulocyte-colony stimulating factor, also known as growth factors, to treat your 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 a fever while your white blood cell count is low.

Call your healthcare provider or nurse right away if you develop any of the following signs of infection:

- Fever
- Chills
- Cough
- Feeling short of breath
- Burning or pain when you urinate

Loose or watery stools (diarrhea)

Diarrhea is common with TRODELVY and can also be severe. Severe diarrhea can lead to the loss of too much body fluid, known as 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 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. 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 like loperamide (IMODIUM®) or similar.

Call your healthcare provider or nurse 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 and body salts, such as feeling lightheaded, feeling dizzy or feeling faint
- If you are unable to take fluids by mouth due to feeling sick or being sick
- If you are not able to get your diarrhea under control within 24 hours

Allergic and infusion-related reactions

TRODELVY can cause serious or life-threatening allergic and infusion-related reactions.

Tell your healthcare provider or nurse right away if you get any of the following symptoms of an allergic or infusion-related reaction during your 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, itching, or flushing of your skin
- Fever
- Difficulty breathing or wheezing
- Lightheadedness, dizziness, feeling faint or passing out
- Chills or shaking chills (rigors)

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 are given 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, delay treatment, or permanently stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

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.
- low levels of red blood cells which cause tiredness and pale skin.
- **Clinical trial**: a study in people that may help to find out how well a medicine works or how safe it is.

- **Fatigue**: extreme tiredness and inability to function due to lack of energy
- **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.
- **Infusion-related reaction**: reaction during or following infusion of a medicine.
- **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.

References

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. Bardia A, Hurvitz SA, Rugo HS, et al. A plain language summary of the ASCENT study: sacituzumab govitecan for metastatic triple-negative breast cancer. *Future Oncol*. Sep 1 2021;17(30):3911-3924.

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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