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.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

Only ADC to provide a **statistically significant OS improvement** in mTNBC

Survival Elevated

In the phase 3 ASCENT trial, TRODELVY demonstrated statistically significant survival in 2L and later mTNBC[1,2]

mTNBC

Nearly 3x LONGER median PFS vs 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*<.0001[1]

~1 YEAR median OS[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*<.0001

ASCENT, a phase 3, randomized, open-label, active-controlled trial (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 information on pages 2 and 3.

2L=second line; ADC=antibody-drug conjugate; BICR=blinded, independent, central review; brain-met=brain metastases; CI=confidence interval; HR=hazard ratio; OS=Overall Survival; PFS=Progression-Free Survival; 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/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.

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ASCENT: a landmark phase 3 trial assessing survival in more than 500 patients with pretreated mTNBC

TRODELVY was studied in a randomized, open-label, active-controlled trial vs single-agent chemotherapy[1]

Patient population (N=529)*

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)

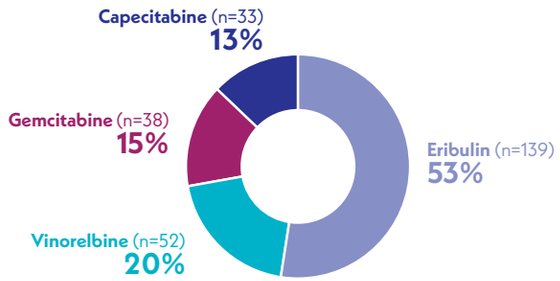
1:1 RANDOMIZATION

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



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

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 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.

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, and 9% with BRCA1/BRCA2 mutational status positive
- ECOG performance status of 0 (43%) or 1 (57%)

In the full population receiving TRODELVY, **1 out of 8 patients (13%)** had **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)

- Efficacy results were consistent with those who had received at least two prior lines in the metastatic setting[1]

88% of patients in the full population were brain-met 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 brain-met negative population (TRODELVY, n=235, and single-agent chemotherapy, n=233)

Primary endpoint[2]

- Median Progression-Free Survival (PFS) in brain-met negative population by BICR based on RECIST 1.1 criteria

Select secondary endpoints[1,2]

- Median PFS in the full population
- Median Overall Survival (OS) in both the brain-met negative and full populations
- Objective Response Rate (ORR)

ECOG=Eastern Cooperative Oncology Group; PD-1=programmed death receptor-1; PD-L1=programmed death-ligand 1; 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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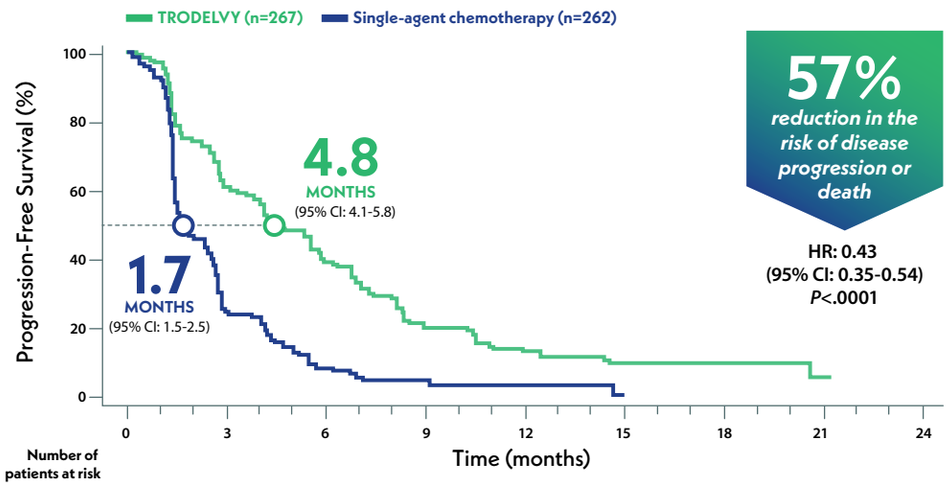
The ASCENT Trial

For the treatment of 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*

Nearly 3x longer median PFS vs single-agent chemotherapy[1]

TRODELVY demonstrated significantly longer median PFS vs single-agent chemotherapy in the full population

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



*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.

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

- Median PFS was **5.6 months** for TRODELVY (95% CI: 4.3-6.3) (n=235) vs **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*<.001

Exploratory findings in previously treated, stable brain-met 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.

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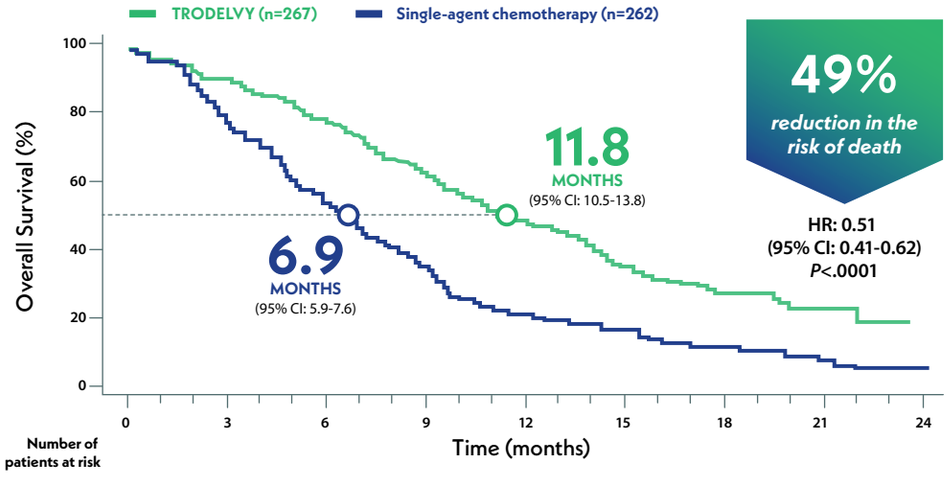
In the full population of ASCENT

Median OS of ~1 year with TRODELVY[1]

TRODELVY significantly improved survival vs single-agent chemotherapy[1,2]

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



In the primary analysis population, TRODELVY demonstrated statistically significant improvement in median OS vs single-agent chemotherapy[2]

- Median OS was **12.1 months** for 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*<.001

Exploratory findings in previously treated, stable brain-met 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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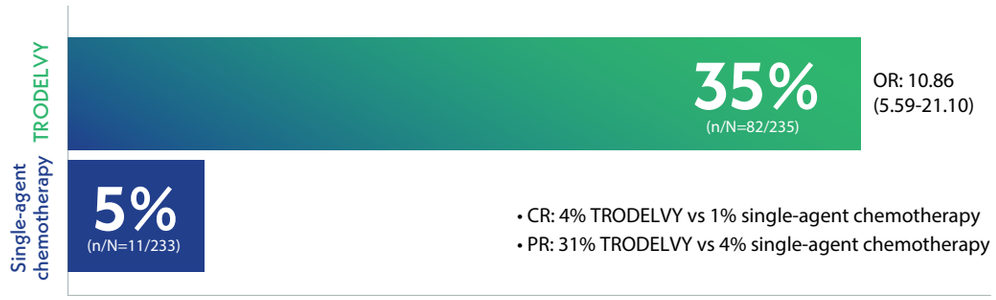
The ASCENT Trial

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 (ORR)* for TRODELVY vs single-agent chemotherapy (brain-met negative population)[2,3]



***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[2,3]

- 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

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

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

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.

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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]

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

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

	TRODELVY (n=258)		Single-agent chemotherapy[a] (n=224)	
Adverse reaction	**All grades (%)**	**Grades 3-4 (%)**	**All grades (%)**	**Grades 3-4 (%)**
Blood and lymphatic system disorders				
Neutropenia[b]	64	52	44	34
Anemia[c]	40	9	28	6
Leukopenia[d]	17	11	12	6
Lymphopenia[e]	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[f]	17	2	13	1
General disorders and administration site conditions				
Fatigue[g]	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[a] (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

[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). Graded per NCI CTCAE v.5.0. [b]Including neutropenia and neutrophil count decreased. [c]Including anemia, hemoglobin decreased, and red blood cell count decreased. [d]Including leukopenia and white blood cell count decreased. [e]Including lymphopenia and lymphocyte count decreased. [f]Including stomatitis, glossitis, mouth ulceration, and mucosal inflammation. [g]Including fatigue and asthenia.

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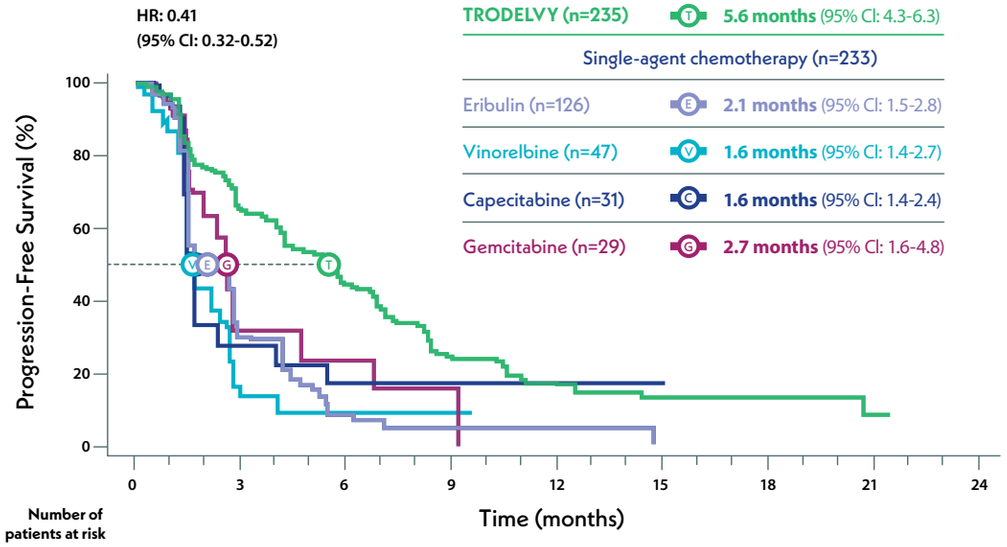
The ASCENT Trial: Post-hoc Subgroup Analysis

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, a post-hoc sub-analysis of the ASCENT trial in brain-met negative patients assessed

Median PFS of TRODELVY vs 4 single-agent chemotherapies in the comparator arm

88% of patients in the ASCENT trial were brain-met negative, and PFS results of this sub-analysis were consistent with the primary findings from ASCENT[1,2,4]

Kaplan-Meier estimates of median PFS by BICR based on RECIST 1.1 criteria (brain-met negative population)[4*†]



Number of patients at risk								
TRODELVY	235	134	81	37	22	13	8	1
Eribulin	126	23	5	2	1	0	0	0
Vinorelbine	47	3	1	1	0	0	0	0
Capecitabine	31	5	3	2	1	1	0	0
Gemcitabine	29	4	3	1	0	0	0	0

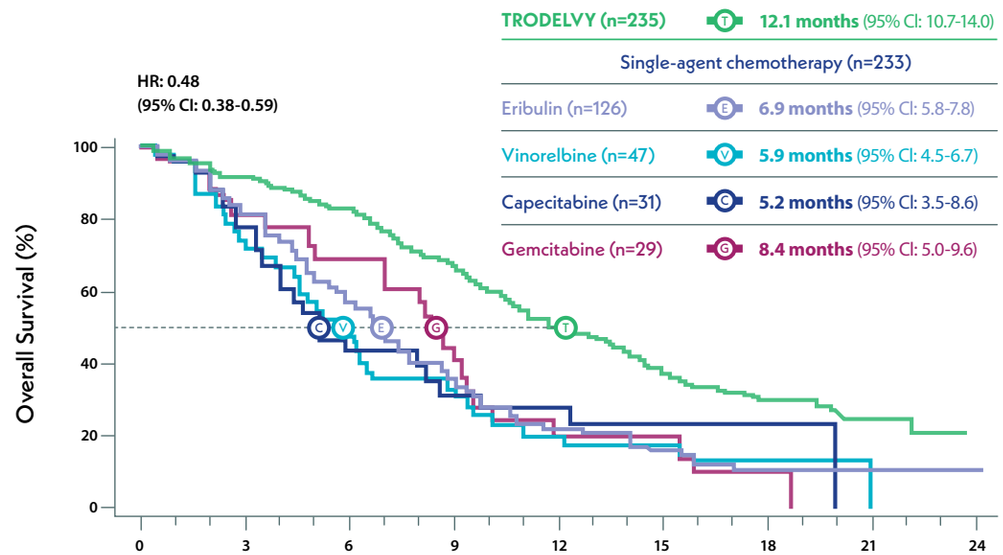
*PFS is defined as the time from the date of randomization to the date of the first radiological disease progression or death due to any cause, whichever comes first.[1]

In a post-hoc subgroup analysis of the ASCENT trial in patients without brain metastases

Median OS of TRODELVY vs 4 single-agent chemotherapies in the comparator arm

OS results of this sub-analysis were consistent with the findings from ASCENT[1,2,4]

Kaplan-Meier estimates of median OS by BICR based on RECIST 1.1 criteria (brain-met negative population)[4†]



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

Assessed by independent central review in the brain-met negative population.[4]

†Limitation: These results are from a post-hoc subgroup analysis of the phase 3 ASCENT trial. 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.

Select safety findings[4]:

- 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

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

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A closer look at the ASCENT trial by IHC score*

IHC and ISH results for the full population of ASCENT were analyzed retrospectively to determine the efficacy of TRODELVY by HER2-negative status[5]

Patient demographics[5]

- Patients with known HER2-positive disease were ineligible for ASCENT
- Demographics and baseline characteristics between the following populations were comparable: ASCENT full population (all patients with and without brain metastases), HER2-evaluable full population including HER2 IHC0 and HER2-low (defined as IHC1+, or IHC2+ with negative ISH)[1,5]

FULL POPULATION OF ASCENT
(N=529; TRODELVY, n=267, AND SINGLE-AGENT CHEMOTHERAPY, n=212)

79% HER2-EVALUABLE BY IHC	21% NON-EVALUABLE BY IHC

Patients missing specific HER2 IHC results:
55 (21%) for TRODELVY vs 58 (22%) for single-agent chemotherapy

HER2-negative status[5†]

HER2-negative status	TRODELVY n (% of 267)	Single-agent chemotherapy n (% of 212)
IHC0	149 (56%)	144 (55%)
HER2-low: IHC1+, or IHC2+ with negative ISH	63 (24%)	60 (23%)

[†]HER2-negative status was based on local assessment of the most recent biopsy/pathology report.[4]

See results for PFS and OS from this post-hoc subgroup analysis on the following pages.

IHC=immunohistochemistry; ISH=in situ hybridization.

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.

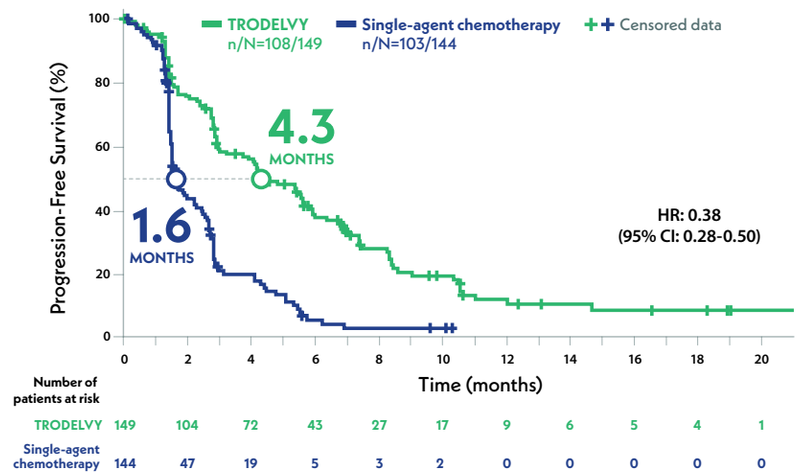
Please see full Important Safety Information throughout, and click to see full Prescribing Information, including BOXED WARNING.

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, the post-hoc subgroup analysis of the ASCENT trial assessed

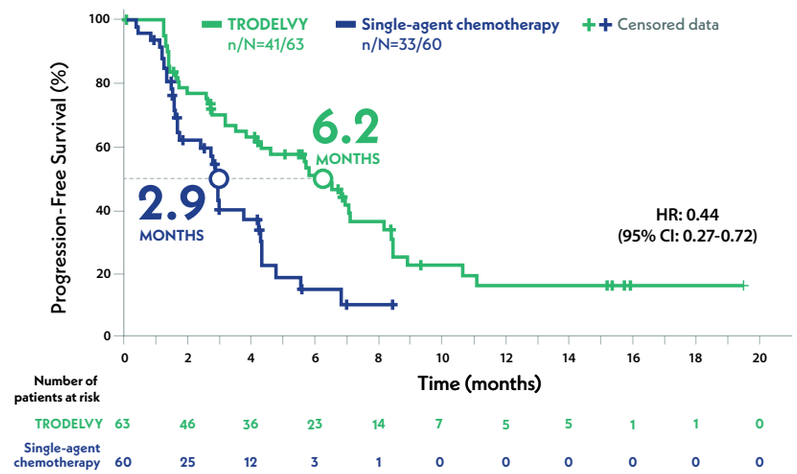
Median PFS of TRODELVY vs single-agent chemotherapy based on HER2-negative status*

Kaplan-Meier estimates of median PFS by BICR based on RECIST 1.1 criteria[5‡]

IHC0



HER2-low[§]



n/N=Events/Total.
[‡]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]
[§]HER2-low is defined as IHC1+, or IHC2+ with negative ISH.[5]

Results of this post-hoc subgroup analysis were consistent with the primary findings of the ASCENT trial in the full population[1,5]

***Limitations:** These results are from a post-hoc subgroup analysis of the phase 3 ASCENT trial, 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.[5]*

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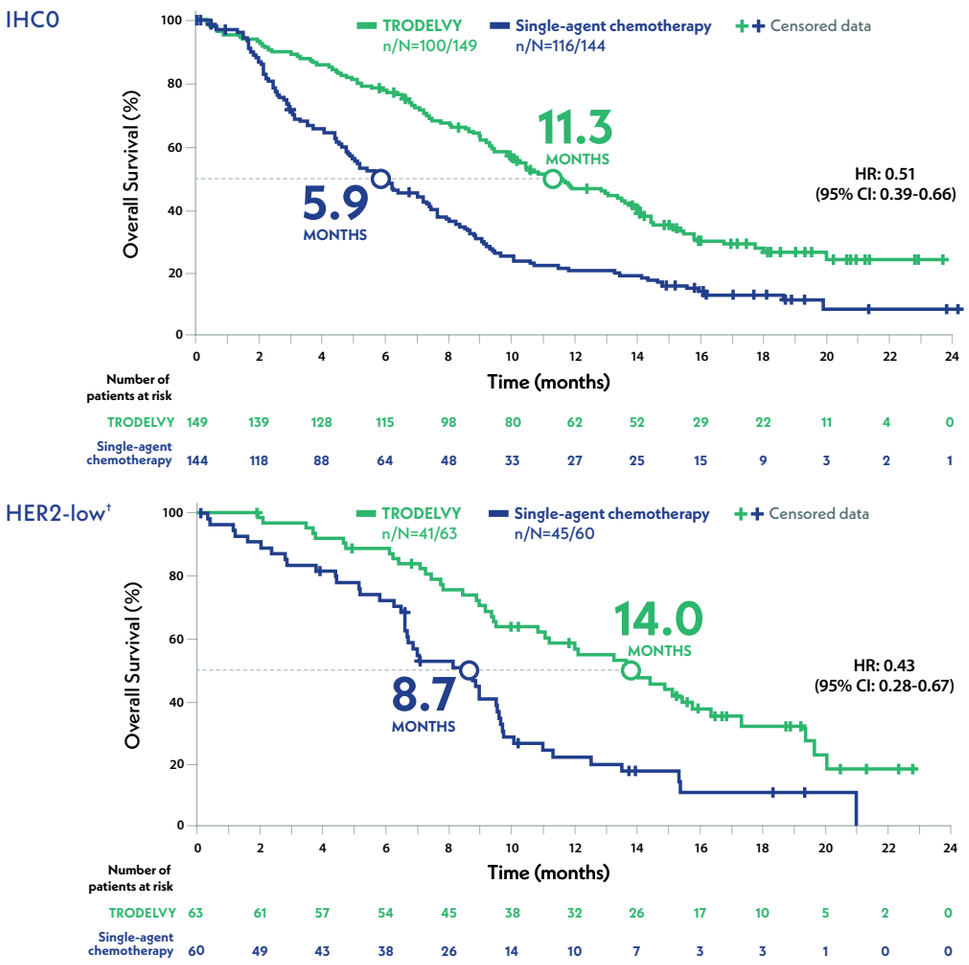
For adult patients with unresectable locally advanced or mTNBC who have received 2 or more prior systemic therapies, at least one of them for metastatic disease

Median OS of TRODELVY vs single-agent chemotherapy based on HER2-negative status*

Kaplan-Meier estimates of median OS[5]



n/N=Events/Total.
†HER2-low is defined as IHC1+, or IHC2+ with negative ISH.[4]

Results of this post-hoc subgroup analysis were consistent with the primary findings of the ASCENT trial in the full population[1,5]

***Limitations:** These results are from a post-hoc subgroup analysis of the phase 3 ASCENT trial, 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.[5]*

Additional safety information

Serious adverse reactions[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%)
- Fatal adverse reactions occurred in 1.2% of patients who received TRODELVY, including respiratory failure (0.8%) and pneumonia (0.4%)

Most common adverse reactions[1]

- 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%)
- In the pooled safety population (N=795), the most common (≥25%) adverse reactions were nausea (66%), diarrhea (65%), fatigue (62%), neutropenia (61%), alopecia (45%), anemia (42%), vomiting (39%), constipation (37%), decreased appetite (34%), rash (32%), and abdominal pain (28%)

Treatment discontinuation[1]

- Adverse reactions leading to permanent discontinuation of TRODELVY occurred in 5% of patients
- Adverse reactions leading to permanent discontinuation in ≥1% of patients who received TRODELVY were pneumonia (1%) and fatigue (1%)

Treatment interruption[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%)

Dose reductions[1]

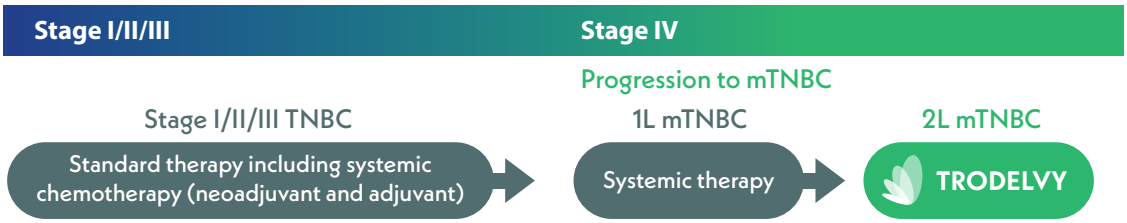
- Adverse reactions leading to a dose reduction occurred in 22% of patients
- The most frequent (>4%) adverse reactions leading to a dose reduction were neutropenia (11%) and diarrhea (5%)
  - Granulocyte colony-stimulating factor (G-CSF) was used in 44% of patients who received TRODELVY

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

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

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 mTNBC who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Think TRODELVY for 2L and later mTNBC



NCCN Category 1 | Preferred for 2L and later mTNBC

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): 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 two or more prior systemic therapies, at least one of them for metastatic disease.[1,6]

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=Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate[6]; NCCN=National Comprehensive Cancer Network.

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/accesssupport, or call **1-844-TRODELVY** (1-844-876-3358) Monday-Friday, 9 AM-7 PM ET.

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. 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, and click to see full Prescribing Information, including BOXED WARNING.

References: 1. TRODELVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; June 2022. **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.** Data on file. Gilead Sciences, Inc. 2021. **4.** 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 (ASCO) Annual Meeting; June 4-8, 2021. **5.** Hurvitz SA, Bardia A, Punie K, et al. Sacituzumab govitecan 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 (ESMO) Breast Cancer Congress; May 3-5, 2022; Berlin, Germany. **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.4.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed June 24, 2022. To view the most recent and complete version of the guidelines, go online to NCCN.org.

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