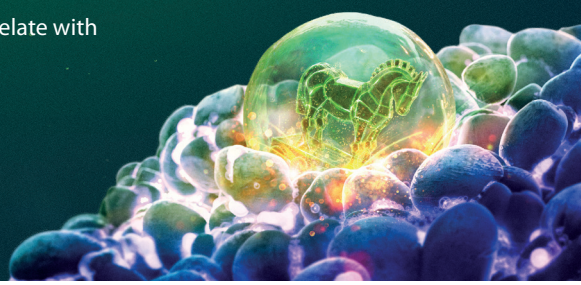
For the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

A **DIFFERENT WAY IN** WITH TRODELVY

TRODELVY attacks mUC as the first antibody-drug conjugate (ADC) that binds to Trop-2.[1]

Based on preclinical data. May not correlate with clinical outcomes.



CLINICAL TRIAL RESULTS

TROPHY was a phase 2, single-arm, open-label, multicenter trial that studied the use of TRODELVY

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.

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/mm³ on Day 1 of any cycle or neutrophil count below 1000/mm³ on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

Please see full Important Safety Information on pages 6-7, and click to see full Prescribing Information, including BOXED WARNING.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

TROPHY WAS A PHASE 2, SINGLE-ARM, OPEN-LABEL, MULTICENTER TRIAL THAT STUDIED THE USE OF TRODELVY

Trial design

Patient population (N=112)

- Adults with locally advanced or mUC who received prior treatment with a platinum-containing chemotherapy and either PD-1 or PD-L1 inhibitor

TRODELVY 10 mg/kg IV on Days 1 and 8 of a 21-day cycle

Continue until disease progression or unacceptable toxicity

Major efficacy outcome measures*

- Overall Response Rate (ORR)
- Duration of Response (DOR)

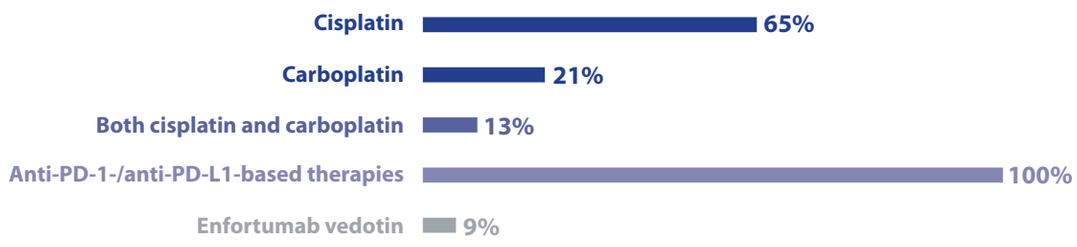
***Assessed using Independent Review Assessment (IRA) based on Response Evaluation Criteria in Solid Tumors (RECIST) 1.1.**

Demographics and baseline patient characteristics (N=112)[1]

- Median age, years (range): 66 years (33-90 years)
- 78% male, 74% White, 3% Asian, 3% Black, and 20% unkown
- ECOG performance status: 0 (28%), 1 (72%)
- 96% of patients had metastatic disease, 67% of patients had visceral metastases, including 34% with liver metastases

ECOG=Eastern Cooperative Oncology Group.

Patients received a median of 3 prior systemic therapies (range: 1-8)[1]



For 34% of patients, the platinum-containing chemotherapy was received in the (neo)adjuvant setting only.

IMPORTANT SAFETY INFORMATION *(cont'd)*

WARNINGS AND PRECAUTIONS

Diarrhea: Diarrhea occurred in 65% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 12% of patients. One patient had intestinal perforation following diarrhea. Neutropenic colitis occurred in 0.5% of patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

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In adult patients with locally advanced or mUC who have previously received a platinum-containing chemotherapy and either PD-1 or PD-L1 inhibitor†

NEARLY 30% OF PATIENTS RESPONDED TO TREATMENT WITH TRODELVY[1]

Overall Response Rate (ORR) by IRA based on RECIST 1.1

27.7%

(95% CI: 19.6–36.9)
N=112

Complete Response (CR): 5.4%
Partial Response (PR): 22.3%

Median Duration of Response (DOR) by IRA based on RECIST 1.1

7.2 months

(95% CI: 4.7, 8.6)
(range: 1.4+,13.7 months)

Number of responders: 31
+: denotes ongoing.

†TRODELVY is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[1]

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 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.

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.

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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ESTABLISHED SAFETY PROFILE OF TRODELVY IN LOCALLY ADVANCED OR mUC

Adverse reactions reported in ≥15% (Grade 1-4) or ≥5% (Grade ≥3) of patients treated with TRODELVY (N=113)[1]

	Grade 1-4 (%)	Grade 3-4 (%)
Any	**94**	**80**
Gastrointestinal disorders		
Diarrhea	72	12
Nausea	66	4
Constipation	34	1
Vomiting	34	1
Abdominal pain[a]	31	2
General disorders and administration site conditions		
Fatigue[b]	68	5
Pyrexia	19	0
Edema[c]	17	2
Skin and subcutaneous tissue disorders		
Alopecia	49	0
Rash[d]	32	2
Metabolism and nutrition disorders		
Decreased appetite	41	3
Weight loss[e]	17	2
Renal and urinary disorders		
Acute kidney injury[f]	24	7
Hematuria	16	1
Infections and infestations		
Any infection[g]	50	25
Urinary tract infection	19	12
Respiratory, thoracic, and mediastinal disorders		
Cough[h]	17	0
Dyspnea	16	0
Musculoskeletal		
Back pain	16	0
Vascular disorders		
Venous thromboembolism[i]	9	6

[a]Includes abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper, gastrointestinal pain.

[b]Includes fatigue and asthenia.

[c]Includes edema genital, edema peripheral, peripheral swelling.

[d]Includes dermatitis acneiform, dermatitis bullous, erythema, lichen planus, photosensitivity reaction, pruritus, pruritus generalized, rash, rash macular, rash maculopapular, rash pruritic, skin papilloma, skin toxicity.

Selected laboratory abnormalities reported in ≥20% (any grade) or ≥5% (Grade 3-4) of patients treated with TRODELVY (N=113)[1]

	Any Grade[j] (%)	Grade 3-4[j] (%)
Laboratory abnormality		
Hematology		
Leukocytes decreased	78	38
Lymphocytes decreased	71	35
Hemoglobin decreased	71	18
Neutrophils decreased	67	43
Platelets decreased	25	2
Chemistry		
Glucose increased	59	8
Albumin decreased	51	4
Calcium decreased	46	9
Sodium decreased	43	1
Phosphate decreased	41	15
Alkaline phosphatase increased	36	0
Creatinine increased	32	5
Magnesium decreased	31	2
Alanine aminotransferase increased	28	2
Lactate dehydrogenase increased	28	0
Potassium decreased	27	0
Aspartate aminotransferase increased	26	2
Coagulation		
Activated partial thromboplastin time increased	33	6

[j]Denominator for each laboratory parameter is based on the number of patients with a baseline and post-treatment laboratory value available (range: 66 to 111 patients).

[e]Includes failure to thrive and weight decreased.

[f]Includes acute kidney injury, blood creatinine increased, nephropathy toxic, renal failure, renal impairment.

[g]Includes bacteremia, body tinea, bronchitis, candida infection, cellulitis, *clostridium difficile* infection, coronavirus infection, device-related infection, diverticulitis, escherichia bacteremia, escherichia pyelonephritis, folliculitis, gastroenteritis, gastroenteritis escherichia coli, herpes zoster, kidney infection, klebsiella sepsis, lung infection, nasopharyngitis, oral candidiasis, oral herpes, pneumonia, pyelonephritis, pyelonephritis acute, respiratory tract infection, rhinitis, sepsis, sinusitis, skin infection, tooth abscess, upper respiratory tract infection, urinary tract infection, urosepsis, vascular device infection, viral infection, viral pharyngitis, vulvovaginal mycotic infection.

[h]Includes cough, productive cough, upper-airway cough syndrome.

[i]Includes deep vein thrombosis, embolism, and pulmonary embolism.

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ADDITIONAL SAFETY INFORMATION

Most common adverse reactions[1]

- The most common adverse reactions in TROPHY (incidence ≥25%) were diarrhea, fatigue, neutropenia, nausea, any infection, alopecia, anemia, decreased appetite, constipation, vomiting, abdominal pain, and rash
- In the pooled safety population (n=795), the most common adverse reactions (incidence ≥25%) 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%)

Serious adverse reactions[1]

- Serious adverse reactions occurred in 44% of patients receiving TRODELVY
- Serious adverse reactions in >1% of patients receiving TRODELVY included infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), sepsis or bacteremia (5%), diarrhea (4%), anemia, venous thromboembolism, and small intestinal obstruction (3% each), pneumonia, abdominal pain, pyrexia, and thrombocytopenia (2% each)
- Fatal adverse reactions occurred in 3.6% of patients, including sepsis, respiratory failure, epistaxis, and completed suicide

Treatment discontinuation[1]

- Adverse reactions leading to permanent discontinuation of TRODELVY occurred in 10% of patients
- The most frequent adverse reaction leading to permanent discontinuation of study drug was neutropenia (4%, including febrile neutropenia in 2%)

Treatment interruption[1]

- Adverse reactions leading to a treatment interruption of TRODELVY occurred in 52% of patients
- The most common adverse reactions leading to dose interruption were neutropenia (27%, including febrile neutropenia in 2%), infection (12%), and acute kidney injury (8%)

Dose reductions[1]

- Adverse reactions leading to a dose reduction of TRODELVY occurred in 42% of patients. The most common (>4%) adverse reactions leading to a dose reduction were neutropenia (13%, including febrile neutropenia in 3%), diarrhea (11%), fatigue (8%), and infection (4%)
  - Granulocyte colony-stimulating factor (G-CSF) was used in 47% of patients who received TRODELVY

Additional safety data[1,2]

- Other clinically significant adverse reactions (≤15%) included: peripheral neuropathy (12%), sepsis or bacteremia (9%), and pneumonia (4%)
  - Cases of Grade 3-4 neuropathy were not reported in Cohort 1 of TROPHY

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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IMPORTANT SAFETY INFORMATION

INDICATION

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

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- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

WARNINGS AND PRECAUTIONS

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ADVERSE REACTIONS

In the TROPHY study (IMMU-132-06), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, neutropenia, nausea, any infection, alopecia, anemia, decreased appetite, constipation, vomiting, abdominal pain, and rash. The most frequent serious adverse reactions (SAR) (≥5%) were infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), and sepsis or bacteremia (5%). SAR were reported in 44% of patients, and 10% discontinued due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPHY study were reduced neutrophils, leukocytes, and lymphocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

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

For adults with locally advanced or mUC who have previously received a platinum-containing chemotherapy and either a PD-1 or PD-L1 inhibitor*

A DIFFERENT WAY IN WITH TRODELVY

TRODELVY attacks mUC as the first ADC that binds to Trop-2.[1]
Based on preclinical data. May not correlate with clinical outcomes.

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ORR†

27.7%

(95% CI: 19.6, 36.9) (5.4% CR, 22.3% PR)

Median DOR†

7.2 months

(95% CI: 4.7, 8.6) (range: 1.4+,13.7 months)
Number of responders: 31

+: denotes ongoing.

†By IRA based on RECIST 1.1. Based on a phase 2, single-arm, open-label, multicenter trial (N=112). See study design on page 2.

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 /bladdercancer/access-support**, or call **1-844-TRODELVY** (1-844-876-3358), Monday–Friday, 9 AM–7 PM ET

INDICATION

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

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Please see full Important Safety Information on pages 6-7, and click to see full Prescribing Information, including BOXED WARNING.

References: 1. TRODELVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2021. **2.** Tagawa ST, Balar AV, Petrylak DP, et al. TROPHY-U-01: a phase II open-label study of sacituzumab govitecan in patients with metastatic urothelial carcinoma progressing after platinum-based chemotherapy and checkpoint inhibitors [published online ahead of print April 30, 2021]. *J Clin Oncol.* doi:10.1200/JCO.20.03489

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