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.[1]

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

Only ADC to provide a statistically significant OS improvement in mTNBC[1]

In the Phase 3 ASCENT study, TRODELVY demonstrated statistically significant survival in **2L and later mTNBC**[1,2]

Survival Elevated

Nearly 3x LONGER median PFS versus single-agent chemotherapy[1]

4.8 months with TRODELVY (95% CI: 4.1–5.8) (n=267) vs **1.7 months** with TPC single-agent chemotherapy (95% CI: 1.5–2.5) (n=262); HR: 0.43 (95% CI: 0.35–0.54); *P*<0.0001

Help give your patients more time:

~5 more months of overall survival versus chemotherapy[1]

11.8 months with TRODELVY (95% CI: 10.5–13.8) (n=267) vs **6.9 months** with TPC single-agent chemotherapy (95% CI: 5.9–7.6) (n=262); HR: 0.51 (95% CI: 0.41–0.62); *P*<0.0001

ASCENT, a Phase 3, randomized, active-controlled, open-label study (N=529) assessed PFS in brain-met–negative patients by BICR based on RECIST 1.1 criteria (primary endpoint, see data inside) and OS as a secondary endpoint[1,2]

- 13% of patients in the TRODELVY group received only 1 prior line of systemic therapy in the metastatic setting and efficacy results were consistent with those who received at least 2 prior lines in the metastatic setting[1]

Please see study design on page 3.

2L=second line; ADC=antibody-drug conjugate; BICR=blinded independent central review; brain-met=brain metastases; CI=confidence interval; HR=hazard ratio; mTNBC=metastatic triple-negative breast cancer; OS=overall survival; PFS=progression-free survival; RECIST=Response Evaluation Criteria in Solid Tumors; TPC=treatment of physician's choice.

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. At the onset of 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.

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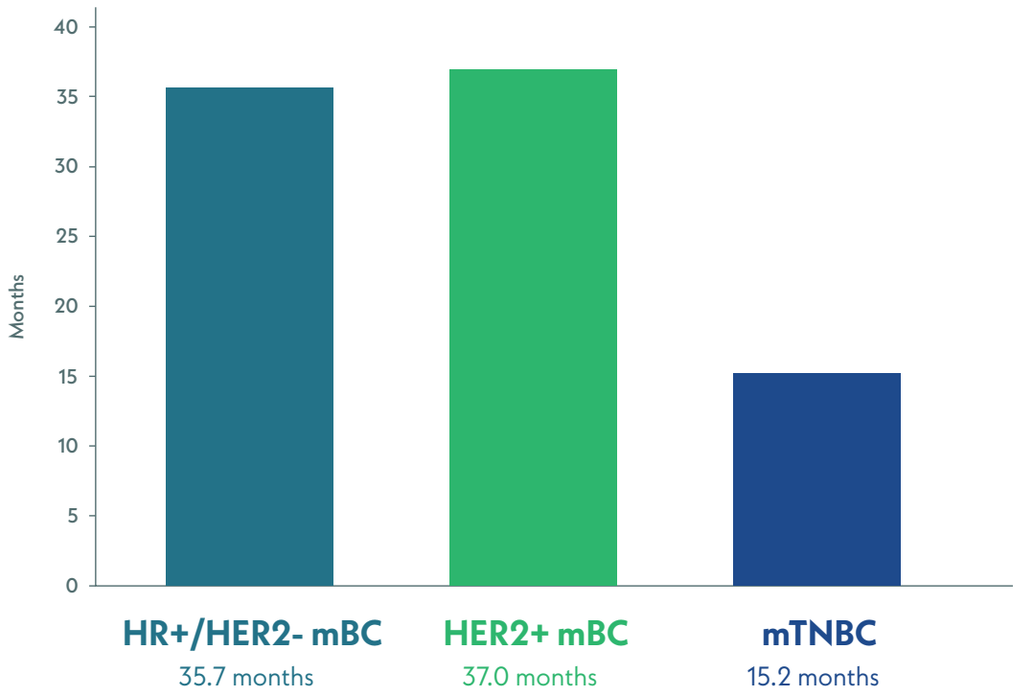
Survival for patients with mTNBC is low, despite access to traditional chemotherapy[3,4]

Median overall survival by subtype[3]



Data based on a retrospective analysis of 844 patients (438 with HR+/HER2- mBC, 161 with HER2+ mBC, and 245 with mTNBC) in the UNC Metastatic Breast Cancer Database from June 2011 to January 2020. Data include patients with both dnMBC and rMBC.[3]

THERE IS A NEED FOR OPTIONS FOLLOWING FAILED TREATMENT THAT ARE DIFFERENTIATED FROM TRADITIONAL CHEMOTHERAPIES AND THAT **MAY EXTEND SURVIVAL AND MAY SUPPORT QUALITY OF LIFE**[5]

dnMBC=de novo metastatic breast cancer; HER2+=human epidermal growth factor receptor 2–positive; HER2-=human epidermal growth factor receptor 2–negative; HR+=hormone receptor–positive; mBC=metastatic breast cancer; rMBC=recurrent metastatic breast cancer; UNC=University of North Carolina at Chapel Hill.

ASCENT: the landmark study evaluating TRODELVY vs chemotherapy in over 500 patients with mTNBC[1,2]

In this randomized, active-controlled, open-label study, TRODELVY was evaluated versus single-agent chemotherapy[1,2]

Patient population (N=529)[1,2,*]

Patients with unresectable locally advanced or mTNBC who had relapsed after at least 2 prior chemotherapies, at least one of them for metastatic disease (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)[1,2]**
- **Single-agent chemotherapy (n=262)[1]**

Continue until disease progression or unacceptable toxicity[1]

ENDPOINTS[2]

Primary
PFS in brain-met–negative population by BICR based on RECIST 1.1 criteria

Select secondary
PFS (investigator assessment)
OS
ORR
Safety

Single-agent chemotherapy was determined by the investigator before randomization from one of the following choices: eribulin (n=139), capecitabine (n=33), gemcitabine (n=38), or vinorelbine (n=52).[1]

Patients with brain metastases were allowed to enroll up to a predefined maximum of 15% of patients in the ASCENT study; MRI 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]

Patient demographics and baseline characteristics in the full population[1]

DEMOGRAPHICS

Median age:	54 years (range: 27–82 years); 81% <65 years 99.6% female
Ethnicity:	79% White 12% Black/African American

DISEASE CHARACTERISTICS

Hepatic metastases (visceral disease):	42%
Brain metastases:	12%
BRCA1/BRCA2 positive:	9%
ECOG performance status:	0 (43%) 1 (57%)

TREATMENT HISTORY

Prior PD-1/PD-L1 therapy:	29%
1 prior line of systemic therapy in metastatic setting†:	13% in TRODELVY group

88% of patients in the full population were brain-met–negative

- 12% had baseline brain metastases previously treated and stable (n=61; 32 in the TRODELVY arm and 29 in the single-agent chemotherapy arm)

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

A DIVERSIFIED POPULATION THAT MAY REPRESENT PATIENTS LIKE YOURS—ASCENT HAD **THE LARGEST ENROLLMENT** OF BLACK PATIENTS IN A PHASE 3 STUDY OF PRETREATED mTNBC[1,2,6-9]

BRCA1/BRCA2=breast cancer gene 1/2; ECOG=Eastern Cooperative Oncology Group; IV=intravenous; MRI=magnetic resonance imaging; ORR=objective response rate; PD-1=programmed death receptor-1; PD-L1=programmed death-ligand 1.

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur and may require dose modification. Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6%. Neutropenic colitis occurred in 1.4%. 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. Administer G-CSF as clinically indicated or indicated in Table 1 of USPI.

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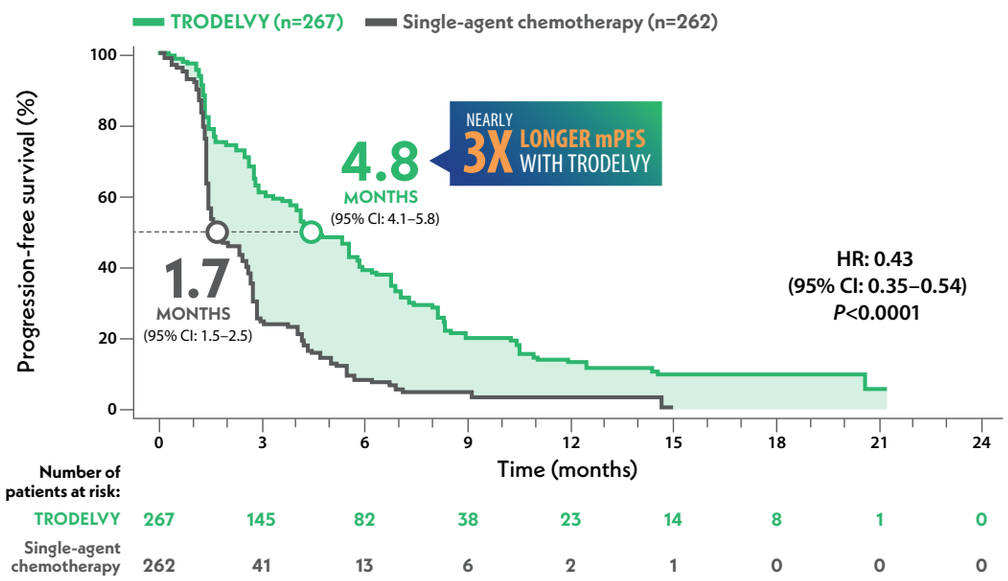
TRODELVY provided a statistically significant and clinically meaningful mPFS benefit versus chemotherapy[1]

Kaplan-Meier estimates of PFS by BICR based on RECIST 1.1 criteria (full population)[1,*]



Primary endpoint: In the primary analysis (brain-met–negative) population, TRODELVY demonstrated statistically significant mPFS results versus single-agent chemotherapy[2]

- mPFS was **5.6 months with TRODELVY** (95% CI: 4.3–6.3) (n=235) versus **1.7 months with single-agent chemotherapy** (95% CI: 1.5–2.6) (n=233); HR: 0.41 (95% CI: 0.32–0.52); *P*<0.001

Exploratory findings in previously treated, stable brain-met–positive patients[1]

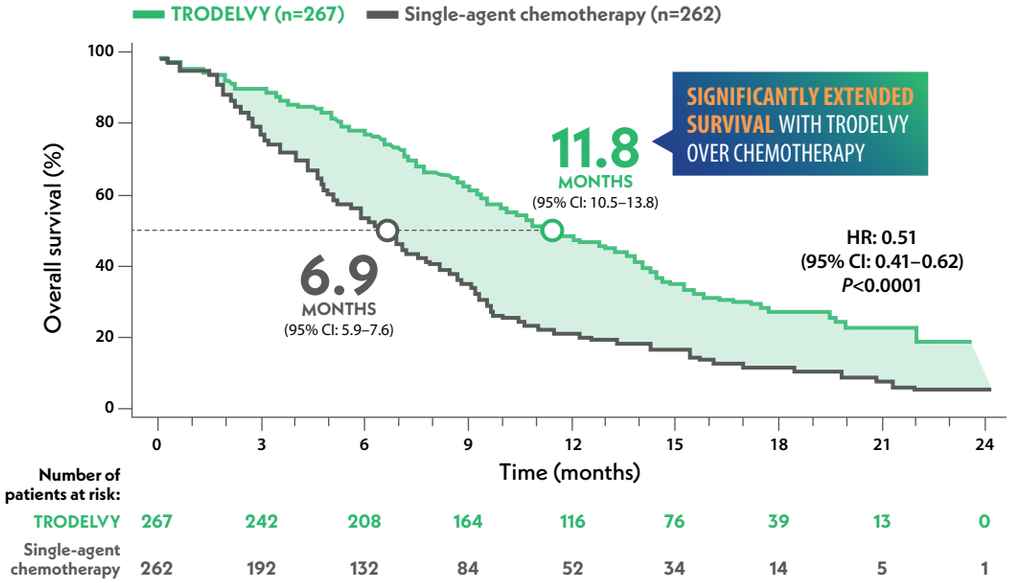
- mPFS was **2.8 months with TRODELVY** (95% CI: 1.5–3.9) versus **1.6 months with single-agent chemotherapy** (95% CI: 1.3–2.9); HR: 0.65 (95% CI: 0.35–1.22)

*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.[1]

mPFS=median progression-free survival.

Help give your patients more time: ~5 more months of overall survival with TRODELVY versus chemotherapy[1]

Kaplan-Meier estimates of OS (full population)[1]



In the primary analysis (brain-met–negative) population, TRODELVY demonstrated statistically significant improvement in mOS versus single-agent chemotherapy[2]

- mOS was **12.1 months with TRODELVY** (95% CI: 10.7–14.0) (n=235) versus **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*<0.001

Exploratory findings in previously treated, stable brain-met–positive patients[1]

- mOS was **6.8 months with TRODELVY** (95% CI: 4.7–14.1) versus **7.4 months with single-agent chemotherapy** (95% CI: 4.7–11.1); HR: 0.87 (95% CI: 0.47–1.63)

2-Year OS FOLLOW-UP ANALYSIS

In a follow-up analysis of the brain-met–negative population (data cutoff: February 25, 2021)[10,†]:

- **2-year OS rate was 22.4% with TRODELVY (95% CI: 16.8–28.5) versus 5.2% with single-agent chemotherapy (95% CI: 2.5–9.4)**

†**Limitation: This analysis was not powered for significance as part of the pivotal study and should be considered descriptive only. Therefore, the results require cautious interpretation and could represent chance findings.**

mOS=median overall survival.

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS *(cont'd)*

Diarrhea: Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all 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.

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS *(cont'd)*

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 35% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

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Explore post hoc results across IHC scores in ASCENT[11,*]

IHC and ISH results for the full population of ASCENT were analyzed retrospectively to determine the efficacy of TRODELVY by HER2-negative status[11]

- Patients with known HER2-positive disease were ineligible for ASCENT[11]
- Demographics and baseline characteristics between the following populations were comparable: the ASCENT full population (all patients with and without brain metastases) and HER2-evaluable full population, including HER2 IHC 0 and HER2-low (defined as IHC 1+, or IHC 2+ with negative ISH)[1,11]

ASCENT enrolled 529 adults across IHC status[11]

	mTNBC[†]
HER2-low (IHC 1+, IHC 2+/ISH-) 23% (n=123) of patients were IHC 1+ or IHC 2+/ISH-[‡]	TRODELVY® sacituzumab govitecan-hziy 180 mg for injection
HER2- IHC 0 55% (n=293) of patients were IHC 0[§]	TRODELVY® sacituzumab govitecan-hziy 180 mg for injection

79% of patients in the ASCENT ITT population (N=529) were HER2-evaluable by IHC and 21% were unevaluable by IHC[11]

- ASCENT included 267 patients treated with TRODELVY and 262 patients treated with single-agent chemotherapy
- 113 patients were missing specific HER2 IHC results (21% for TRODELVY, n=55; and 22% for single-agent chemotherapy, n=58)

Patients who were HER2-evaluable were divided into 2 groups by IHC status: HER2-low (IHC 1+, IHC 2+/ISH-) and HER2 IHC 0[11,‖]

- HER2-low (24% for TRODELVY, n=63 and 23% for single-agent chemotherapy, n=60)
- IHC 0 (56% for TRODELVY, n=149 and 55% for single-agent chemotherapy, n=144)

***Limitations:** These results are from a post hoc subgroup analysis of the Phase 3 ASCENT study, were not powered for statistical analysis, and should be considered descriptive only. The lack of central assessment for HER2 expression and the 21% of patients in the ASCENT full population with missing specific HER2 IHC results are known limitations of this study. Therefore, these results require cautious interpretation and could represent chance findings.[11]

TRODELVY WAS **STUDIED ACROSS HER2- IHC STATUS** IN PRETREATED mTNBC[1]

[†]21% of the patients (n=113) in ASCENT were IHC unevaluable.[11]
[‡]Of the 23% HER2-low (IHC 1+, IHC 2+/ISH-) patients in ASCENT, 12% and 11% of the ITT population were treated with TRODELVY and chemotherapy, respectively.[11]
[§]Of the 55% HER2- IHC 0 patients in ASCENT, 28% and 27% of the ITT population were treated with TRODELVY and chemotherapy, respectively.[11]
[‖]HER2-negative status was based on local assessment of the most recent biopsy/pathology report.[11]
HER2=human epidermal growth factor receptor 2; IHC=immunohistochemistry; ISH=in situ hybridization; ITT=intent-to-treat.

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS *(cont'd)*

Nausea and Vomiting: Nausea occurred in 64% of all patients treated with TRODELVY and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 35% of patients and Grade 3-4 vomiting occurred in 2% 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.

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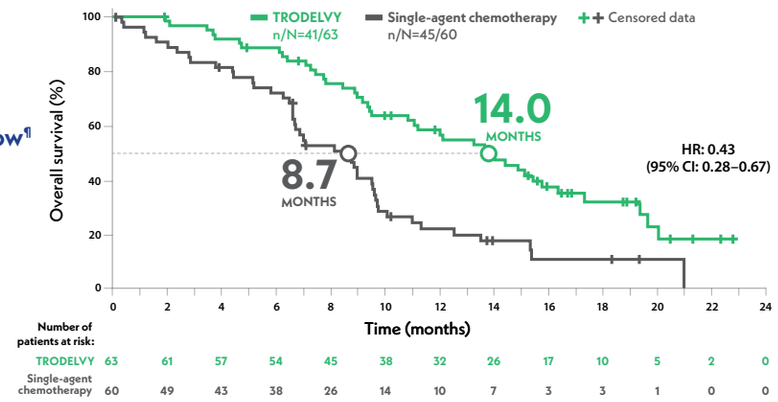
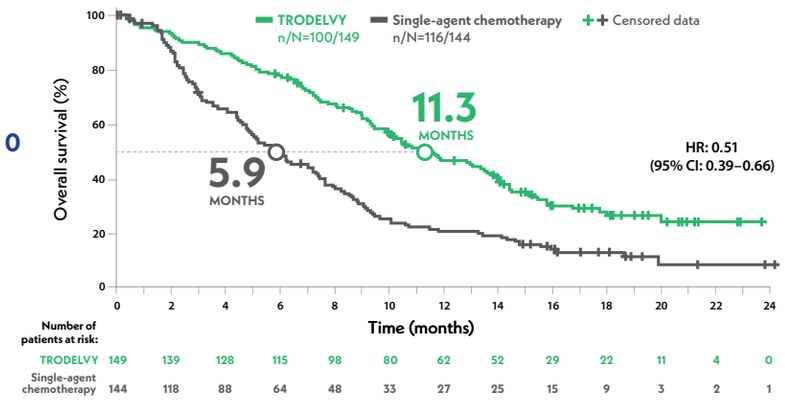
Results from the post hoc subgroup analysis of HER2-negative status by IHC score[11]

Kaplan-Meier estimates of OS[11]

HER2-low[¶]



IHC 0



Consistent OS results across HER2-IHC status compared to the full population

~1/3 OF HER2-EVALUABLE PATIENTS IN ASCENT **HAD HER2-LOW STATUS[11]**

[¶]HER2-low defined as IHC 1+ or IHC 2+/ISH-.

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS *(cont'd)*

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 58% in patients homozygous for the UGT1A1*28, 49% in patients heterozygous for the UGT1A1*28 allele, and 43% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 21% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 9% 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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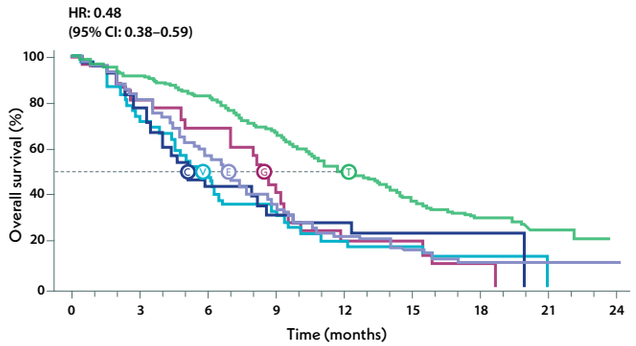
In a post hoc subgroup analysis of the ASCENT study in patients without brain metastases[12]

Median OS of TRODELVY versus 4 single-agent chemotherapies in the comparator arm[12,*]

Kaplan-Meier estimates of OS by BICR based on RECIST 1.1 criteria (brain-met–negative population)[12]



TRODELVY (n=235) **12.1 months** (95% CI: 10.7–14.0)

Single-agent chemotherapy (n=233)

Eribulin (n=126) **6.9 months** (95% CI: 5.8–7.8)

Vinorelbine (n=47) **5.9 months** (95% CI: 4.5–6.7)

Capecitabine (n=31) **5.2 months** (95% CI: 3.5–8.6)

Gemcitabine (n=29) **8.4 months** (95% CI: 5.0–9.6)

Number of patients at risk:

TRODELVY	235	214	190	153	107	70	37	13	0
Eribulin	126	98	68	42	25	16	7	3	1
Vinorelbine	47	31	20	13	8	5	1	0	0
Capecitabine	31	23	12	8	7	5	2	0	0
Gemcitabine	29	21	17	11	5	4	1	0	0

- 88% of patients in the ASCENT study were brain-met–negative[2]
- Within the single-agent chemotherapy arm, eribulin was the most commonly chosen chemotherapy (n=126), followed by vinorelbine (n=47), capecitabine (n=31), and gemcitabine (n=29)[12]

***Limitation:** These results are from a post hoc subgroup analysis of the Phase 3 ASCENT study. The single-agent chemotherapy arms were not powered for statistical analysis or designed to compare against individual agents and should be considered descriptive only. Therefore, the results require cautious interpretation and could represent chance findings.[11]**

OS RESULTS OF THIS SUBANALYSIS WERE CONSISTENT WITH THE FINDINGS FROM ASCENT[12]

Select safety findings[12]:

- Key Grade ≥3 treatment-related adverse events (TRAEs) with TRODELVY vs eribulin included neutropenia (51% vs 31%), leukopenia (10% vs 5%), diarrhea (10% vs 0%), anemia (8% vs 2%), febrile neutropenia (6% vs 2%), fatigue (3% vs 5%), nausea (3% vs 1%), and vomiting (1% vs 1%)
- Key Grade ≥3 TRAEs with TRODELVY vs vinorelbine, capecitabine, and gemcitabine combined included neutropenia (51% vs 36%), leukopenia (10% vs 6%), diarrhea (10% vs 1%), anemia (8% vs 8%), febrile neutropenia (6% vs 2%), fatigue (3% vs 6%), nausea (3% vs 0%), and vomiting (1% vs 0%)
- Discontinuation rates due to treatment-emergent adverse events for TRODELVY, eribulin, vinorelbine, capecitabine, and gemcitabine were 5%, 2%, 10%, 7%, and 9%, respectively
- 1 treatment-related death was reported for the single-agent chemotherapy arm (eribulin; neutropenic sepsis) and none with TRODELVY

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ORR of TRODELVY versus single-agent chemotherapy[2,13]

Secondary endpoint: ORR† for TRODELVY versus single-agent chemotherapy (brain-met–negative population)

OR: 10.86 (5.59–21.10)

CR: 4% with TRODELVY versus 1% with single-agent chemotherapy

PR: 31% with TRODELVY versus 4% with single-agent chemotherapy

Results for ORR in the full population

- 31% with TRODELVY (n/N=83/267) vs 4% with single-agent chemotherapy (n/N=11/262), OR: 10.99 (5.66–21.36)
- CR: 4% TRODELVY vs 1% single-agent chemotherapy
- PR: 27% TRODELVY vs 3% 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.

WHEN EVERY RESPONSE MATTERS: HIGHER ORR WITH TRODELVY VS SINGLE-AGENT CHEMOTHERAPY

CR=complete response; OR=odds ratio; PR=partial response.

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS *(cont'd)*

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 pooled safety population, the most common (≥25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (84%), decreased neutrophil count (75%), decreased hemoglobin (69%), diarrhea (64%), nausea (64%), decreased lymphocyte count (63%), fatigue (51%), alopecia (45%), constipation (37%), increased glucose (37%), decreased albumin (35%), vomiting (35%), decreased appetite (30%), decreased creatinine clearance (28%), increased alkaline phosphatase (28%), decreased magnesium (27%), decreased potassium (26%), and decreased sodium (26%).

In the ASCENT study, the most common adverse reactions (incidence ≥25%) were fatigue, diarrhea, nausea, alopecia, 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.

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QoL is an important consideration for treatment: HRQoL subanalysis[5,14]

Limitation: The EORTC QLQ-C30 is not all inclusive and does not include adequate assessment of additional expected treatment-related symptoms or overall side effect bother from the patient perspective. The results should be interpreted with caution due to the open-label design of the study and because the HRQoL endpoint was not powered for statistical analysis and was assessed in a post hoc subgroup analysis. Additionally, analyses were not adjusted for multiple comparisons and correlations between domains were not analyzed.[5]

Using MMRM analysis, LS mean change from baseline in primary HRQoL domains:	TRODELVY (n=236)	Treatment difference (95% CI)	Single-agent chemotherapy (n=183)
Role functioning*	-2.24 (-6.13, 1.65)	5.59 (1.13, 10.05)	-7.83 (-12.41, -3.25)
Global health status/QoL†	0.66 (-2.21, 3.53)	4.08 (0.82, 7.35)	-3.42 (-6.77, -0.08)
Physical functioning*	1.31 (-1.38, 3.99)	5.69 (2.63, 8.76)	-4.39 (-7.52, -1.26)
Fatigue‡	1.97 (-1.20, 5.13)	-5.17 (-8.81, -1.52)	7.13 (3.40, 10.87)
Pain‡	-8.93 (-12.57, -5.30)	-7.04 (-11.24, -2.85)	-1.89 (-6.18, 2.40)

Favors TRODELVY

*Higher score = higher functioning. †Higher score = higher QoL. ‡Higher score = worse symptoms.

TRODELVY WAS NONINFERIOR OR WAS FAVORABLE COMPARED WITH SINGLE-AGENT CHEMOTHERAPY IN THE 5 PRIMARY HRQoL DOMAINS OF THE EORTC QLQ-C30[5,14]

Secondary HRQoL domains[5,14]

- Among the secondary HRQoL domains, the TRODELVY arm had greater symptomatology and was inferior to the single-agent chemotherapy arm for nausea/vomiting and diarrhea. TRODELVY was noninferior to single-agent chemotherapy for all other secondary-focused HRQoL domains

HRQoL subanalysis overview[5,14]

- HRQoL was a prespecified secondary endpoint of the ASCENT study assessed in a post-hoc subgroup analysis; it was not powered for statistical analysis
- HRQoL was reviewed at baseline (≤28 days before cycle 1 on Day 1), on Day 1 of each cycle, and at the final study visit (4 weeks after the last dose of study drug or at premature study termination) using the EORTC QLQ-C30
- Global health status/QoL, physical functioning, role functioning, pain, and fatigue were chosen as the primary HRQoL domains in this investigation, as they may be clinically relevant to this patient population. The remaining EORTC QLQ-C30 domains were assessed as secondary HRQoL domains
- HRQoL-evaluable patients included those in the full population who completed the EORTC QLQ-C30 at baseline and ≥1 postbaseline assessment (an evaluable assessment was defined as completion of ≥1 of the 15 EORTC QLQ-C30 domains)
- The HRQoL-evaluable population comprised 236 patients randomized to TRODELVY (88.4% of the ASCENT full population, n=267) and 183 patients randomized to single-agent chemotherapy (69.8% of the ASCENT full population, n=262)

HRQoL subanalysis methods[5,14]

- Linear MMRM were used to assess between-group differences in data collected up to cycle 6 (when n was ≥25 in both treatment arms), adjusting for baseline scores, treatment visit, and stratification factors
- LS mean changes from baseline HRQoL scores were estimated for TRODELVY and single-agent chemotherapy and were compared between treatment arms
- Time to first clinically meaningful improvement or deterioration of HRQoL (improvement or worsening above a prespecified threshold of 10 points) was analyzed by the Kaplan-Meier product limit method

IMPORTANT SAFETY INFORMATION *(cont'd)*

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 reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

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

TRODELVY has a manageable safety profile[15,*]

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

Adverse reaction	TRODELVY (n=258) All grades (%)	TRODELVY (n=258) Grades 3–4 (%)	Single-agent chemo[a] (n=224) All grades (%)	Single-agent chemo[a] (n=224) Grades 3–4 (%)
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[b]	17	2	13	1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
Fatigue[c]	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
METABOLISM AND NUTRITION DISORDERS				
Decreased appetite	28	2	21	1
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

*The discontinuation rate in ASCENT was 5%, demonstrating that a majority of patients were able to remain on TRODELVY with proper management of adverse reactions.[15]

[a]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).[1]

[b]Including stomatitis, glossitis, mouth ulceration, and mucosal inflammation.[1]

[c]Including fatigue and asthenia.[1]

EORTC QLQ-C30=European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; HRQoL=health-related quality of life; LS=least-squares; MMRM=mixed-effect models for repeated measures; QoL=quality of life.

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180 mg for injection

TRODELVY has a manageable safety profile[15,*] *(cont'd)*

Strategy for managing neutropenia[1]

Talk	Talk to patients about the possibility of experiencing neutropenia while on TRODELVY, which can be severe, life-threatening, or fatal
Encourage	Encourage patients to notify their healthcare team if they experience fever, chills, or other signs of infection
Consider	Consider secondary prophylactic use of G-CSF to manage neutropenia
Modify or interrupt	Dose modifications or interruptions may be required to manage severe neutropenia and may help patients continue treatment as appropriate – 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
	Withhold or discontinue TRODELVY to manage adverse reactions as described in the table above. Do not re-escalate the TRODELVY dose after a dose reduction for adverse reactions has been made[1]
	Slow or interrupt the infusion rate of TRODELVY if the patient develops an infusion-related reaction. Permanently discontinue TRODELVY for life-threatening infusion-related reactions[1]

Planning and preparing for the management of diarrhea[1]

Talk	Talk to patients about the possibility of experiencing diarrhea while on TRODELVY, which can be severe
Initiate	Initiate loperamide at the onset of diarrhea unless an infectious cause is identified – (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)
	Initiate other supportive measures, such as administration of fluids or electrolytes, as clinically appropriate – Patients who exhibit an excessive cholinergic response to treatment with TRODELVY can receive appropriate premedication (eg, atropine) for subsequent treatments
Modify or interrupt	Dose modifications or interruptions may be required to manage Grade 3–4 diarrhea and may help patients continue treatment as appropriate – Withhold TRODELVY for Grade 3–4 diarrhea at the time of scheduled treatment administration and resume when resolved to ≤Grade 1
	Withhold or discontinue TRODELVY to manage adverse reactions as described in the table below. Do not re-escalate the TRODELVY dose after a dose reduction for adverse reactions has been made
	Slow or interrupt the infusion rate of TRODELVY if the patient develops an infusion-related reaction. Permanently discontinue TRODELVY for life-threatening infusion-related reactions

Adverse reaction[1]	Occurrence	Dose modification
SEVERE NEUTROPENIA		
Grade 4 neutropenia ≥7 days **OR** Grade 3–4 febrile neutropenia **OR** At time of scheduled treatment, Grade 3–4 neutropenia which delays dosing by 2 or 3 weeks for recovery to ≤Grade 1	First	25% dose reduction and administer G-CSF
	Second	50% dose reduction and administer G-CSF
	Third	Discontinue treatment and administer G-CSF
At time of scheduled treatment, Grade 3–4 neutropenia which delays dosing beyond 3 weeks for recovery to ≤Grade 1	First	Discontinue treatment and administer G-CSF

Adverse reaction[1]	Occurrence	Dose modification
SEVERE NON-NEUTROPENIC TOXICITY		
Grade 4 non-hematologic toxicity of any duration **OR** Any Grade 3–4 nausea, vomiting or diarrhea due to treatment that is not controlled with antiemetics and anti-diarrheal agents **OR** Other Grade 3–4 non-hematologic toxicity persisting >48 hours despite optimal medical management **OR** At time of scheduled treatment, Grade 3–4 non-neutropenic hematologic or non-hematologic toxicity, which delays dose by 2 or 3 weeks for recovery to ≤Grade 1	First	25% dose reduction
	Second	50% dose reduction
	Third	Discontinue treatment
In the event of Grade 3–4 non-neutropenic hematologic or non-hematologic toxicity, which does not recover to ≤Grade 1 within 3 weeks	First	Discontinue treatment

Events of neutropenia with TRODELVY[1,15]

- Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3–4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6% of patients. Neutropenic colitis occurred in 1.4% of patients[1]
- The median time to first onset of neutropenia (including febrile neutropenia) was 16 days and has occurred earlier in some patient populations. Includes patients from IMMU-132-01, TROPHY, ASCENT, and TROPiCS-02 studies[1]
- In a post hoc descriptive analysis of the ASCENT study, median time to onset for any grade neutropenia related to TRODELVY was 20 days, and the median duration was 7 days[15]

Events of diarrhea with TRODELVY

- Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3–4 diarrhea occurred in 11% of all patients treated with TRODELVY. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients[1]
- In a post hoc descriptive analysis of the ASCENT study, median time to onset for any grade diarrhea related to TRODELVY was 12 days, and the median duration was 5 days[15]

*The discontinuation rate in ASCENT was 5%, demonstrating that a majority of patients were able to remain on TRODELVY with proper management of adverse reactions.[15]

G-CSF=granulocyte-colony stimulating factor.

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TRODELVY has a manageable safety profile[15,*] *(cont'd)*

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

- Adverse reactions leading to permanent discontinuation in ≥1% of patients who received TRODELVY were pneumonia (1%) and fatigue (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%)

Most common adverse reactions and lab abnormalities in ASCENT[1]

- The most common (≥25%) adverse reactions, including lab abnormalities, were decreased hemoglobin (94%), decreased lymphocyte count (88%), decreased leukocyte count (86%), decreased neutrophil count (78%), fatigue (65%), diarrhea (59%), nausea (57%), increased glucose (49%), alopecia (47%), constipation (37%), decreased calcium (36%), vomiting (33%), decreased magnesium (33%), decreased potassium (33%), increased albumin (32%), abdominal pain (30%), decreased appetite (28%), increased aspartate aminotransferase (27%), increased alanine aminotransferase (26%), increased alkaline phosphatase (26%), and decreased phosphate (26%)

Treatment interruption and dose reductions[1]

- Adverse reactions leading to a treatment interruption occurred in 63% of patients
- The most frequent (≥5%) adverse reactions leading to a treatment interruption were neutropenia (47%), diarrhea (5%), respiratory infection (5%), and leukopenia (5%)
- Adverse reactions leading to a dose reduction of TRODELVY occurred in 22% of patients
- The most frequent (>4%) adverse reactions leading to a dose reduction were neutropenia (11%) and diarrhea (5%)
- G-CSF was used in 44% of patients who received TRODELVY

For more safety information including lab abnormalities, see Table 3 of the full Prescribing Information or visit www.trodelvyhcp.com/mtnbc/safety

TRODELVY DOES NOT REQUIRE INCREASED MONITORING FOR ILD†

*The discontinuation rate in ASCENT was 5%, demonstrating that a majority of patients were able to remain on TRODELVY with proper management of adverse reactions.[15]

†In ASCENT, out of 258 patients treated with TRODELVY, one (<0.5%) experienced pneumonitis and no other cases of ILD were observed.[15]

Chemo=chemotherapy; G-CSF=granulocyte-colony stimulating factor; ILD=interstitial lung disease; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

When your patient progresses, try sacituzumab govitecan-hziy (TRODELVY), a Category 1 preferred option in 2L and later mTNBC[1,16]

NCCN Category 1 | Preferred option for 2L and later mTNBC[16]

National Comprehensive Cancer Network® (NCCN®): Sacituzumab govitecan-hziy (TRODELVY) is recommended as a Category 1 preferred treatment option 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. It may be considered for later line if not used as second-line therapy.

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

Category 1 indicates that based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[16]

Consider TRODELVY, a standard-of-care option for your patients with 2L and later mTNBC[1]

Stage I/II/III | **Stage IV**

Progression to mTNBC

Stage I/II/III TNBC → Standard therapy including systemic chemotherapy (neoadjuvant or adjuvant)

1L mTNBC → Systemic therapy

2L mTNBC → **TRODELVY**

1L=first line; NCCN=National Comprehensive Cancer Network; TNBC=triple-negative breast cancer.

SELECT 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. At the onset of 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.**

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TRODELVY® ACCESS SUPPORT

Access support for your patients when they need it most—regardless of insurance coverage

The TRODELVY ACCESS SUPPORT Program Includes:

- Coverage verification
- Prior Authorization information
- Claim status information
- Billing and coding information
- Additional assistance options

Patient Access and Reimbursement Program

- TRODELVY Savings Program for eligible patients with commercial or private insurance*
- Gilead Patient Assistance Program for qualified uninsured or underinsured patients to receive TRODELVY at no cost

WITH THE TRODELVY SAVINGS PROGRAM,* PATIENTS MAY PAY AS LITTLE AS **$0 OUT OF POCKET** FOR TRODELVY

The Program only assists with cost of TRODELVY, patient is responsible for cost-share of treatment and office visits. This Program does not support any claims covered, paid, or reimbursed, in whole or in part by Medicaid, Medicare, or other federal or state healthcare programs.

*Terms and conditions apply. Limited to $25,000 annually.

For additional information, contact a TRODELVY ACCESS SUPPORT Patient Access Coordinator
Monday-Friday, 9 AM-7 PM EST
at 1-844-TRODELVY (1-844-876-3358).
www.trodelvy.com/financial-assistance

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/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. At the onset of 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 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6%. Neutropenic colitis occurred in 1.4%. 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. Administer G-CSF as clinically indicated or indicated in Table 1 of USPI.

Diarrhea: Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all 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.

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 35% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

Nausea and Vomiting: Nausea occurred in 64% of all patients treated with TRODELVY and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 35% of patients and Grade 3-4 vomiting occurred in 2% 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.

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IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS *(cont'd)*

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 58% in patients homozygous for the UGT1A1*28, 49% in patients heterozygous for the UGT1A1*28 allele, and 43% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 21% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 9% 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.

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 pooled safety population, the most common (≥25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (84%), decreased neutrophil count (75%), decreased hemoglobin (69%), diarrhea (64%), nausea (64%), decreased lymphocyte count (63%), fatigue (51%), alopecia (45%), constipation (37%), increased glucose (37%), decreased albumin (35%), vomiting (35%), decreased appetite (30%), decreased creatinine clearance (28%), increased alkaline phosphatase (28%), decreased magnesium (27%), decreased potassium (26%), and decreased sodium (26%).

In the ASCENT study, the most common adverse reactions (incidence ≥25%) were fatigue, diarrhea, nausea, alopecia, 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 reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

References: 1. TRODELVY. Prescribing information. Gilead Sciences, Inc.; February 2023. **2.** Bardia A, Hurvitz SA, Tolaney SM, et al. Sacituzumab govitecan in metastatic triple-negative breast cancer. *N Engl J Med*. 2021;384(16):1529-1541. **3.** File DM, Pascual T, Deal AM, et al. Clinical subtype, treatment response, and survival in de novo and recurrent metastatic breast cancer. *Breast Cancer Res Treat.* 2022;196(1):153-162. **4.** Gupta GK, Collier AL, Lee D, et al. Perspectives on triple-negative breast cancer: current treatment strategies, unmet needs, and potential targets for future therapies. *Cancers (Basel).* 2020;12(9):2392. **5.** Loibl S, Loirat D, Tolaney SM, et al. Health-related quality of life in the phase III ASCENT trial of sacituzumab govitecan versus standard chemotherapy in metastatic triple-negative breast cancer. *Eur J Cancer*. 2023;178:23-33. **6.** Cortes J, Cescon DW, Rugo HS, et al. Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer (KEYNOTE-355): a randomised, placebo-controlled, double-blind, phase 3 clinical trial. *Lancet*. 2020;396(10265):1817-1828. **7.** Modi S, Jacot W, Yamashita T, et al. Trastuzumab deruxtecan in previously treated HER2-low advanced breast cancer. *N Engl J Med*. 2022;387(1):9-20. **8.** Schmid P, Adams S, Rugo HS, et al. Atezolizumab and nab-paclitaxel in advanced triple-negative breast cancer. *N Engl J Med.* 2018;379(22):2108-2121. **9.** Miles D, Gligorov J, André F, et al. Primary results from IMpassion131, a double-blind, placebo-controlled, randomised phase III trial of first-line paclitaxel with or without atezolizumab for unresectable locally advanced/metastatic triple-negative breast cancer. *Ann Oncol*. 2021;32(8):994-1004. **10.** Bardia A, Tolaney SM, Loirat D, et al. Sacituzumab govitecan versus treatment of physician's choice in patients with previously treated metastatic triple-negative breast cancer: final data from the phase 3 ASCENT study. Poster presented at: American Society of Clinical Oncology Annual Meeting; June 3-7, 2022; Chicago, IL. Poster 1071. **11.** Hurvitz SA, Bardia A, Punie K, et al. Sacituzumab govitecan efficacy in patients with metastatic triple-negative breast cancer by HER2 immunohistochemistry status: findings from the phase 3 ASCENT study. Poster presented at: European Society for Medical Oncology Breast Cancer Congress; May 3-5, 2022; Berlin, Germany. Poster 168P. **12.** O'Shaughnessy J, Punie K, Oliveira M, et al. Assessment of sacituzumab govitecan vs treatment of physician's choice cohort by agent in the phase 3 ASCENT study of patients with metastatic triple-negative breast cancer. Poster presented at: Virtual American Society of Clinical Oncology Annual Meeting; June 4-8, 2021. Poster 1077. **13.** Data on file. Gilead Sciences, Inc. 2021. **14.** Loibl S, Loirat D, Tolaney S, et al. Health-related quality of life (HRQoL) in the ASCENT study of sacituzumab govitecan (SG) in metastatic triple-negative breast cancer (mTNBC). Poster presented at: European Society for Medical Oncology Virtual Congress; September 16-21, 2021; Poster 257P. **15.** Rugo HS, Tolaney SM, Loirat D, et al. Safety analyses from the phase 3 ASCENT trial of sacituzumab govitecan in metastatic triple-negative breast cancer. *NPJ Breast Cancer*. 2022;8(1):98. **16.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.4.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed July 11, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.

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For more information visit www.TRODELVYHCP.com

Help give your patients more time

~5 more months of overall survival with TRODELVY versus chemotherapy in patients with mTNBC[1]

ASCENT: mTNBC[1]

In patients who have received 2 or more prior systemic therapies, at least 1 of them for metastatic disease

mPFS

Nearly 3x longer mPFS versus single-agent chemotherapy

mPFS was **4.8 months with TRODELVY** (95% CI: 4.1–5.8) (n=267) versus **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*<0.0001

mOS

The only ADC with a proven survival benefit: ~1-year mOS

mOS was **11.8 months with TRODELVY** (95% CI: 10.5–13.8) (n=267) versus **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*<0.0001

TRODELVY has a well-characterized safety profile based on a clinical study[15]

See study design and safety results on pages 3 and 11–14

NCCN Guidelines for sacituzumab govitecan-hziy in mTNBC[16]

NCCN® Category 1 | Preferred option for 2L and later mTNBC

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. It may be considered for later line if not used as second-line therapy.

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Category 1 indicates that based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[16]

OFFER YOUR PATIENTS THE OPPORTUNITY FOR A **PROVEN SURVIVAL BENEFIT** IN **2L AND LATER mTNBC WITH TRODELVY**[1]

SELECT 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. At the onset of 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.

IN THE ASCENT STUDY, the most common adverse reactions (≥25%), including lab abnormalities, were decreased hemoglobin, decreased lymphocyte count, decreased leukocyte count, decreased neutrophil count, fatigue, diarrhea, nausea, increased glucose, alopecia, constipation, decreased calcium, vomiting, decreased magnesium, decreased potassium, increased albumin, abdominal pain, decreased appetite, increased aspartate aminotransferase, increased alanine aminotransferase, increased alkaline phosphatase, and decreased phosphate.

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