GILEAD | Medical Information

TRODELVY® (sacituzumab govitecan-hziy)

Can TRODELVY be used alone to treat 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[1-3]

In the **ASCENT-03** clinical trial, 558 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 (TNBC) that had spread to nearby tissues (locally advanced) or to other parts of the body (metastatic), and could not be removed by surgery. Either TRODELVY or chemotherapy, a treatment that kills cancer cells or stops them from dividing, were given as the first treatment in the metastatic setting to people who were not candidates for medicines called PD-1 or PD-L1 inhibitors.[3]

PD-L1 is a protein that is present on some people's tumors, and that can be targeted by specific medications called anti-PD-1 or anti-PD-L1 treatments.

Results of the trial showed that people lived with no sign of cancer progression, known as progression-free survival, for a median of **9.7 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 ASCENT-03 trial were:

- low levels of white blood cells, also known as **neutropenia**, in 67 out of 100 people who were given TRODELVY and in 57 out of 100 people who were given chemotherapy
- feeling sick, also known as **nausea**, in 61 out of 100 people who were given TRODELVY and in 34 out of 100 people who were given chemotherapy
- hair loss, also known as alopecia, in 55 out of 100 people who were given TRODELVY and in 27 out of 100 people who were given chemotherapy.

In the **ASCENT** clinical trial, 529 people had TNBC that had spread to other parts of the body or could not be removed by surgery. These people were chosen at random to receive either TRODELVY or chemotherapy. Everyone had already received 2 different chemotherapies, but they had stopped working.[2]

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.[2]

The 3 most commonly reported side effects in people treated with TRODELVY in the ASCENT trial were[2,3]:

- 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, 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.

Who is TRODELVY for?[1]

TRODELVY is a prescription medicine used in adults to treat:

- a type of cancer called **triple-negative breast cancer (TNBC)** which is estrogen and progesterone hormone receptor (HR)-negative and human epidermal growth factor receptor 2 (HER2)-negative that has spread to nearby tissues (locally advanced) or to other parts of the body (metastatic)

As the first treatment:

- alone when your TNBC cannot be removed by surgery and you are not a candidate for PD-1 or PD-L1 inhibitor-based therapy

As the second or later treatment:

- after you have received 2 or more prior therapies throughout the body (systemic) for TNBC that cannot be removed by surgery and at least 1 of the therapies was for metastatic TNBC.

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. TNBC 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-03 clinical trial tell us?[3]

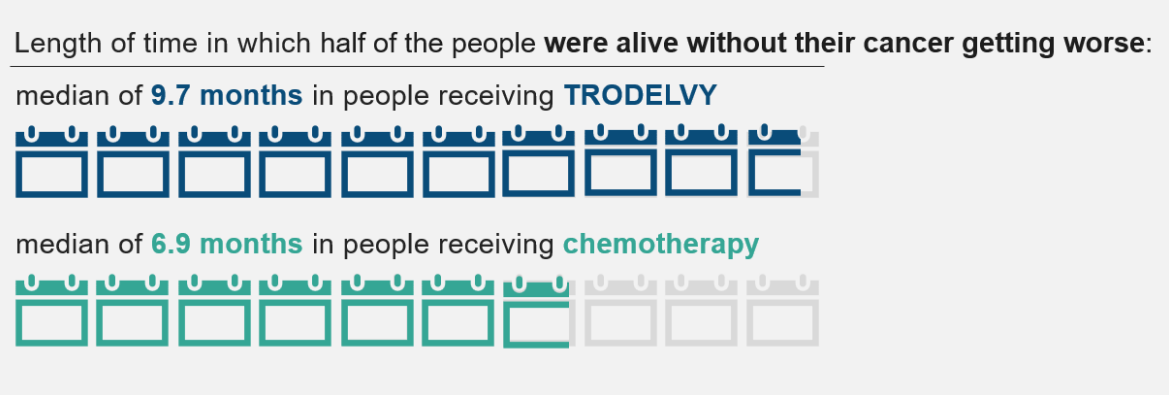
ASCENT-03 included 558 people with TNBC that had spread to nearby tissues (locally advanced) or to other parts of the body (metastatic) and could not be removed by surgery. In the trial, either TRODELVY or chemotherapy were given as the first treatment in the metastatic setting to people who were not candidates for medicines called PD-1 or PD-L1 inhibitors. There were 279 people who were given TRODELVY and 279 people who were given chemotherapy, either paclitaxel, nab-paclitaxel, or gemcitabine and carboplatin.

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?

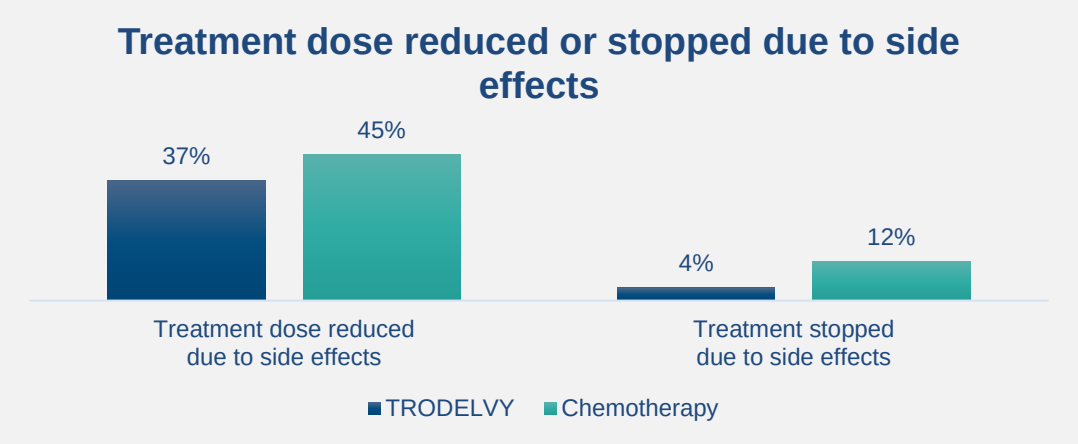
The trial showed that some people who were given TRODELVY lived longer without their cancer getting worse, known as progression-free survival, compared to those who were given chemotherapy.



What side effects were reported in this trial?

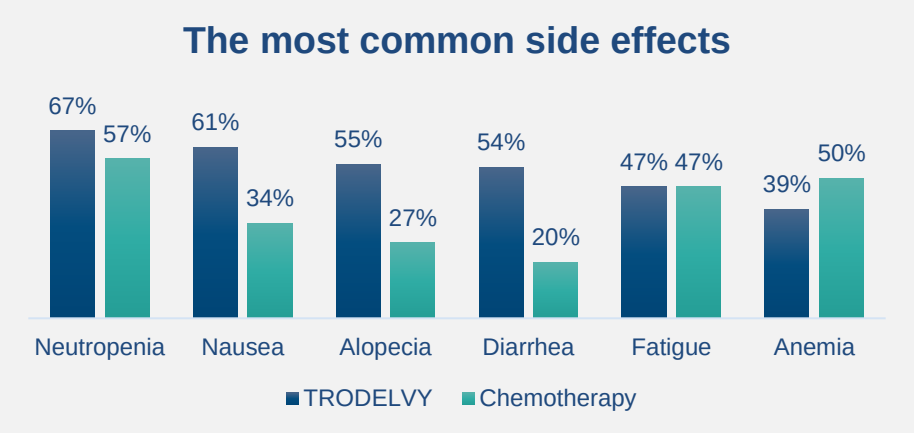
Side effects were experienced in 99 out of 100 people who were given TRODELVY and in 97 out of 100 people who were given chemotherapy.

Less people who had been given TRODELVY had their treatment dose reduced or their treatment stopped because of side effects compared to people who had been given chemotherapy. 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.



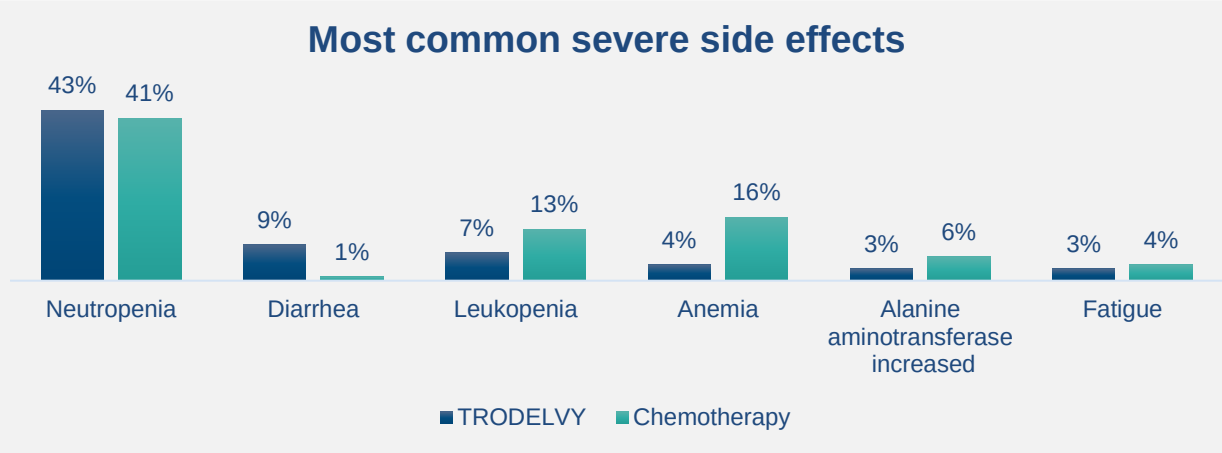
What were the most common side effects in this trial?

The most common side effects in the ASCENT-03 clinical trial are summarized below:



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

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



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.

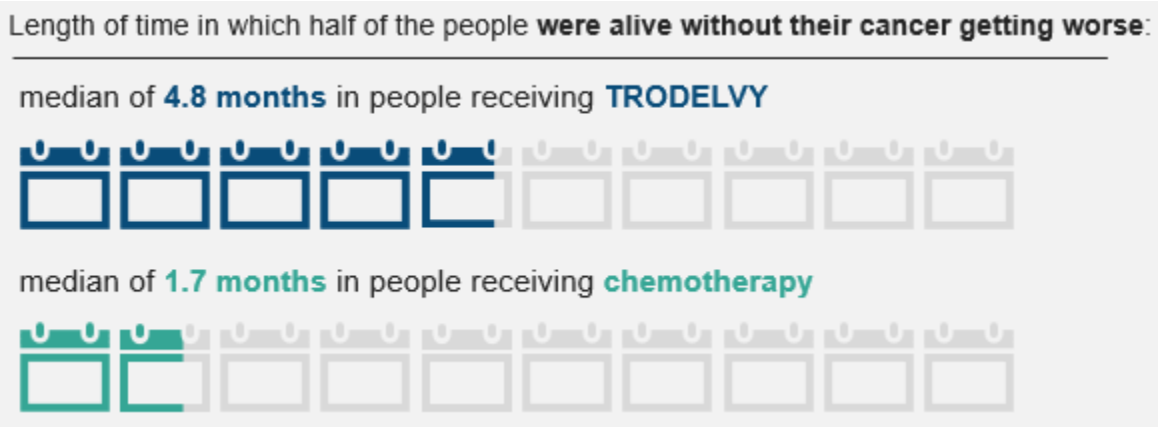
Everyone in the trial had previously been given at least 2 chemotherapies, one of them had to be a taxane. These treatments did not work well or had stopped working.

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.

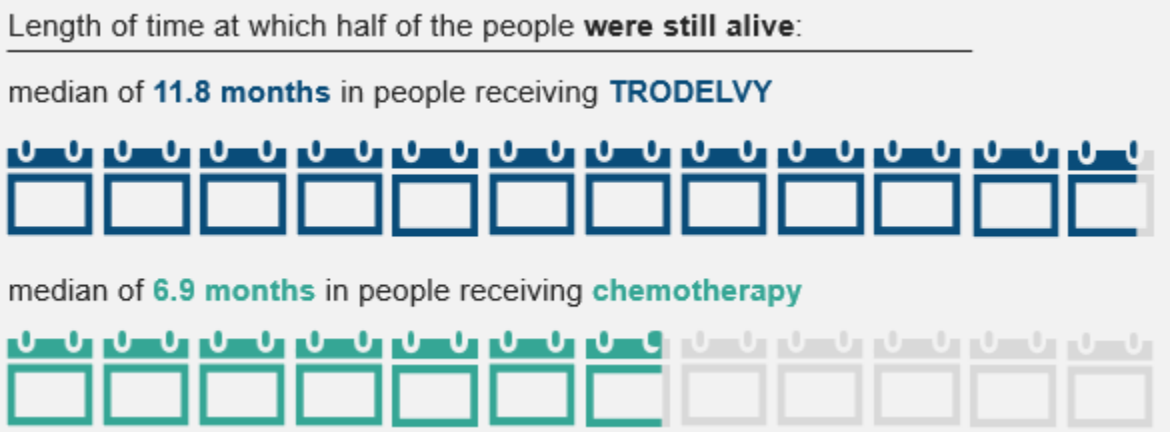
How long did people live without their cancer getting worse?

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.



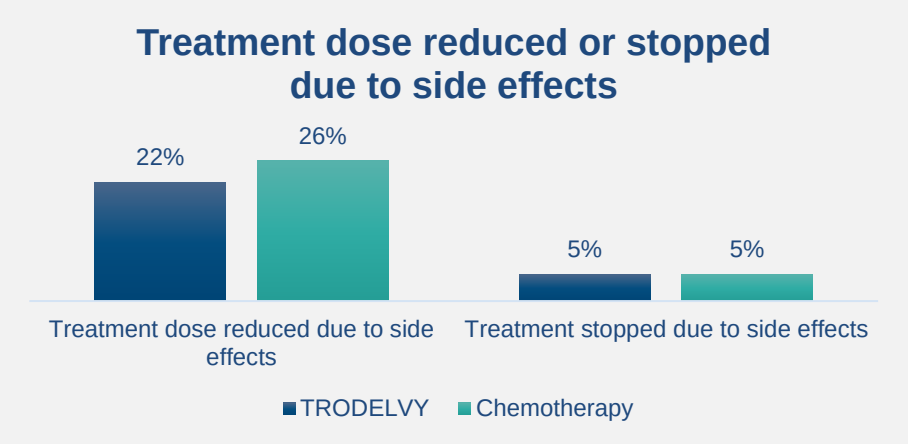
How long did people live with or without their cancer getting worse?

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



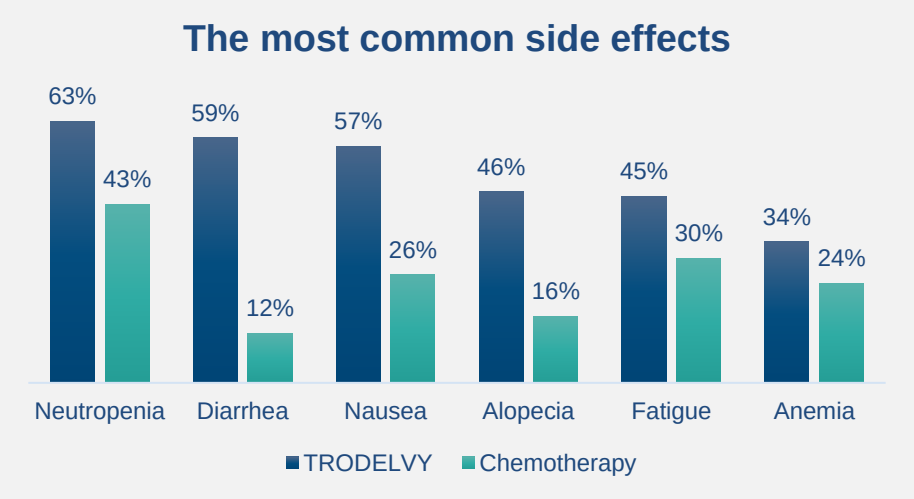
What side effects were reported in this trial?

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.



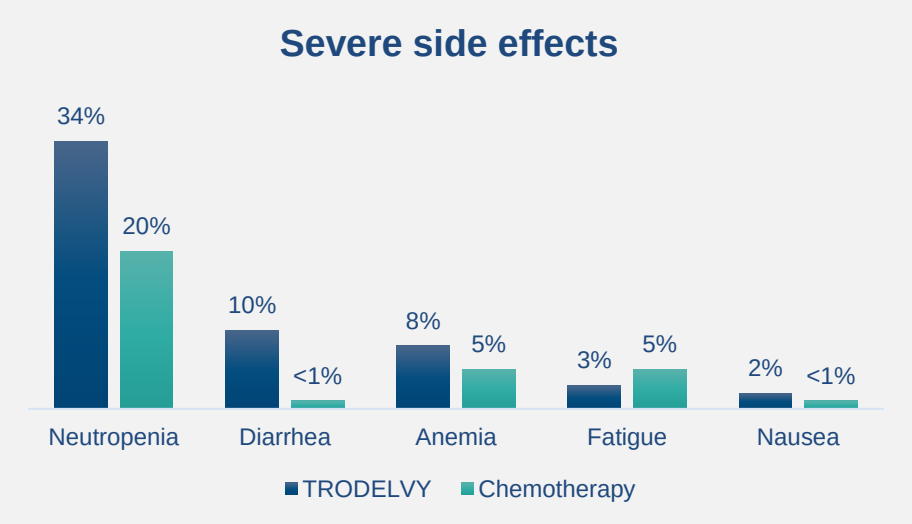
What were the most common side effects in this trial?

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.

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, 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 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

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.

Glossary

- **Alanine aminotransferase:** an alanine aminotransferase test, also called an ALT test, is a blood test to check the health of your liver.
- **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.
- **Chemotherapy**: a treatment that kills cancer cells or stops them from dividing.
- **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
- **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
- **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.
- **PD-L1**: a protein that is present on some people's tumors, and that can be targeted by specific medications called anti-PD-1 or anti-PD-L1 treatments.
- **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. 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*. 2021;17(30):3911-3924.
3. Cortés J, Punie K, Barrios C, et al. Sacituzumab govitecan in untreated, advanced triple-negative breast cancer. *N Engl J Med*. 2025;393(19):1912-1925.

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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