

# Trodelvy<sup>®</sup> (sacituzumab govitecan-hziy)

## Efficacy by Trop-2 Expression in mUC

This document is in response to your request for information regarding the efficacy of Trodelvy<sup>®</sup> (sacituzumab govitecan-hziy [SG]) by trophoblast cell-surface antigen 2 (Trop-2) expression in patients with metastatic urothelial carcinoma (mUC).

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

**Trodelvy is not indicated for use in patients with mUC. The full indication, important safety information, and boxed warnings for neutropenia and diarrhea are available at: [www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi).**

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## Efficacy of SG by Trop-2 Expression in mUC

### TROPHY-U-01

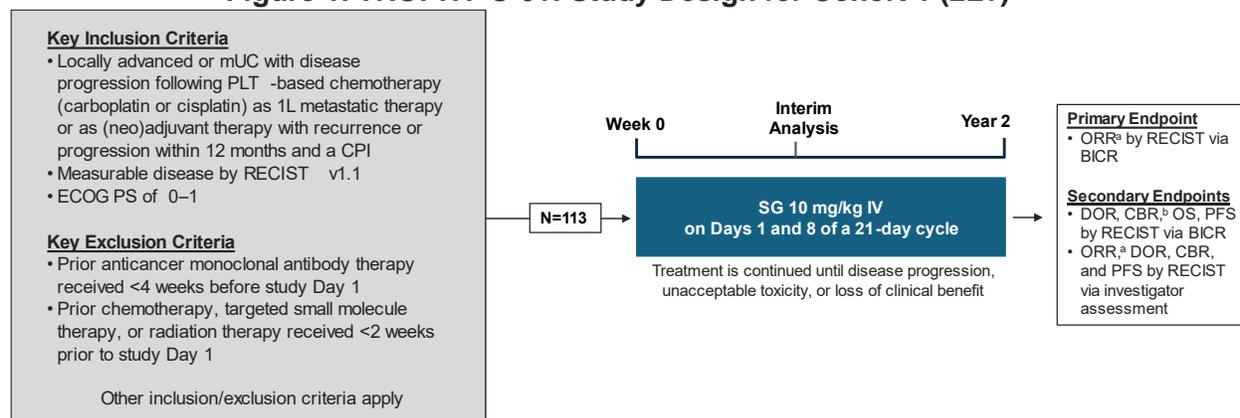
#### Study design

TROPHY-U-01 ([NCT03547973](https://clinicaltrials.gov/ct2/show/study/NCT03547973)), is an ongoing global, open-label phase 2, multi-cohort study of SG in patients with unresectable locally advanced/mUC. Approximately 827 patients are anticipated to be enrolled.<sup>1</sup> An analysis of efficacy by Trop-2 expression was performed on archival tumor samples collected from patients enrolled in Cohorts 1 through 3 (n=192 at data cutoff).<sup>2</sup> Further details of specific cohorts included in this analysis, including patient populations and treatment regimens are briefly described below.

#### **Cohort 1<sup>1,3</sup>**

Cohort 1 investigated the safety and efficacy of SG in patients with mUC who were previously treated with PLT-based therapy ± CPIs (Figure 1).

**Figure 1. TROPHY-U-01: Study Design for Cohort 1 (2L+)<sup>1,3</sup>**



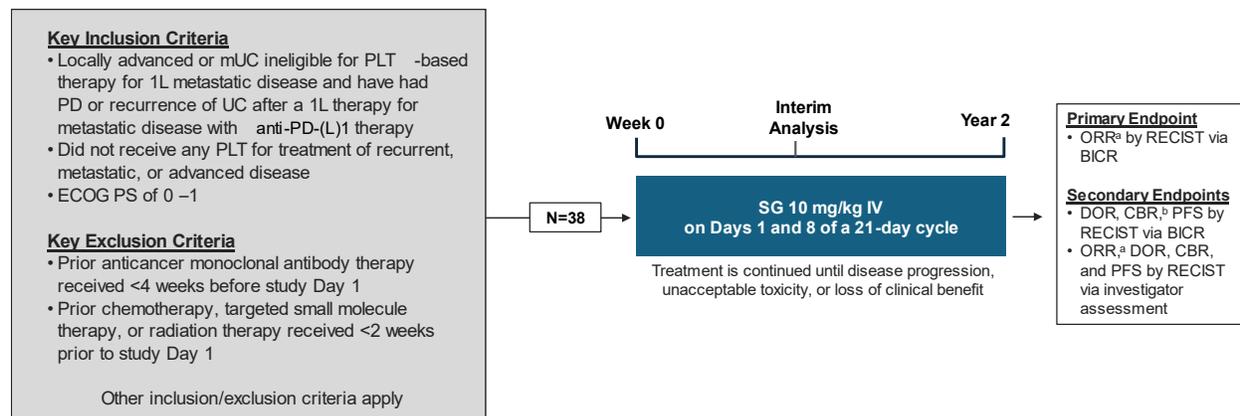
<sup>a</sup>Defined as the rate of the best overall response of CR + PR.

<sup>b</sup>Defined as CR, PR, and SD for ≥6 months.

### Cohort 2<sup>1,4</sup>

Cohort 2 is investigating the safety and efficacy of SG in PLT-ineligible patients with mUC who had progressed after CPI-only therapy (Figure 2).

**Figure 2. TROPHY-U-01: Study Design for Cohort 2 (2L+)<sup>1,4</sup>**



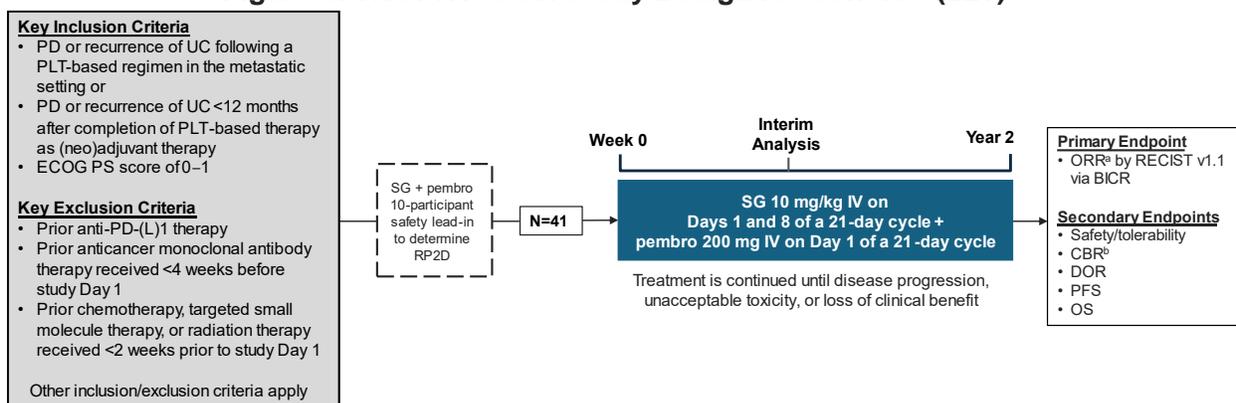
<sup>a</sup>Defined as the rate of the best overall response of CR + PR.

<sup>b</sup>Defined as CR, PR, and SD for ≥6 months.

### Cohort 3<sup>1,5</sup>

Cohort 3 is a single-arm design investigating the safety and efficacy of SG + pembro in CPI-naive patients who had progression of urothelial cancer after PLT-based chemotherapy in the metastatic setting or ≤12 months after completion of PLT in the (neo)adjuvant setting (Figure 3).

**Figure 3. TROPHY-U-01: Study Design for Cohort 3 (2L+)<sup>1,5</sup>**



Abbreviation: RP2D=recommended phase 2 dose.

<sup>a</sup>Defined as the rate of the best overall response of CR + PR.

<sup>b</sup>Defined as CR, PR, and SD for ≥6 months.

## Efficacy by Trop-2 expression analysis<sup>2</sup>

Of the patients enrolled in Cohorts 1 through 3 of TROPHY-U-01, 144 patients (75%) had tumor tissue samples evaluable for Trop-2 testing, and 139 patients (72%) were evaluable for efficacy analysis based on Trop-2 expression. Baseline characteristics for patients with evaluable samples were consistent with the overall population.

Trop-2 protein was highly expressed in tumor tissue samples of patients across Cohorts 1 through 3. Median (IQR) Trop-2 H-score and percentage of Trop-2 membrane-positive tumor cells for evaluable patient samples were 215 (180–247) and 92% (75–98%), respectively ( $\rho=0.82$ ,  $P<0.001$ ).

All Trop-2 expression groups exhibited a response to SG, and no difference was observed in ORR with different Trop-2 expression when categorized by median or tertile cut.

### Cohort 1

ORRs for Cohort 1 samples with below (n=42) and above (n=45) median Trop-2 H-scores were 29% and 36%, respectively ( $P=0.49$ ); median PFS was 3.4 and 6.7 months, respectively (HR, 0.77; 95% CI: 0.48–1.22;  $P=0.26$ ); and median OS was 9.9 and 10.9 months, respectively (HR, 0.98; 95% CI: 0.61–1.58;  $P=0.93$ ).

Tertile categorization groups were determined by stratifying patients into three similarly sized groups based off Trop-2 H-scores: T1, n=28; T2, n=29; and T3, n=30.

- Median PFS for T1, T2, and T3 was 3.9, 6.9, and 5.5 months, respectively;
  - T2 vs T1: HR, 1.06; 95% CI: 0.59–1.9;  $P=0.85$ ;
  - T3 vs T2: HR, 1.04; 95% CI: 0.58–1.87;  $P=0.89$ .
- Median OS for T1, T2, and T3 was 11, 10.6, and 10.4 months, respectively;
  - T2 vs T1: HR, 1.18; 95% CI: 0.65–2.13;  $P=0.59$ ;
  - T3 vs T2: HR, 1.11; 95% CI: 0.61–2.01;  $P=0.73$ .

### Cohort 2

ORRs for Cohort 2 samples with below (n=8) and above (n=8) median Trop-2 H-scores were 38% and 38%, respectively ( $P=1$ ); median PFS was 5.5 and 6.9 months, respectively (HR, 0.74; 95% CI: 0.23–2.34;  $P=0.6$ ); and median OS was 14 and 15.6 months, respectively (HR, 0.34; 95% CI: 0.06–1.79;  $P=0.2$ ).

### Cohort 3

ORRs for Cohort 3 samples with below (n=21) and above (n=15) median Trop-2 H-scores were 48% and 40%, respectively ( $P=0.65$ ); median PFS was 5.5 and 4 months, respectively (HR, 1.16; 95% CI: 0.52–2.57;  $P=0.71$ ); and median OS was 12.5 and 16.6 months, respectively (HR, 0.94; 95% CI: 0.36–2.48,  $P=0.9$ ).

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## References

1. ClinicalTrials.gov. Phase II Open Label Study of IMMU-132 in Metastatic Urothelial Cancer. ClinicalTrials.gov Identifier: NCT03547973. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT03547973>. Accessed: 13 February 2026. Last Updated 15 April 2025.
2. Loriot Y, Balar AV, Petrylak DP, et al. Efficacy of sacituzumab govitecan (SG) in locally advanced (LA) or metastatic urothelial cancer (mUC) by trophoblast cell surface antigen 2 (Trop-2) expression. [Abstract 4579]. Presented at: American Society of Clinical Oncology (ASCO); June 2-6, 2023; Chicago, Illinois.
3. Tagawa ST, Balar AV, Petrylak DP, et al. Updated outcomes in TROPHY-U-01 cohort 1, a phase 2 study of sacituzumab govitecan in patients with metastatic urothelial cancer who progressed after platinum-based chemotherapy and a checkpoint inhibitor [Poster 526]. Presented at: American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium; 16-18 February, 2023; San Francisco, CA.
4. Petrylak DP, Tagawa ST, Jain RK, et al. Primary analysis of TROPHY-U-01 cohort 2, a phase 2 study of sacituzumab govitecan in platinum-ineligible patients with metastatic urothelial cancer who progressed after prior checkpoint inhibitor therapy [Poster 520]. Presented at: American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium; 16-18 February, 2023; San Francisco, CA.
5. Grivas P, Pouessel D, Park C H, et al. TROPHY-U-01 Cohort 3: Sacituzumab Govitecan (SG) in Combination With Pembrolizumab (Pembro) in Patients (pts) With Metastatic Urothelial Cancer (mUC) Who Progressed After Platinum (PLT)-Based Regimens [Presentation]. Presented at: ASCO Genitourinary Cancers Symposium; 16 February, 2022; San Francisco, CA and Online.

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## Abbreviations

1L=first line  
2L+=second-line and later  
BICR=blinded independent central review  
CBR=clinical benefit rate  
CPI=checkpoint inhibitor  
CR=complete response  
DOR=duration of response  
ECOG PS=Eastern Cooperative Oncology Group Performance Status  
H-score=histological score

HR=hazard ratio  
mUC=metastatic urothelial carcinoma  
ORR=objective response rate  
OS=overall survival  
PD=progressive disease  
PD-(L)1=protein cell death (ligand) 1  
pembro=pembrolizumab  
PFS=progression-free survival  
PLT=platinum

PR=partial response  
RECIST=Response Evaluation Criteria in Solid Tumors v1.1  
SD=stable disease  
SG=sacituzumab govitecan-hziy  
Trop-2=trophoblast cell surface antigen 2  
UC=urothelial cancer

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## Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Trodelvy US Prescribing Information available at:

[www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi).

## Follow Up

For any additional questions, please contact Trodelvy Medical Information at:

☎ 1-888-983-4668 or 🌐 [www.askgileadmedical.com](http://www.askgileadmedical.com)

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🌐 [www.gilead.com/utility/contact/report-an-adverse-event](http://www.gilead.com/utility/contact/report-an-adverse-event)

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 [www.accessdata.fda.gov/scripts/medwatch](http://www.accessdata.fda.gov/scripts/medwatch)

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