TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

The first and only Trop-2–directed **ADC** for mUC[1]

Elevate the Possibilities With TRODELVY®

mUC

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. 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.

Clinical results from the TROPHY study

A Phase 2, single-arm, open-label, multicenter study that evaluated the use of TRODELVY

ADC=antibody-drug conjugate.

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

Think TRODELVY for 2L or later mUC[1]

TRODELVY in 2L

Treatment pathway 1 Diagnosed with resectable UC[1-3]	Treatment pathway 2 Diagnosed with resectable UC[1-3]	Treatment pathway 3 Diagnosed with locally advanced/mUC[1-3]
Adjuvant/neoadjuvant platinum-containing chemotherapy	Adjuvant nivolumab	
Progressed to locally advanced/mUC	Progressed to locally advanced/mUC	
1L PD-1/PD-L1 inhibitor	1L Platinum-containing chemotherapy	1L Platinum-containing chemotherapy Avelumab maintenance
2L TRODELVY	2L TRODELVY	2L TRODELVY

TRODELVY in subsequent lines

Treatment pathway Diagnosed with locally advanced/mUC		
1L Platinum-containing chemotherapy	2L PD-1/PD-L1 inhibitor	SUBSEQUENT LINES TRODELVY

These specific treatment scenarios are for illustrative purposes only.
1L=first line; 2L=second line.

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.

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TROPHY: a Phase 2 study of TRODELVY in pretreated mUC

TRODELVY was studied in a single-arm, open-label, multicenter study

Patient population (N=112)*
Adults with locally advanced or mUC who previously received a platinum-containing chemotherapy and either a 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

For Illustrative purposes only. Not an actual patient.

Major efficacy outcome measures*

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

*Assessed using IRA based on RECIST 1.1.

Demographics and baseline patient characteristics[1]

- Median age, years (range): 66 years (33-90 years)
- 78% male, 74% White, 3% Asian, 3% Black, and 20% unknown
- 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; IRA=independent review assessment; IV=intravenous; RECIST=Response Evaluation Criteria in Solid Tumors.

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.

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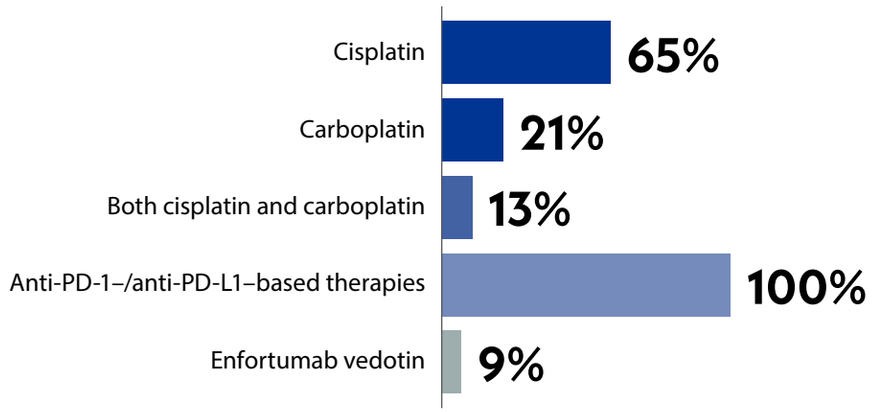
TRODELVY is approved for 2L and later locally advanced or mUC based on the TROPHY study

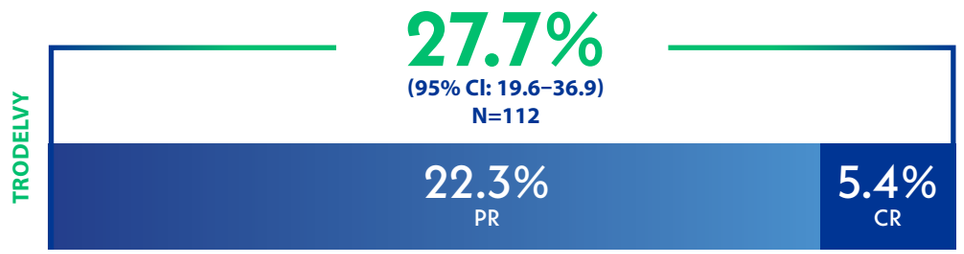
Patients received a median of 3 prior systemic therapies (range: 1-8)[1]



For 34% of patients, the platinum-containing chemotherapy was received in the neoadjuvant/adjuvant setting only

TRODELVY treatment results: nearly 30% of patients responded, with ~5% experiencing complete response[1]

ORR by IRA based on RECIST 1.1



7.2 months
(range 1.4+, 13.7)

Median DOR by IRA based on RECIST 1.1

(95% CI: 4.7–8.6) Number of responders: 31
+: denotes ongoing

CI=confidence interval.

See more data from the TROPHY trial at **trodelvyhcp.com**

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. 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.

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 TROPHY study, the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, any infection, alopecia, decreased appetite, constipation, vomiting, rash, and abdominal pain. 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 reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

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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]

Adverse Reaction	Grade 1–4 (%)	Grade 3–4 (%)
Any adverse reaction	**94**	**80**
Gastrointestinal disorders		
Diarrhea	72	12
Nausea	66	4
Constipation	34	1
Vomiting	34	1
Abdominal pain[i]	31	2
General disorders and administration site conditions		
Fatigue[ii]	68	5
Pyrexia	19	0
Edema[iii]	17	2
Skin and subcutaneous tissue disorders		
Alopecia	49	0
Rash[iv]	32	2
Metabolism and nutrition disorders		
Decreased appetite	41	3
Weight loss[v]	17	2

Adverse Reaction	Grade 1–4 (%)	Grade 3–4 (%)
Any adverse reaction	**94**	**80**
Renal and urinary disorders		
Acute kidney injury[vi]	24	7
Hematuria	16	1
Infections and infestations		
Any infection[vii]	50	25
Urinary tract infection	19	12
Respiratory, thoracic, and mediastinal disorders		
Cough[viii]	17	0
Dyspnea	16	0
Musculoskeletal disorders		
Back pain	16	0
Vascular disorders		
Venous thromboembolism[ix]	9	6

Graded per NCI CTCAE v.5.0.

[i] Includes abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper, gastrointestinal pain

[ii] Includes fatigue and asthenia

[iii] Includes edema genital, edema peripheral, peripheral swelling

[iv] Includes dermatitis acneiform, dermatitis bullous, erythema, lichen planus, photosensitivity reaction, pruritus, pruritus generalised, rash, rash macular, rash maculo-papular, rash pruritic, skin papilloma, skin toxicity

[v] Includes failure to thrive and weight decreased

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

[vii] Includes bacteremia, body tinea, bronchitis, candida infection, cellulitis, clostridium difficile infection, corona virus 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

[viii] Includes cough, productive cough, upper-airway cough syndrome

[ix] Includes deep vein thrombosis, embolism, and pulmonary embolism

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

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

Adverse Reaction	Any Grade* (%)	Grade 3–4* (%)
Hematology		
Decreased leukocyte count	78	38
Decreased lymphocyte count	71	35
Decreased hemoglobin	71	18
Decreased neutrophil count	67	43
Decreased platelet count	25	2
Chemistry		
Increased glucose	59	8
Decreased albumin	51	4
Decreased calcium	46	9
Decreased sodium	43	1

Adverse Reaction	Any Grade* (%)	Grade 3–4* (%)
Chemistry *(cont'd)*		
Decreased phosphate	41	15
Increased alkaline phosphatase	36	0
Increased creatinine	32	5
Decreased magnesium	31	2
Increased alanine aminotransferase	28	2
Increased lactate dehydrogenase	28	0
Decreased potassium	27	0
Increased aspartate aminotransferase	26	2
Coagulation		
Increased activated partial thromboplastin time	33	6

*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).

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

Most common adverse reactions[1]

- The most common (≥25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (78%), diarrhea (72%), decreased hemoglobin (71%), decreased lymphocyte count (71%), decreased neutrophil count (67%), nausea (66%), increased glucose (59%), fatigue (56%), decreased albumin (51%), alopecia (49%), decreased calcium (46%), decreased sodium (43%), decreased appetite (41%), decreased phosphate (41%), increased alkaline phosphatase (36%), constipation (34%), vomiting (34%), increased activated partial thromboplastin time (33%), increased creatinine (32%), decreased magnesium (31%), increased alanine aminotransferase (28%), increased lactate dehydrogenase (28%), abdominal pain (27%), decreased potassium (27%), increased aspartate aminotransferase (26%), and decreased platelet count (25%)

Additional safety data[1,4]

- Other clinically significant adverse reactions TROPHY (≤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

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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.

TRODELVY treatment results: nearly 30% of patients responded, with ~5% experiencing complete response

TRODELVY attacks mUC as the first and only ADC that binds to Trop-2[1]

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

ORR*

27.7%

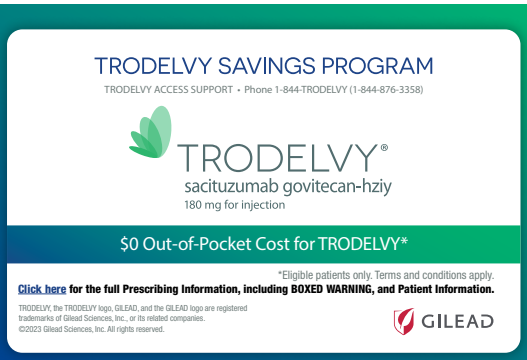
(95% CI: 19.6-36.9)
Complete Response (CR): 5.4%
Partial Response (PR): 22.3%
N=112

Median DOR*

7.2 months (range 1.4+, 13.7)

(95% CI: 4.7-8.6)
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 3.



TRODELVY ACCESS SUPPORT can help your patients determine their benefits and coverage.

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

TRODELVY support may vary based on application criteria and is subject to change or discontinuation. Physician office must submit prior authorizations and appeals.

†The TRODELVY Savings Program is not available to patients with any form of government insurance. Patients must meet certain eligibility criteria to qualify for this program. Once enrolled the patient pays as little as $0 out-of-pocket for TRODELVY, with maximum benefit of $25,000 per year.

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- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

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References: 1. TRODELVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; February 2023. **2.** NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Bladder Cancer V.2.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed June 28, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Bajorin DF, Witjes JA, Gschwend JE, et al. Adjuvant nivolumab versus placebo in muscle-invasive urothelial carcinoma. *N Engl J Med.* 2021;384(22):2102-2114. **4.** 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. *J Clin Oncol.* 2021;39(22):2474-2485.

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