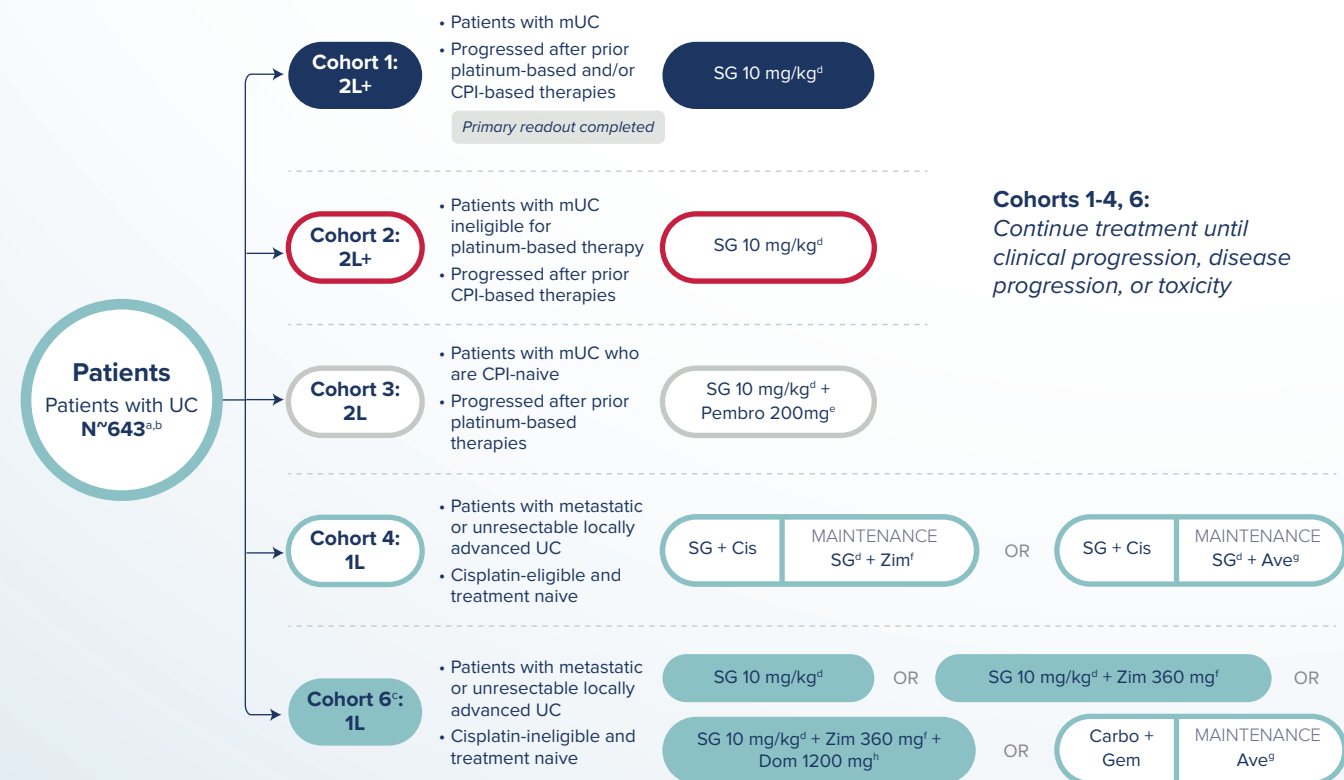


# TROPHY U-01: A Phase 2 Open-Label Study of Sacituzumab Govitecan in Unresectable Locally Advanced/Metastatic Urothelial Cancer

## Study Design<sup>1,2</sup>



## Key Eligibility Criteria<sup>1,2</sup>

### Key Inclusion Criteria

- ECOG of 0 or 1
- Adequate renal and hepatic function
- Adequate hematologic parameters without transfusional support

### Key Exclusion Criteria

- Active second malignancy
- Active CNS metastases and/or carcinomatous meningitis
- Active Hepatitis B or C

## Endpoints<sup>1,2</sup>

### Primary Endpoint

- Cohorts 1-4, 6: ORR<sup>i</sup>

### Key Secondary Endpoints

- Safety/tolerability
- ORR<sup>ij</sup>
- CBR<sup>ij</sup>
- DOR<sup>ij</sup>
- PFS<sup>ij</sup>
- OS

<sup>a</sup>Approximate enrollment. Actual enrollment numbers may vary. <sup>b</sup>Cohort 5 has been canceled, effective December 2023. <sup>c</sup>Cohort 6 will begin with two separate 6-8 patient safety lead-ins of SG+ zimberelimab and SG + zimberelimab + domvanalimab. <sup>d</sup>SG 10 mg/kg intravenously on Days 1 and 8 of a 21-day cycle. <sup>e</sup>Pembro 200 mg only on Day 1 of a 21-day cycle. <sup>f</sup>Zim 360 mg every 3 weeks on Day 1 of a 21-day cycle. <sup>g</sup>Ave 800 mg every 2 weeks beginning on Cycle 1, Day 1 and every 2 weeks thereafter. <sup>h</sup>Dom 1200 mg IV every 3 weeks on Day 1 of a 21-day cycle. <sup>i</sup>Per RECIST v1.1. <sup>j</sup>Cohort 3 will be evaluated by Modified RECIST v1.1 for Immune-Based Therapeutics (iRECISTv1.1).

1L, first line; 2L, second line; ave, avelumab; Carbo, carboplatin; Cis, cisplatin; CBR, clinical benefit rate; CNS, central nervous system; CPI, checkpoint inhibitor; Dom, domvanalimab; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; Gem, gemcitabine; mUC, metastatic urothelial cancer; ORR, objective response rate; OS, overall survival; Pembro, pembrolizumab; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; SG, sacituzumab govitecan; UC, urothelial cancer; v, version; Zim, zimberelimab.

### References

1. Clinicaltrials.gov website. Accessed May 3, 2024. <https://clinicaltrials.gov/ct2/show/NCT03547973>
2. Data on file. Gilead Sciences, Inc. 2022.

**The safety and efficacy of these investigational agents have not been established, and they have not received marketing authorization in this setting. There is no guarantee that these investigational agents and/or uses will receive Health Authority approval and/or become commercially available.** Visit [clinicaltrials.gov](https://clinicaltrials.gov) for more information. Clinicaltrials.gov: NCT03547973