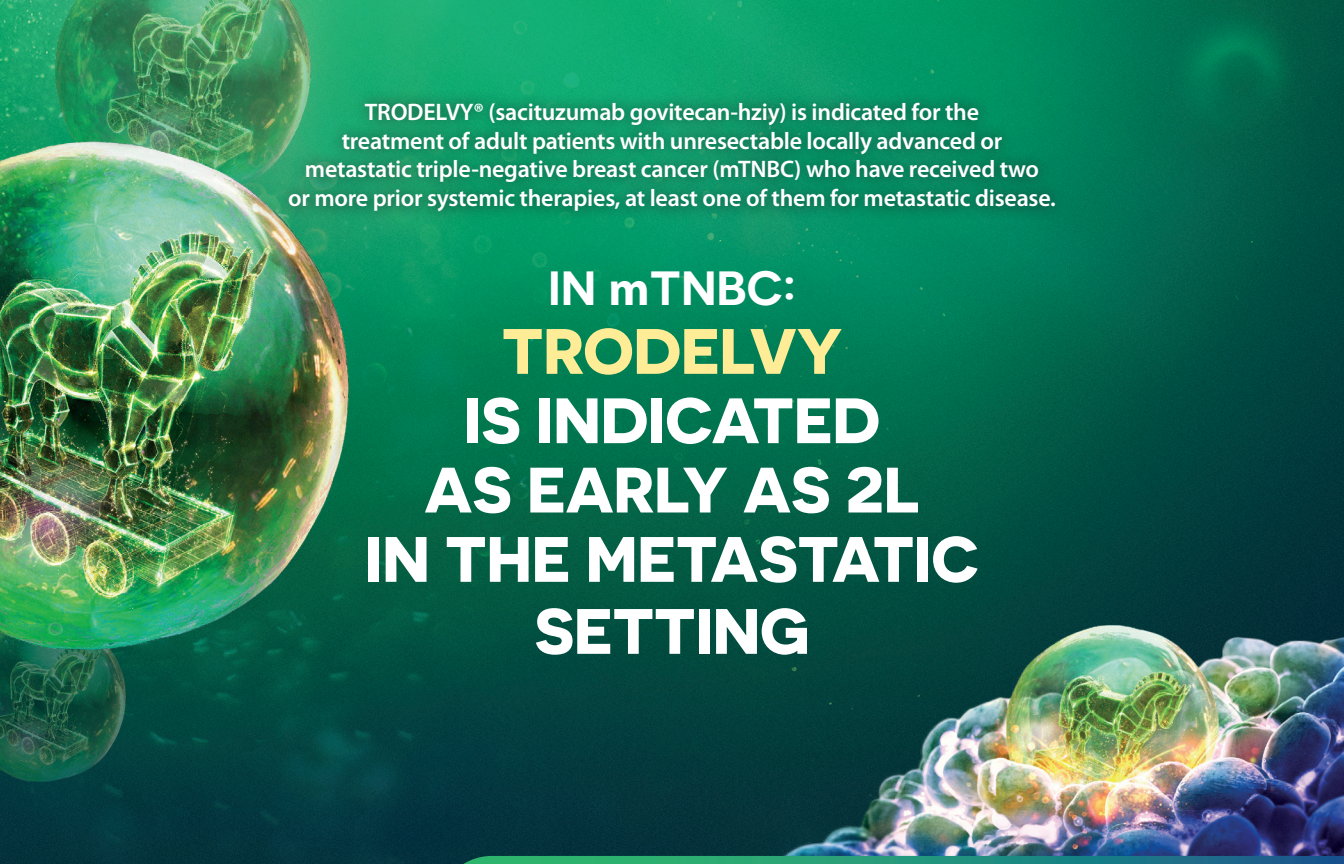

TRODELVY® (sacituzumab govitecan-hziy) is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

IN mTNBC: TRODELVY IS INDICATED AS EARLY AS 2L IN THE METASTATIC SETTING

SEE LANDMARK, PHASE 3 DATA

CLINICAL TRIAL RESULTS

TRODELVY was studied in ASCENT, a landmark, confirmatory phase 3 trial that evaluated the use of TRODELVY vs single-agent chemotherapy. The primary endpoint was Progression-Free Survival in brain metastases-negative patients and a secondary endpoint was Overall Survival.[1]

In the ASCENT trial, 13% of patients in the TRODELVY group in the full population received only 1 prior line of systemic therapy in the metastatic setting (in addition to having disease recurrence or progression within 12 months of neoadjuvant/adjuvant systemic therapy).[1]

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 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/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

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TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

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[1]

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)

1:1 RANDOMIZATION

TRODELVY 10 mg/kg IV on Days 1 and 8 of a 21-day cycle
(n=267)

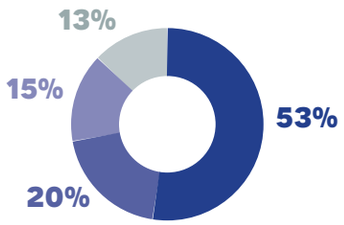
Single-agent chemotherapy
(n=262)

Continue until disease progression or unacceptable toxicity

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.[1]

*All patients received previous taxane treatment in either the adjuvant, neoadjuvant, or advanced stage unless there was a contraindication or intolerance to taxanes during or at the end of the first taxane cycle.[1]

Single-agent chemotherapy comparator arm (n=262)[1]



- **Eribulin** (n=139)
- **Vinorelbine** (n=52)
- **Gemcitabine** (n=38)
- **Capecitabine** (n=33)

53% of patients in the single-agent chemotherapy arm received eribulin

IMPORTANT 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.

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PATIENT DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Demographics and baseline characteristics in the full population[1]

- 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.[1]

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

88% of patients in the full population were BM-negative[1]

- 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[1]

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

Select secondary endpoints[1,2]

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

BICR=blinded, independent central review; BM=brain metastases; ECOG=Eastern Cooperative Oncology Group; OS=Overall Survival; PD-1=programmed death receptor-1; PD-L1=programmed death-ligand 1; PFS=Progression-Free Survival; RECIST=Response Evaluation Criteria in Solid Tumors.

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS

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 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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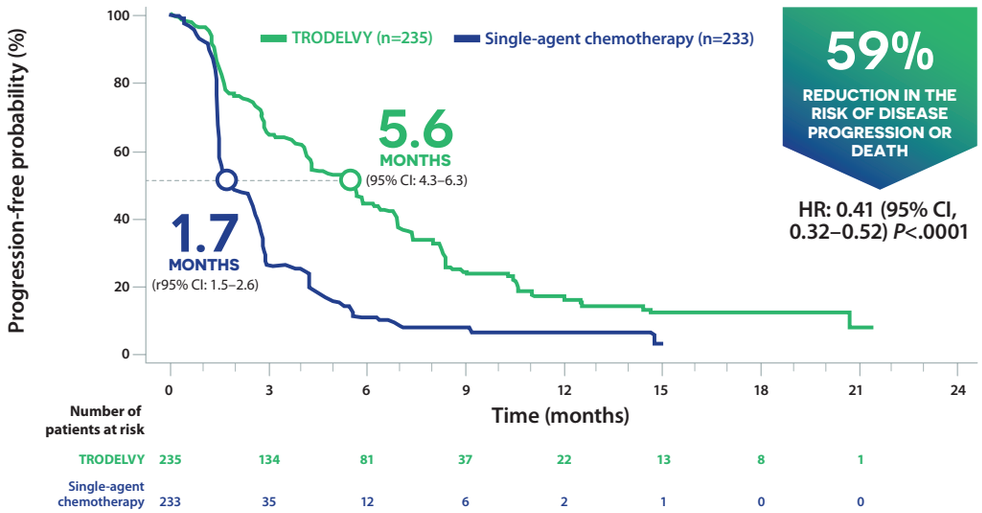
180 mg for injection

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,[1] and PFS and OS results were statistically significant across both the BM-neg and full populations[2]

Primary endpoint: Kaplan-Meier estimates of median PFS by BICR based on RECIST 1.1 criteria (BM-neg population)[2]*



*PFS is defined as the time from the date of randomization to the date of the first radiological disease progression or death due to any cause, whichever comes first.

In the full population, TRODELVY demonstrated statistically significant median PFS results vs single-agent chemotherapy[1]

- Median PFS was 4.8 months for TRODELVY (95% CI: 4.1–5.8) (n=267) vs 1.7 months with single-agent chemotherapy (95% CI: 1.5–2.5) (n=262); HR: 0.43 (95% CI: 0.35–0.54) *P*<.0001

Exploratory findings in previously treated, stable BM-positive patients[1]

- Median PFS was 2.8 months for TRODELVY (95% CI: 1.5–3.9) vs 1.6 months with single-agent chemotherapy (95% CI: 1.3–2.9); HR: 0.65 (95% CI: 0.35–1.22)

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS

Nausea and Vomiting: Nausea occurred in 66% of all patients treated with TRODELVY and Grade 3 nausea occurred in 4% of these patients. Vomiting occurred in 39% of patients and Grade 3-4 vomiting occurred in 3% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

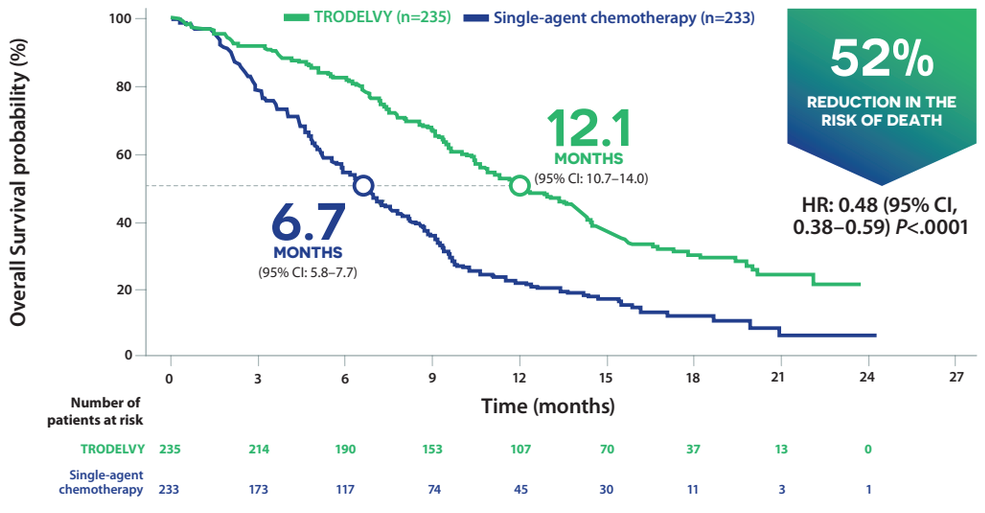
Please see full Important Safety Information throughout, and click to see full Prescribing Information, including BOXED WARNING.

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[1,2]

Secondary endpoint: Kaplan-Meier plot of median OS (BM-neg population)[2]



In the full population, TRODELVY demonstrated statistically significant improvement in median OS vs single-agent chemotherapy[1]

- Median OS was 11.8 months for TRODELVY (95% CI: 10.5–13.8) (n=267) vs 6.9 months with single-agent chemotherapy (95% CI: 5.9–7.6) (n=262); HR: 0.51 (95% CI: 0.41–0.62) *P*<.0001

Exploratory findings in previously treated, stable BM-positive patients[1]

- Median OS was 6.8 months for TRODELVY (95% CI: 4.7–14.1) vs 7.4 months with single-agent chemotherapy (95% CI: 4.7–11.1); HR: 0.87 (95% CI: 0.47–1.63)

IMPORTANT SAFETY INFORMATION *(cont'd)*

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, 46% in patients heterozygous for the UGT1A1*28 allele and 46% in patients homozygous for the wild-type 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.

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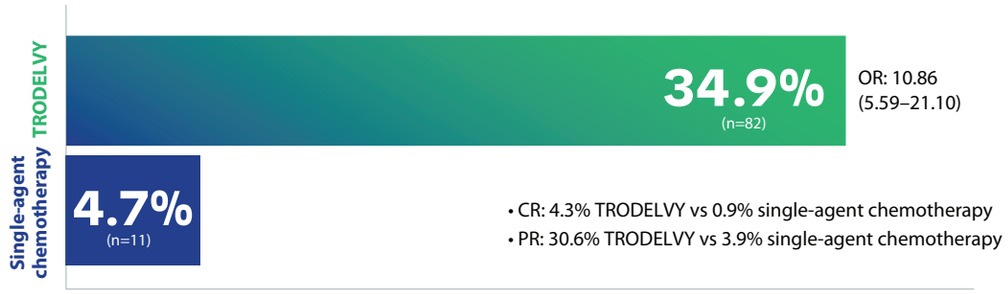
For adult patients with unresectable locally advanced or mTNBC who have received 2 or more prior systemic therapies, at least one of them for metastatic disease

ORR OF TRODELVY VS SINGLE-AGENT CHEMOTHERAPY

Secondary endpoint: Objective Response Rate* for TRODELVY vs single-agent chemotherapy (BM-neg population)[2]



- CR: 4.3% TRODELVY vs 0.9% single-agent chemotherapy
- PR: 30.6% TRODELVY vs 3.9% single-agent chemotherapy

***Limitation:** This secondary endpoint was not powered for statistical analysis and should be considered descriptive only. Therefore, the results require cautious interpretation and could represent chance findings.

Results for ORR in the full population[2]

- 31.1% with TRODELVY (n=267) vs 4.2% with single-agent chemotherapy (n=262), OR: 10.99 (5.66–21.36)
  - –CR: 3.7% TRODELVY vs 0.8% single-agent chemotherapy
  - –PR: 27.3% TRODELVY vs 3.4% single-agent chemotherapy

CR=Complete Response; PR=Partial Response; OR=odds ratio.

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.

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A WELL-CHARACTERIZED SAFETY PROFILE IN UNRESECTABLE LOCALLY ADVANCED OR mTNBC

Adverse reactions that led to discontinuation of TRODELVY occurred in 5% of patients[1]

- Serious adverse reactions occurred in 27% of patients receiving TRODELVY
- Serious adverse reactions in >1% of patients receiving TRODELVY included neutropenia (7%), diarrhea (4%), and pneumonia (3%)
- Adverse reactions leading to permanent discontinuation in ≥1% of patients who received TRODELVY were pneumonia (1%) and fatigue (1%)

Adverse reactions in ≥10% of patients with mTNBC in the ASCENT trial[1]

	TRODELVY (n=258)		Single-agent chemotherapy* (n=224)	
Adverse reaction	**All grades (%)**	**Grades 3–4 (%)**	**All grades (%)**	**Grades 3–4 (%)**
Blood and lymphatic system disorders				
Neutropenia†	64	52	44	34
Anemia‡	40	9	28	6
Leukopenia§	17	11	12	6
Lymphopenia‖	10	2	6	2
Gastrointestinal disorders				
Diarrhea	59	11	17	1
Nausea	57	3	26	0.4
Vomiting	33	2	16	1
Constipation	37	0.4	23	0
Abdominal pain	30	3	12	1
Stomatitis¶	17	2	13	1
General disorders and administration site conditions				
Fatigue#	65	6	50	9
Pyrexia	15	0.4	14	2
Infections and infestation				
Urinary tract infection	13	0.4	8	0.4
Upper respiratory tract infection	12	0	3	0
Investigations				
Alanine aminotransferase increased	11	1	10	1

	TRODELVY (n=258)		Single-agent chemotherapy* (n=224)	
Adverse reaction	**All grades (%)**	**Grades 3–4 (%)**	**All grades (%)**	**Grades 3–4 (%)**
Metabolism and nutrition disorders				
Decreased appetite	28	2	21	1
Hypokalemia	16	3	13	0.4
Hypomagnesaemia	12	0	6	0
Musculoskeletal and connective tissue disorders				
Back pain	16	1	14	2
Arthralgia	12	0.4	7	0
Nervous system disorders				
Headache	18	0.8	13	0.4
Dizziness	10	0	7	0
Psychiatric disorders				
Insomnia	11	0	5	0
Respiratory, thoracic, and mediastinal disorders				
Cough	24	0	18	0.4
Skin and subcutaneous tissue disorders				
Alopecia	47	0	16	0
Rash	12	0.4	5	0.4
Pruritus	10	0	3	0

*Single-agent chemotherapy included one of the following single agents: eribulin (n=139), capecitabine (n=33), gemcitabine (n=38), or vinorelbine (except if patient had ≥Grade 2 neuropathy, n=52). Graded per NCI CTCAE v.5.0.

†Including neutropenia and neutrophil count decreased. ‡Including anemia, hemoglobin decreased, and red blood cell count decreased. §Including leukopenia and white blood cell count decreased. ‖Including lymphopenia and lymphocyte count decreased. ¶Including stomatitis, glossitis, mouth ulceration, and mucosal inflammation. #Including fatigue and asthenia.

- The most common adverse reactions in ASCENT (≥25%) were fatigue (65%), neutropenia (64%), diarrhea (59%), nausea (57%), alopecia (47%), anemia (40%), constipation (37%), vomiting (33%), abdominal pain (30%), and decreased appetite (28%)

For information on select laboratory abnormalities, please refer to Table 3 of the Prescribing Information.

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sacituzumab govitecan-hziy
180 mg for injection

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 IS THE FIRST AND ONLY TROP-2–DIRECTED ADC WITH A PROVEN SURVIVAL BENEFIT IN mTNBC[1]

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

In BM-neg population

3X LONGER MEDIAN PFS

vs single-agent chemotherapy

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

In BM-neg population

1 YEAR MEDIAN OS

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

88% of patients in the full population were BM-neg[1] and results were similar across both groups[2]

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

INDICATED 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 setting[1]**

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

TRODELVY™ ACCESS SUPPORT

To enroll a patient into **TRODELVY Access Support,** please complete the Enrollment Form with your patient and fax to 1-833-851-4344.

For more information on the TRODELVY Savings Program, visit **TRODELVYHCP.com/hcp/access-support**, or call **1-844-TRODELVY** (1-844-876-3358), Monday–Friday, 9 AM–7 PM ET

INDICATION

TRODELVY® (sacituzumab govitecan-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.

References: 1. TRODELVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2021. **2.** Data on file. Gilead Sciences, Inc. 2021.

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