# TRODELVY™ (sacituzumab govitecan-hziy) FACT SHEET

## ABOUT TRODELVY


TRODELVY is the first antibody-drug conjugate (ADC) approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who received at least two prior therapies for metastatic disease.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

TNBC is an aggressive form of breast cancer with limited treatment options and poor prognosis. TNBC cells do not have estrogen receptors, progesterone receptors or human epidermal growth factor receptor 2 – hence the term triple negative. This means that medicines that target these receptors are not typically effective in TNBC.

## HOW TRODELVY WORKS

TRODELVY is an ADC. ADCs combine three components:

- an antibody, to direct delivery of the cancer-killing therapy;
- a linker, which joins (conjugates) the antibody and anti-cancer drug; and
- an anti-cancer drug, or cytotoxic payload, which is most often a chemotherapy drug.

TRODELVY uses an antibody directed to the protein Trop-2, which is found in approximately 90% of TNBC tumors **and several other types of cancers**. This antibody directs delivery of the anti-cancer drug SN-38 inside a tumor cell. SN-38 is a active metabolite of a commonly used chemotherapy agent. Once inside the tumor, the novel linker, which connects the antibody and anti-cancer drug, breaks down and releases SN-38 to kill tumor cells.

## CLINICAL TRIAL RESULTS

TRODELVY, which was previously granted Breakthrough Therapy Designation, was approved under the FDA's Accelerated Approval pathway based on the objective response rate (ORR) and duration of response (DoR) observed in an open-label, single-arm, multicenter Phase 2 study. The results of the study were also published in the *New England Journal of Medicine* (NEJM).

Study details included:

| PATIENT POPULATION | TREATMENT | OUTCOMES |
|---|---|---|
| **Efficacy data from 108 patients with mTNBC**<br>• mTNBC confirmed on most recent biopsy<br>• Received ≥ 2 prior treatments for metastatic disease<br><br>**Safety data from 408 patients**<br>• All patients had advanced solid tumors | **TRODELVY**<br>• 10 mg/kg intravenously on Days 1 and 8 of a 21-day cycle until disease progression or intolerance to the therapy | **Major efficacy outcomes**<br>• Investigator assessed ORR<br>• Investigator assessed DoR |

In the study, TRODELVY showed:

- An **overall response rate of 33.3%** (95% confidence interval, 24.6, 43.1), as determined by local assessment in 108 heavily pre-treated patients with mTNBC
    - Overall response rate is the percentage of people with a complete or partial response, defined as 30% or more tumor shrinkage following treatment
- A **median duration of response of 7.7 months** (95% confidence interval, 4.6 to 11.3), among 36 responders

Serious adverse reactions include severe neutropenia and severe diarrhea. The most common adverse reactions (incidence >25%) in patients with mTNBC were nausea, neutropenia, diarrhea, fatigue, anemia, vomiting, alopecia, constipation, decreased appetite, rash and abdominal pain. Two percent of patients permanently discontinued due to adverse events. See Important Safety Information including boxed Warning on the next page.

## INIDCATION AND IMPORTANT SAFETY INFORMATION

**TRODELVY can cause serious side effects, including:**

- **Low white blood cell count (neutropenia).** Low white blood cell counts are common with TRODELVY and can sometimes be severe and lead to infections that can be life-threatening. Your healthcare provider should check your blood cell counts during treatment with TRODELVY. If your white blood cell count is too low, your healthcare provider may need to lower your dose of TRODELVY, 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 during treatment with TRODELVY:** fever, chills, cough, shortness of breath, or burning or pain when you urinate.

- **Severe diarrhea.** Diarrhea is common with TRODELVY and can also be severe. 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 fluids (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 the diarrhea 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 losing too much body fluid (dehydration) and body salts, 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.

**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 uridine diphosphate-glucuronosyl transferase A1 (UGT1A1)*28. People who carry this gene have an increased risk of getting side effects with TRODELVY, especially low white 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.
    - 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.

**TRODELVY can cause serious side effects, including:**

- See "**TRODELVY can cause serious side effects"** above for information about low white blood cell count and diarrhea.
    - **Severe and life-threatening allergic reactions.** TRODELVY can cause severe and life-threatening allergic reactions during infusion (infusion-related reactions). Tell your healthcare provider or nurse right away if you get any of the following symptoms of an allergic reaction during an 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 or flushing of your skin; difficulty breathing or wheezing; lightheadedness, dizziness, feeling faint, or pass out; chills or shaking chills (rigors); or fever.
- **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 receive 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 or stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

The most common side effects of TRODELVY also include tiredness, decreased red blood cell count, hair loss, constipation, rash (See **"Severe and life-threatening allergic reactions"** above), decreased appetite and stomach-area (abdomen) pain.

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.

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.

Please see full Prescribing information, including **Boxed Warning**, and **Patient information** at accessdata.fda.gov.

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