TRODELVY® (sacituzumab govitecan-hziy) is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

**IN mTNBC:**

**EXPANDED INDICATION FOR TRODELVY AS EARLY AS 2L IN THE METASTATIC SETTING**

**IMPORTANT SAFETY INFORMATION**

**BOXED WARNING: NEUTROPENIA AND DIARRHEA**

- Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm³ or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.

- Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.

**CONTRAINDICATIONS**

- Severe hypersensitivity reaction to TRODELVY.

**WARNINGS AND PRECAUTIONS**

**Neutropenia:** Severe, life-threatening, or fatal neutropenia can occur and may require dose modification. Neutropenia occurred in 61% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 47% of patients. Febrile neutropenia occurred in 7%. Withhold TRODELVY for absolute neutrophil count below 1500/mm³ on Day 1 of any cycle or neutrophil count below 1000/mm³ on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

Please see full Important Safety Information throughout. Please see full Prescribing Information, including BOXED WARNING.
**TRODELVY RESPONDS TO THE UNMET NEED FOR PHASE 3 SURVIVAL DATA IN PRETREATED mTNBC**

**ASCENT was a landmark, phase 3, randomized, open-label, active-controlled trial (N=529) that studied the use of TRODELVY vs single-agent chemotherapy**

- **Patient population**
  - Patients with unresectable locally advanced or mTNBC who had relapsed after at least 2 prior chemotherapies for breast cancer
  - One of which could be in the neoadjuvant or adjuvant setting provided progression occurred within a 12-month period

- **TRODELVY 10 mg/kg IV on Days 1 and 8 of a 21-day cycle (n=267)**
  - **Continue until disease progression or unacceptable toxicity**

- **Single-agent chemotherapy (n=262)**
  - **Patients with brain metastases were allowed to enroll up to a predefined maximum of 15% of patients in the ASCENT trial**
  - **Magnetic resonance imaging (MRI) to determine brain metastases was required prior to enrollment for patients with known or suspected brain metastases.**
  - **Patients with known Gilbert’s disease or bone-only disease were excluded.**
  - **Patients with brain metastases were allowed to enroll up to a predefined maximum of 15% of patients in the ASCENT trial; magnetic resonance imaging (MRI) was not required for patients with known or suspected brain metastases.**

**Importantly Safety Information (cont’d) – Warnings and Precautions**

**Diarrhea**: Diarrhea occurred in 65% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 12% of patients. One patient had intestinal perforation following diarrhea. Neutropenic colitis occurred in 0.5% of patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

**Patient Demographics and Baseline Characteristics**

- **Demographics and baseline characteristics in the full population**
  - Median age of 54 years (range: 27–82 years)
  - 81% <65 years
  - 99.6% female
  - 79% White; 12% Black/African American
  - 29% of patients had received prior PD-1/PD-L1 therapy
  - Patients included 42% with hepatic metastases (visceral disease), 12% with brain metastases (previously treated and stable), and 9% with BRCA1/BRCA2 mutational status positive
  - ECOG performance status of 0 (43%) or 1 (57%)

- **~1 out of 8 patients (13%) in the TRODELVY group in the full population received only 1 prior line of systemic therapy in the metastatic setting.**
  - Efficacy results in this subgroup were consistent with those who received at least 2 prior lines in the metastatic setting.

- **88% of patients in the full population were BM-negative**
  - 12% had baseline brain metastases previously treated and stable (n=61; 32 on TRODELVY arm and 29 on single-agent chemotherapy arm)

**The primary analysis was in the BM-neg population (TRODELVY, n=235, and single-agent chemotherapy, n=233)**

- **Primary endpoint**
  - Median PFS in BM-neg population by BICR based on RECIST 1.1 criteria

- **Select secondary endpoints**
  - Median PFS in the full population
  - Median OS in both the BM-neg and full populations
  - Objective Response Rate (ORR)

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**Hypersensitivity and Infusion-Related Reactions**: Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 4% of patients and 37% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.3%. The incidence of anaphylactic reactions was 0.3%. Pre-infusion medication is recommended. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Medication to treat such reactions, as well as emergency equipment, should be available for immediate use. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

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Please see full Important Safety Information throughout. Please see full Prescribing Information, including BOXED WARNING.
For adult patients with unresectable locally advanced or mTNBC who have received 2 or more prior systemic therapies, at least one of them for metastatic disease, TRODELVY demonstrated

**3X LONGER MEDIAN PFS VS SINGLE-AGENT CHEMOTHERAPY**

88% of patients in the full population were BM-neg, and PFS and OS results were statistically significant across both the BM-neg and full populations.

In patients without brain metastases

**MEDIAN OS OF 1 YEAR WITH TRODELVY**

Statistically significant results were demonstrated vs patients treated with single-agent chemotherapy across both the BM-neg and full populations.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

**Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity:** Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of Grade 3-4 neutropenia was 67% in patients homozygous for the UGT1A1*28 allele and 46% in patients heterozygous for the UGT1A1*28 allele. The incidence of Grade 3-4 anemia was 25% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 11% in patients homozygous for the wild-type allele.

Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

Please see full Important Safety Information throughout. Please see full Prescribing Information, including BOXED WARNING.
For adults with unresectable locally advanced or mTNBC who have received 2 or more prior systemic therapies, at least one of them for metastatic disease

**ORR OF TRODELVY VS SINGLE-AGENT CHEMOTHERAPY**

<table>
<thead>
<tr>
<th>Adverse reactions</th>
<th>TRODELVY (n=258)</th>
<th>Grades 3–4 (%)</th>
<th>Single-agent chemotherapy* (n=224)</th>
<th>Grades 3–4 (%)</th>
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<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
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<tr>
<td>Neutropenia</td>
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<td>Anemia</td>
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<td>Lymphopenia</td>
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<td>Gastrointestinal disorders</td>
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<td>Diarrhea</td>
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<td>Nausea</td>
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<tr>
<td>Vomiting</td>
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<td>General disorders and administration site conditions</td>
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<td>Infections and infestations</td>
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</table>

**IMPORTANT SAFETY INFORMATION (cont’d)**

**WARNINGS AND PRECAUTIONS**

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

ADVERSE REACTIONS

In the ASCENT study (IMMU-132-05), the most common adverse reactions (incidence ≥25%) were fatigue, neutropenia, diarrhea, nausea, alopecia, anemia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent serious adverse reactions (SAR) (≥1%) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR were reported in 27% of patients, and 5% discontinued therapy due to adverse reactions. The most common Grade 3–4 lab abnormalities (incidence ≥25%) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.

**DRUG INTERACTIONS**

**UGT1A1 Inhibitors**: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

**UGT1A1 Inducers**: Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

Please see full Important Safety Information throughout. Please see full Prescribing Information, including BOXED WARNING.
TRODELVY IS THE FIRST AND ONLY TROP-2–DIRECTED ADC WITH A PROVEN SURVIVAL BENEFIT IN mTNBC¹

For adult patients with unresectable locally advanced or mTNBC who have received 2 or more prior systemic therapies, at least one of them for metastatic disease

In ASCENT, a landmark, phase 3, randomized, open-label, active-controlled trial, TRODELVY demonstrated:²⁻³

In BM-neg population

- 3X LONGER MEDIAN PFS vs single-agent chemotherapy
  - 5.6 months with TRODELVY (range: 4.3–6.3) (n=235) vs 1.7 months with single-agent chemotherapy (range: 1.5–2.5) (n=233); 95% CI, HR: 0.41 (0.32–0.52) P<.0001

- 1 YEAR MEDIAN OS
  - 12.1 months with TRODELVY (range: 10.7–14.0) (n=235) vs 6.7 months with single-agent chemotherapy (range: 5.8–7.7) (n=233); 95% CI, HR: 0.48 (0.38–0.59) P<.0001

88% of patients in the full population were BM-neg¹ and results were similar across both groups²

See study design and results for the full population on pages 2–5.

NEW INDICATION AS EARLY AS 2L IN THE METASTATIC SETTING

for patients who have received 2 or more prior systemic therapies, at least one of them for metastatic disease

THE ABILITY TO OFFER PATIENTS AN EARLIER OPTION

- 13% of patients in the TRODELVY group in the full population received only 1 prior line of systemic therapy in the metastatic setting,* and efficacy results in this subgroup were consistent with those who received at least 2 prior lines in the metastatic setting¹

*In addition to having disease recurrence or progression within 12 months of neoadjuvant/adjuvant systemic therapy.

INDICATION

TRODELVY® (sacituzumab govtcenc-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm³ or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.

- Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.

WARNINGS AND PRECAUTIONS include neutropenia, diarrhea, hypersensitivity and infusion-related reactions, nausea and vomiting, increased risk of adverse reactions in patients with reduced UGT1A1 activity, and embryo-fetal toxicity.

The most common adverse reactions in ASCENT (≥25%) were fatigue, neutropenia, diarrhea, nausea, alopecia, anemia, constipation, vomiting, abdominal pain, and decreased appetite.


Please see full Important Safety Information throughout. Please see full Prescribing Information, including BOXED WARNING.

EXPLORE MORE POSSIBILITIES. VISIT TRODELVYHCP.COM.