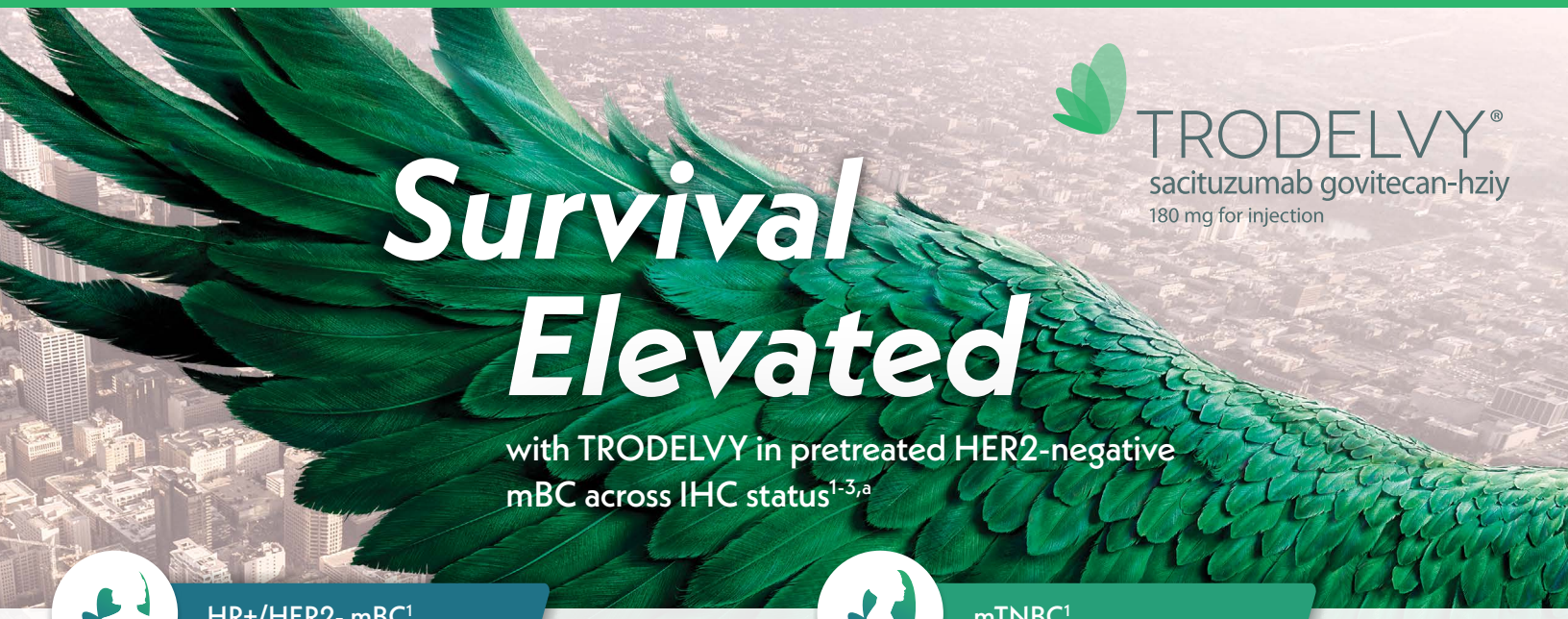


Survival Elevated

with TRODELVY in pretreated HER2-negative mBC across IHC status[1-3,a]

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

HR+/HER2- mBC[1]

Median progression-free survival (PFS)

5.5 months with TRODELVY (95% CI: 4.2-7.0) (n = 272) vs **4.0 months with chemotherapy** (95% CI: 3.1-4.4) (n = 271)

HR: 0.66 (95% CI: 0.53-0.83, *P*=0.0003)

Median overall survival (OS)

14.4 months with TRODELVY (95% CI: 13.0-15.7) (n = 272) vs **11.2 months with chemotherapy** (95% CI: 10.1-12.7) (n = 271)

HR: 0.79 (95% CI: 0.65-0.96, *P*=0.02)

TROPiCS-02: Phase 3, randomized, active-controlled, open-label trial (N = 543) that assessed PFS by BICR based on RECIST 1.1 criteria[b] and OS.[1,2,c]

mTNBC[1]

Median PFS

4.8 months with TRODELVY (95% CI: 4.1-5.8) (n = 267) vs **1.7 months with chemotherapy** (95% CI: 1.5-2.5) (n = 262)

HR: 0.43 (95% CI: 0.35-0.54, *P*<0.0001)

Median OS

11.8 months with TRODELVY (95% CI: 10.5-13.8) (n = 267) vs **6.9 months with chemotherapy** (95% CI: 5.9-7.6) (n = 262)

HR: 0.51 (95% CI: 0.41-0.62, *P*<0.0001)

ASCENT: Phase 3, randomized, active-controlled, open-label trial (N = 529) that assessed PFS in brain-metastases negative (brain-met negative) patients by BICR based on RECIST 1.1 criteria[b] (see inside) and OS.[1,3,c]

[a] ITT population included HER2- patients with IHC statuses of IHC 0, IHC 1+, or IHC 2+/ISH-.[4,5]
[b] Primary endpoint.[2,3] [c] Secondary endpoint.[2,3]

INDICATIONS

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.
- Unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

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

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

BICR, blinded independent central review; CI, confidence interval; HER2-, human epidermal growth factor receptor 2-negative; HR, hazard ratio; HR+, hormone receptor-positive; IHC, immunohistochemistry; ISH, in situ hybridization; mBC, metastatic breast cancer; mTNBC, metastatic triple-negative breast cancer; OS, overall survival; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumor.

TROPiCS-02 evaluated outcomes with TRODELVY in pretreated HR+/HER2- mBC compared with chemotherapy

TROPiCS-02 study overview[1,2,4]

In the phase 3, multicenter, randomized, active-controlled, open-label trial, TRODELVY was studied versus single-agent chemotherapy. TRODELVY was studied in patients with unresectable locally advanced or metastatic HR+/HER2- breast cancer (N = 543) whose disease had progressed after:

- ≥1 endocrine therapy, CDK4/6 inhibitor, and taxane in any setting (neoadjuvant, adjuvant, or metastatic)
- 2-4 lines of chemotherapy for metastatic disease
  - Neoadjuvant/adjuvant therapy for early-stage disease qualified as a prior line of chemotherapy if disease recurred within 12 months
- Measurable disease by RECIST 1.1

The primary endpoint was PFS by BICR based on RECIST 1.1 criteria, and select secondary endpoints included OS, QoL measures, and safety.

Patients were randomized (1:1) to receive TRODELVY 10 mg/kg as an IV infusion on Days 1 and 8 of a 21-day cycle (n = 272) or physician's choice of single-agent chemotherapy (n = 271), which included eribulin, vinorelbine, gemcitabine, or capecitabine. Patients were treated until disease progression or unacceptable toxicity.

TRODELVY offers a well-characterized safety profile in patients with pretreated HR+/HER2- mBC[1]

- Serious adverse reactions occurred in 28% of patients receiving TRODELVY
- Serious adverse reactions in >1% of patients receiving TRODELVY included diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting (each 2%)
- TRODELVY was permanently discontinued for adverse reactions in 6% of patients. The most frequent (≥0.5%) adverse reactions leading to permanent discontinuation in patients who received TRODELVY were asthenia, general physical health deterioration, and neutropenia (each 0.7%)
- The most common (≥25%) adverse reactions, including lab abnormalities, were decreased leukocytes (88%), decreased neutrophils (83%), decreased hemoglobin (73%), decreased lymphocytes (65%), diarrhea (62%), fatigue (60%), nausea (59%), alopecia (48%), increased glucose (37%), constipation (34%), and decreased albumin (32%)
- **There were no events of ILD with TRODELVY[2]**

Scan for the full TROPiCS-02 study design, efficacy, and safety results

TROPiCS-02 efficacy data

In a prespecified descriptive analysis, 3x more patients remained progression-free at 12 months with TRODELVY versus single-agent chemotherapy[2]

Primary endpoint: Median PFS was **5.5 months** for TRODELVY (95% CI: 4.2-7.0) (n = 272) versus **4.0 months** with single-agent chemotherapy (95% CI: 3.1-4.4) (n = 271); HR: 0.66 (95% CI: 0.53-0.83, *P*=0.0003)[1]

12-month PFS rate was **21%** with TRODELVY (95% CI: 15-28) versus **7%** with single-agent chemotherapy (95% CI: 3-14).[2] Not powered for statistical analysis

14.4-month median OS[1]

Median OS was **14.4 months** for TRODELVY (95% CI: 13.0-15.7) (n = 272) versus **11.2 months** with single-agent chemotherapy (95% CI: 10.1-12.7) (n = 271); HR: 0.79 (95% CI: 0.65-0.96, *P*=0.02)[1]

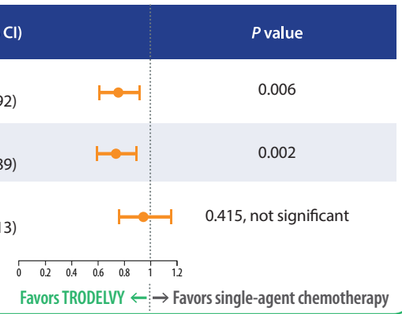
Abbreviations: BICR, blinded independent central review; CDK4/6, cyclin-dependent kinase 4/6; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; ILD, interstitial lung disease; IV, intravenous; mBC, metastatic breast cancer; OS, overall survival; PFS, progression-free survival; QoL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors

TRODELVY extended time to deterioration (TTD) of global health status/QoL[6]

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

EORTC QLQ-C30 TTD in global health status/QoL, fatigue, and pain[6]

	TRODELVY	Single-agent chemotherapy		
TTD	**Median TTD, mo (95% CI)**	**Median TTD, mo (95% CI)**	**HR (95% CI)**	***P* value**
Global health status/QoL	4.3 (3.1-5.7) n = 234	3.0 (2.2-3.9) n = 207	0.75 (0.61-0.92)	0.006
Fatigue	2.2 (1.6-2.8) n = 234	1.4 (1.1-1.9) n = 205	0.73 (0.60-0.89)	0.002
Pain	3.8 (2.8-5.0) n = 229	3.5 (2.8-5.0) n = 202	0.92 (0.75-1.13)	0.415, not significant



- TTD of global health status/QoL, fatigue, and pain were prespecified secondary endpoints in the statistical hierarchy[4,a,b]
- HRQoL-evaluable patients included those in the ITT population who completed the EORTC QLQ-C30 at baseline and at least 1 postbaseline visit, with HRQoL assessed at baseline, Day 1 of each treatment cycle from Cycle 2, EOT visit, and at the long-term follow-up visit. Baseline mean QoL scores were comparable between both study arms[4,6]

Limitation: 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 TTD may be confounded by events not related to disease/treatment.

[a] Patients who had not experienced 10-point deterioration at the time of analysis were censored on the last nonmissing assessment date. Patients without baseline or postbaseline patient-reported outcome assessments were censored at the randomization date.[4]
[b] TTD was defined as the time from randomization to the first date a patient achieved ≥10-point deterioration from baseline or died due to any cause, whichever occurred first.[4]

Abbreviations: CI, confidence interval; EORTC QLQ, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; EOT, end of treatment; HR, hazard ratio; HRQoL, health-related quality of life; ITT, intent-to-treat; OS, overall survival; QoL, quality of life; TTD, time to deterioration

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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ASCENT: A landmark phase 3 trial assessing survival in more than 500 patients with pretreated mTNBC[1,3]

ASCENT study overview[1,3]

In the phase 3, randomized, active-controlled, open-label trial, TRODELVY was studied versus single-agent chemotherapy.

TRODELVY was studied in patients with unresectable locally advanced or mTNBC who had relapsed after at least 2 prior chemotherapies, at least one of them for metastatic disease.

The primary endpoint was PFS in brain-metastases negative (brain-met negative) patients by BICR based on RECIST 1.1 criteria (primary endpoint), and select secondary endpoints included PFS for the full population (all patients with and without brain metastases) and OS.

Patients were randomized (1:1) to receive TRODELVY 10 mg/kg as an IV infusion on Days 1 and 8 of a 21-day cycle (n = 267) or physician's choice of single-agent chemotherapy (n = 262). Patients were treated until disease progression or unacceptable toxicity.

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. 88% of patients in the full population were brain-met negative (n = 468; 235 in the TRODELVY arm and 233 in the single-agent chemotherapy arm).

A well-characterized safety profile in unresectable locally advanced or mTNBC[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%)
- TRODELVY was permanently discontinued for adverse reactions in 5% of patients. Adverse reactions leading to permanent discontinuation in ≥1% of patients who received TRODELVY were pneumonia (1%) and fatigue (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%), increase aspartate aminotransferase (27%), increased alanine aminotransferase (26%), increased alkaline phosphatase (26%), and decreased phosphate (26%)

Scan for the full ASCENT study design, efficacy, and safety results

Abbreviations: BICR, blinded independent central review; IV, intravenous; mTNBC, metastatic triple-negative breast cancer; OS, overall survival; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

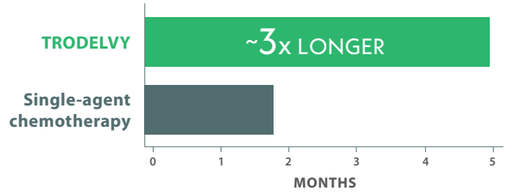
Hypersensitivity and Infusion-Related Reactions: Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity 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.

ASCENT efficacy data

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

Nearly 3x LONGER median progression-free survival (PFS) versus single-agent chemotherapy[1]

Median PFS in the full population[1]



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)[1]

~1 YEAR median overall survival (OS)[1]

Median OS in the full population[1]

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)[1]

Primary endpoint: In the primary analysis (brain-met negative) population, TRODELVY demonstrated statistically significant median PFS results versus single-agent chemotherapy[3]:

- Median PFS 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)

In the primary analysis (brain-met negative) population, TRODELVY demonstrated statistically significant improvement in median OS versus single-agent chemotherapy[3]:

- Median OS 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)

Abbreviations: CI, confidence interval; HR, hazard ratio; OS, overall survival; PFS, progression-free survival

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.

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.

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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 (cont'd): 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 (locally advanced or metastatic triple-negative breast cancer), 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.

In the TROPiCS-02 study (locally advanced or metastatic HR-positive, HER2-negative breast cancer), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, alopecia, and constipation. The most frequent serious adverse reactions (SAR) (>1%) were diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting (each 2%). SAR were reported in 28% of patients, and 6% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPiCS-02 study were reduced neutrophils and leukocytes.

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

References: 1. Trodelvy. Package insert. Gilead Sciences, Inc; February 2023. **2.** Rugo HS, Bardia A, Marmé F, et al. Sacituzumab govitecan in hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer. *J Clin Oncol.* 2022;40(29):3365-3376. doi:10.1200/JCO.22.01002 **3.** 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. doi:10.1056/NEJMoa2028485 **4.** Immunomedics, Inc. Phase 3 study of sacituzumab govitecan (IMMU-132) versus treatment of physician's choice (TPC) in subjects with hormonal receptor-positive (HR+) human epidermal growth factor receptor 2 (HER2) negative metastatic breast cancer (MBC) who have failed at least two prior chemotherapy regimens. Published December 21, 2018. Accessed December 5, 2022. https://ascopubs.org/doi/suppl/10.1200/JCO.22.01002/suppl_file/protocol_JCO.22.01002.pdf **5.** Immunomedics, Inc. An international multi-center, open-label, randomized, phase III trial of sacituzumab govitecan versus treatment of physician choice in patients with metastatic triple-negative breast cancer who received at least two prior treatments. Published November 18, 2015. Updated June 22, 2017. Accessed January 3, 2023. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2028485/suppl_file/nejmoa2028485_protocol.pdf **6.** Rugo HS, Schmid P, Tolaney SM, et al. Health-related quality of life (HRQoL) in the phase 3 TROPiCS-02 trial of sacituzumab govitecan (SG) vs chemotherapy in HR+/HER2- metastatic breast cancer (mBC). Presented at: European Society for Medical Oncology Congress; September 9-13, 2022; Paris, France. Presentation 15530.

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TRODELVY®
sacituzumab govitecan-hziy
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