TRODELVY® is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with 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.

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

The only Trop-2–directed ADC to provide significantly improved overall survival[1,2]

Survival Elevated

with TRODELVY in pretreated HR+/HER2- mBC[1,2]

HR+/HER2- mBC

mPFS[1]*

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[1]

mOS[1†]

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[1]

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

*Primary endpoint.[2] †Secondary endpoint.[2]

ADC=antibody-drug conjugate; 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; mOS=median overall survival; mPFS=median progression-free survival; OS=overall survival; PFS=progression-free survival; RECIST=Response Evaluation Criteria in Solid Tumors.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

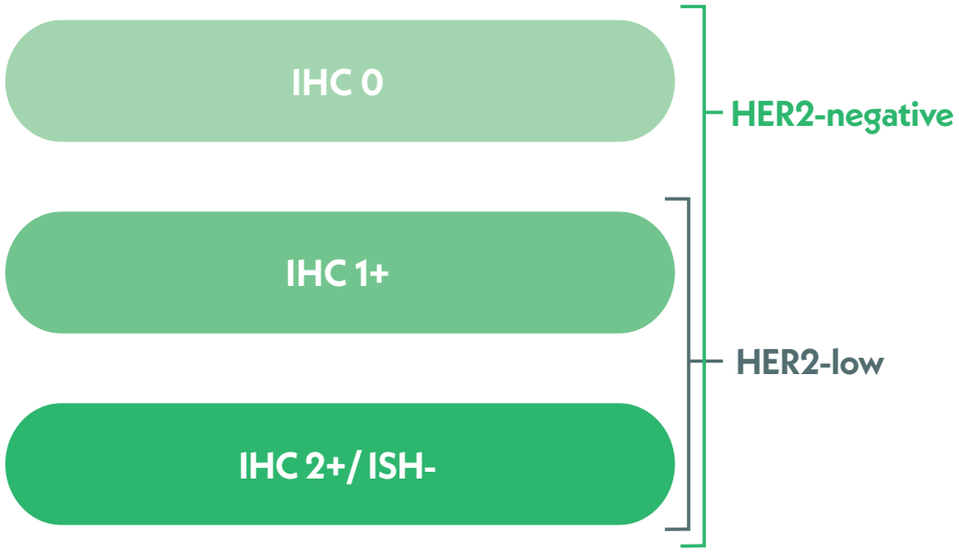
- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia 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.

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

HER2-negative mBC includes HER2-low and IHC 0[3,4]

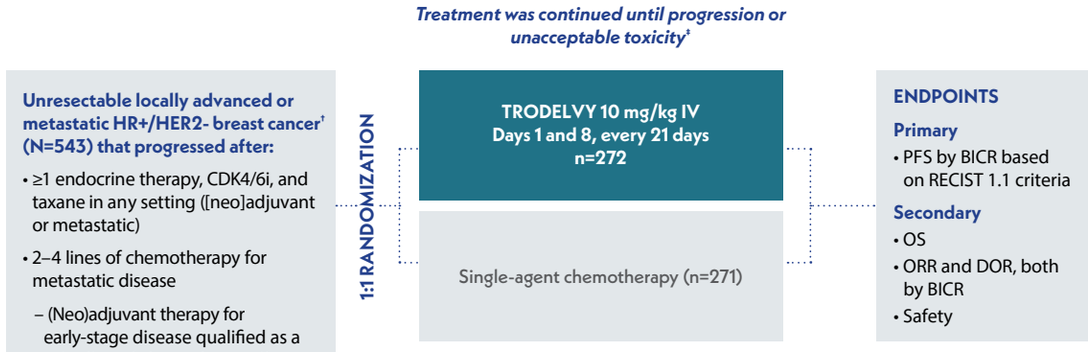


TRODELVY is indicated across HER2- IHC status in pretreated HR+/HER2- mBC[1,5]*

*Indicated in HR+/HER2- mBC for patients who have received endocrine-based therapy and at least 2 additional systemic therapies in the metastatic setting.[1]

TROPiCS-02 evaluated outcomes with TRODELVY compared with chemotherapy[2]

TROPiCS-02 was a Phase 3, randomized, active-controlled, open-label trial[1,2,5]:



Single-agent chemotherapy was determined by the investigator before randomization from one of the following choices: eribulin (n=130), vinorelbine (n=63), gemcitabine (n=56), or capecitabine (n=22).

Stratification:
- Visceral metastasis (yes/no)
- Endocrine therapy in metastatic setting ≥6 months (yes/no)
- Prior lines of chemotherapy for metastatic disease (2 vs 3/4)

†Disease histology based on the ASCO/CAP criteria.[5] ‡Administration of TRODELVY was permitted beyond RECIST-defined disease progression if the patient was clinically stable and considered by the investigator to be deriving clinical benefit.[1]

ASCO=American Society of Clinical Oncology; CAP=College of American Pathologists; CDK4/6i=cyclin-dependent kinase 4/6 inhibitor; DOR=duration of response; IV=intravenous; ORR=objective response rate.

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.

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

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.

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The population of TROPiCS-02 has characteristics that may resemble those of your patients

Not an actual patient.

Demographics[1]

- Median age of 56 (range: 27–86 years); 26% ≥65 years
- 99% female
- 67% White; 4% Black; 3% Asian; 26% of unknown race

Disease characteristics[1,2,5,6]

- ECOG performance status of 0 (45%) or 1 (55%)
- 95% had visceral metastases
- Median time of 47.8 months from initial metastatic diagnosis
- 52% HER2-low, 40% HER2 IHC 0, and 8% missing HER2 IHC status*

Treatment history[1,2]

- Median of 7 (range: 3–17) prior systemic regimens in any setting and 3 (range: 0–8) prior systemic chemotherapy regimens in the metastatic setting
- ~42% received 2 prior chemotherapy regimens for metastatic disease; 58% received 3–4 prior chemotherapy regimens
- 86% received prior endocrine therapy in the metastatic setting for ≥6 months
- 99% had prior CDK4/6i use in the metastatic setting, and 60% received it for ≤12 months

*39 patients with HER2 IHC 2+ did not have ISH data documentation available for verification and were presumed to be HER2-low.[6]

ECOG=Eastern Cooperative Oncology Group.

IMPORTANT SAFETY INFORMATION *(cont'd)*

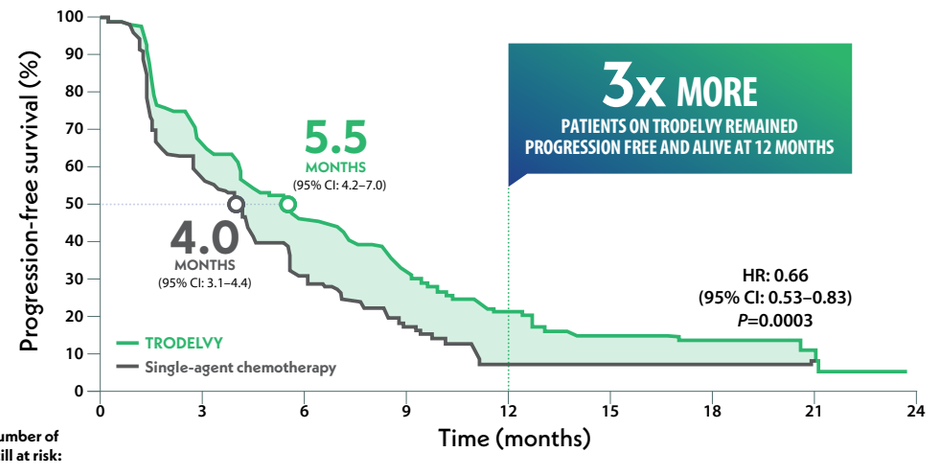
WARNINGS AND PRECAUTIONS *(cont'd)*

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.

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

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

Kaplan-Meier estimates of PFS by BICR based on RECIST 1.1 criteria (ITT population)[1,2]*



Number of patients still at risk:									
TRODELVY	272	148	82	44	22	12	6	3	0
Single-agent chemotherapy	271	105	41	17	4	1	1	0	

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

TRODELVY gives you the power that may delay disease progression or death

*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]

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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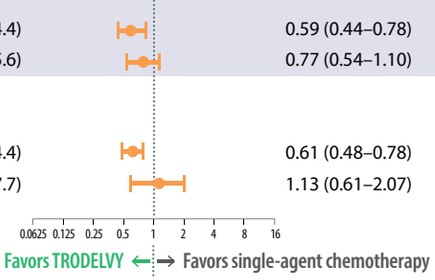
TROPiCS-02: PFS analysis across key subgroups*

mPFS by BICR based on RECIST 1.1 criteria[2†]

Subgroup	TRODELVY mPFS, mo (95% CI)	Single-agent chemotherapy mPFS, mo (95% CI)	HR (95% CI)
Overall (N=543)	5.5 (4.2–7.0)	4.0 (3.1–4.4)	0.66 (0.53–0.82)
Visceral metastasis			
Yes (n=517)	5.5 (4.2–7.0)	4.0 (3.1–4.4)	0.66 (0.53–0.83)
No (n=26)	9.1 (1.3–NE)	5.6 (1.6–NE)	0.78 (0.25–2.40)
Age group			
<65 years (n=403)	5.5 (4.1–6.9)	4.1 (3.0–4.4)	0.69 (0.53–0.89)
≥65 years (n=140)	6.7 (4.2–9.0)	3.5 (1.7–5.6)	0.59 (0.38–0.93)
Race			
White (n=362)	5.3 (4.2–7.0)	4.2 (3.0–4.5)	0.66 (0.51–0.86)
Non-White (n=42)	3.1 (1.5–8.5)	4.0 (1.4–8.9)	1.23 (0.55–2.75)
Early relapse‡			
Yes (n=42)	5.8 (2.7–NE)	1.4 (1.2–1.7)	0.10 (0.04–0.28)
No (n=488)	5.5 (4.2–7.0)	4.2 (3.4–5.4)	0.72 (0.57–0.91)
Number of prior lines of chemotherapy in the metastatic setting			
≤2 (n=233)	5.7 (4.2–8.3)	4.2 (2.8–5.5)	0.62 (0.45–0.85)
≥3 (n=310)	5.3 (4.0–6.9)	3.7 (2.7–4.4)	0.70 (0.52–0.95)
Prior CDK inhibitor duration			
≤12 months (n=327)	6.0 (4.6–8.3)	4.0 (2.8–4.4)	0.59 (0.44–0.78)
>12 months (n=208)	4.4 (3.3–7.0)	4.2 (2.7–5.6)	0.77 (0.54–1.10)
Endocrine therapy in the metastatic setting			
For ≥6 months			
Yes (n=469)	5.6 (4.4–7.4)	4.1 (3.1–4.4)	0.61 (0.48–0.78)
No (n=74)	3.9 (2.5–5.8)	3.5 (1.6–7.7)	1.13 (0.61–2.07)



***Limitation:** **These results are from a subgroup analysis of the Phase 3 TROPiCS-02 trial. These endpoints were not powered for statistical analysis and should be considered descriptive only. Therefore, the results require cautious interpretation and could represent chance findings.**

Consistent outcomes across patient subgroups[2]

†PFS is defined as the time from the date of randomization to the date of the first radiological disease progression or death due to any cause, whichever comes first.[1] ‡Defined as relapse to metastatic disease within 1 year of the end of (neo)adjuvant chemotherapy.[2]

CDK=cyclin-dependent kinase; NE=not evaluable.

IMPORTANT SAFETY INFORMATION *(cont'd)*

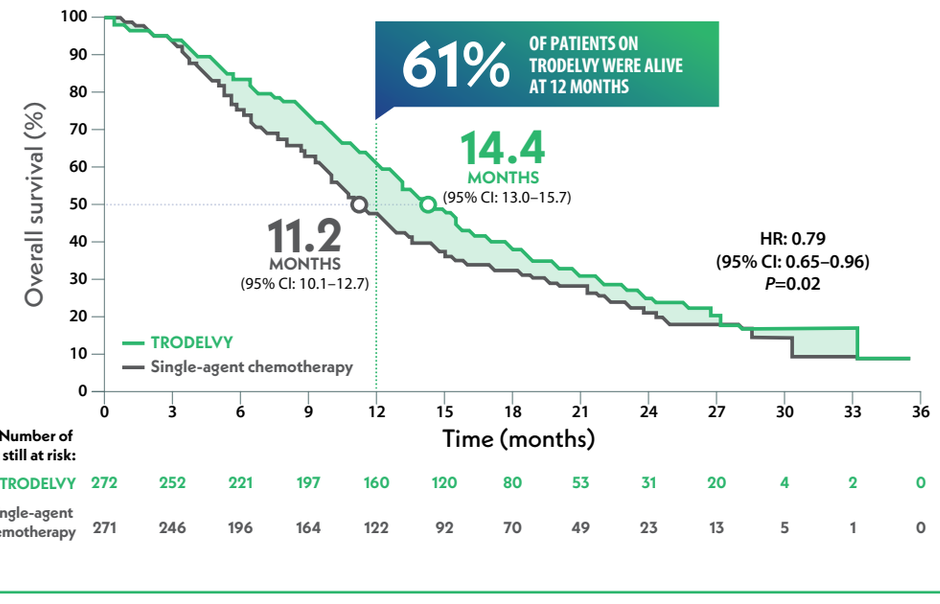
WARNINGS AND PRECAUTIONS *(cont'd)*

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.

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

Help give your patients more time: 3.2 more months of overall survival with TRODELVY[1]

Kaplan-Meier estimates of OS (ITT population)[1,2,7]



- In a prespecified, descriptive analysis, 12-month OS rate was **61% with TRODELVY** (95% CI: 55–66) vs **47% with single-agent chemotherapy** (95% CI: 41–53). Not powered for statistical analysis[7]

TRODELVY may be your next opportunity to extend survival[7]

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.

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TRODELVY has a well-characterized safety profile[2]

Adverse reactions in ≥10% of patients with HR+/HER2- mBC in TROPiCS-02[1]

Adverse reaction	TRODELVY (n=268) All grades (%)	TRODELVY (n=268) Grades 3–4 (%)	Single-agent chemotherapy[a] (n=249) All grades (%)	Single-agent chemotherapy[a] (n=249) Grades 3–4 (%)
Gastrointestinal disorders				
Diarrhea	62	10	23	1
Nausea	59	1	35	3
Constipation	34	1	25	0
Vomiting	23	1	16	2
Abdominal pain	20	0	14	0
Dyspepsia[b]	11	0	6	0
General disorders and administration site conditions				
Fatigue[c]	60	8	51	4
Metabolism and nutrition disorders				
Decreased appetite	21	2	21	0
Hypokalemia	10	2	4	0
Musculoskeletal and connective tissue disorders				
Arthralgia	15	0	12	0
Nervous system disorders				
Headache	16	1	15	1
Respiratory, thoracic, and mediastinal disorders				
Dyspnea[d]	20	0	17	0
Cough	12	0	7	0
Skin and subcutaneous tissue disorders				
Alopecia	48	0	19	0
Pruritus	12	0	2	0

Other clinically significant adverse reactions (≤10%) included hypotension (5%), pain (5%), rhinorrhea (5%), hypocalcemia (3%), nasal congestion (3%), skin hyperpigmentation (3%), colitis or neutropenic colitis (2%), hyponatremia (2%), pneumonia (2%), proteinuria (1%), and enteritis (0.4%).[1]

Graded per NCI CTCAE v.5.0.[1]

[a]Single-agent chemotherapy included one of the following single agents: eribulin (n=130), vinorelbine (n=63), gemcitabine (n=56), or capecitabine (n=22).[1] [b]Including dyspepsia, gastroesophageal reflux disease.[1] [c]Including fatigue, asthenia.[1] [d]Including dyspnea; dyspnea exertional.[1]

NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

IMPORTANT SAFETY INFORMATION *(cont'd)*

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 TROPiCS-02 study, 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.

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

TRODELVY has a well-characterized safety profile[2]

Serious adverse reactions in TROPiCS-02[1]

- Serious adverse reactions occurred in 28% of patients taking 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%)

Treatment discontinuation, reduction, and interruption in TROPiCS-02[1,2]

- **Similar rates of discontinuation due to adverse reactions: 6% with TRODELVY versus 4% with single-agent chemotherapy**
  - The most frequent (≥0.5%) adverse reactions leading to permanent discontinuation of TRODELVY were asthenia, general physical health deterioration, and neutropenia (each 0.7%)
- Adverse reactions leading to dose reduction occurred in 33% of patients treated with TRODELVY
  - The most frequent (>5%) adverse reactions leading to dose reduction were neutropenia (16%) and diarrhea (8%)
- Adverse reactions leading to dose interruption occurred in 66% of patients treated with TRODELVY
  - The most frequent (≥5%) adverse reaction leading to treatment interruption was neutropenia (50%)
- G-CSF was used in 54% of patients who received TRODELVY

Most common adverse reactions and lab abnormalities in TROPiCS-02[1]

- The most common (≥25%) adverse reactions, including lab abnormalities, with TRODELVY 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]

For more information on laboratory abnormalities, please refer to Table 7 of the full Prescribing Information.

Safety profile was consistent with previous TRODELVY trials[1]

G-CSF=granulocyte-colony stimulating factor; ILD=interstitial lung disease.

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.

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Guideline recommended for patients like yours

Sacituzumab govitecan-hziy (TRODELVY) has a National Comprehensive Cancer Network® (NCCN®) Category 1 recommendation* as a preferred treatment option in HR+/HER2- mBC[8]

NCCN Category 1 | Preferred Systemic Therapy Regimen

NCCN: Sacituzumab govitecan-hziy (TRODELVY) is recommended as a Category 1 preferred treatment option for adult patients with recurrent unresectable or metastatic HR+/HER2- breast cancer who have received prior treatment, including endocrine therapy, a CDK4/6 inhibitor, and at least 2 lines of chemotherapy (including a taxane), at least one of which in the metastatic setting. It may be considered for later line if not used as second-line† therapy.[8]

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.[8]

†If not a candidate for fam-trastuzumab deruxtecan-nxki.[8]

The NCCN recommendation differs from the TRODELVY Prescribing Information.

TRODELVY may help your appropriate patients with HR+/HER2- mBC extend survival[1]

CLARA

Not an actual patient.

HER METASTATIC DISEASE IS FAST PROGRESSING

HR+/HER2- IHC 0

- On ET + CDK4/6i for 6 months
- Became ET-resistant
- Received 2 chemotherapies

EILEEN

Not an actual patient.

SHE HAS A METASTATIC RECURRENCE AFTER YEARS OF REMISSION

HR+/HER2- IHC 2+/ISH-

- On ET + targeted therapy for ~2 years
- Became ET-resistant
- Received chemotherapy
- Received ADC

Could your patients with HR+/HER2- mBC benefit from treatment with TRODELVY?

ET=endocrine therapy; NCCN=National Comprehensive Cancer Network® (NCCN®).

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.**

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/mm³ on Day 1 of any cycle or neutrophil count below 1000/mm³ on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Administer G-CSF as clinically indicated or indicated in Table 1 of USPI.

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

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.

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.

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 TROPiCS-02 study, 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.

References: 1. TRODELVY [package insert]. Foster City, CA: 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. **3.** Allison KH, Hammond MEH, Dowsett M, et al. Estrogen and progesterone receptor testing in breast cancer: ASCO/CAP guideline update. *J Clin Oncol.* 2020;38(12):1346-1366. **4.** Tarantino P, Hamilton E, Tolaney SM, et al. HER2-low breast cancer: pathological and clinical landscape. *J Clin Oncol.* 2020;38(17):1951-1962. **5.** 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 **6.** Schmid P, Cortes J, Marmé F, et al. Sacituzumab govitecan efficacy in HR+/HER2– metastatic breast cancer by HER2 immunohistochemistry status in the phase 3 TROPiCS-02 study. Presented at: European Society for Medical Oncology Congress; September 9-13, 2022; Paris, France. Presentation FPN 214MO. **7.** Rugo HS, Bardia A, Marmé F, et al. Overall survival results from the phase 3 TROPiCS-02 study of sacituzumab govitecan vs treatment of physician's choice in patients with HR+/HER2- metastatic breast cancer. Presented at: European Society for Medical Oncology Congress; September 9-13, 2022; Paris, France. Presentation LBA76. **8.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.2.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed February 17, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org.

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

After ET and ≥2 additional systemic therapies in the metastatic setting[1]

TRODELVY is the only Trop-2–directed ADC to provide significantly improved overall survival in pretreated HR+/HER2- mBC[1,2]

In a prespecified, descriptive analysis,

3x more patients remained progression free at 12 months with TRODELVY than with single-agent chemotherapy[2]

- mPFS was **5.5 months with 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). Not powered for statistical analysis[2]

14.4-month mOS[1]

- mOS was **14.4 months with 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

See study design and full efficacy and safety results for TROPiCS-02 on pages 3-9

TRODELVY has a well-characterized safety profile based on clinical studies[2]

You have the potential to extend survival. Choose TRODELVY

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.**

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 TROPiCS-02 study (locally advanced or metastatic HR-positive, HER2-negative breast cancer), the most common (≥25%) adverse reactions and Grade 3-4 lab abnormalities were diarrhea, fatigue, nausea, reduced neutrophils, alopecia, reduced leukocytes, and constipation.

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

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TRODELVY®
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180 mg for injection