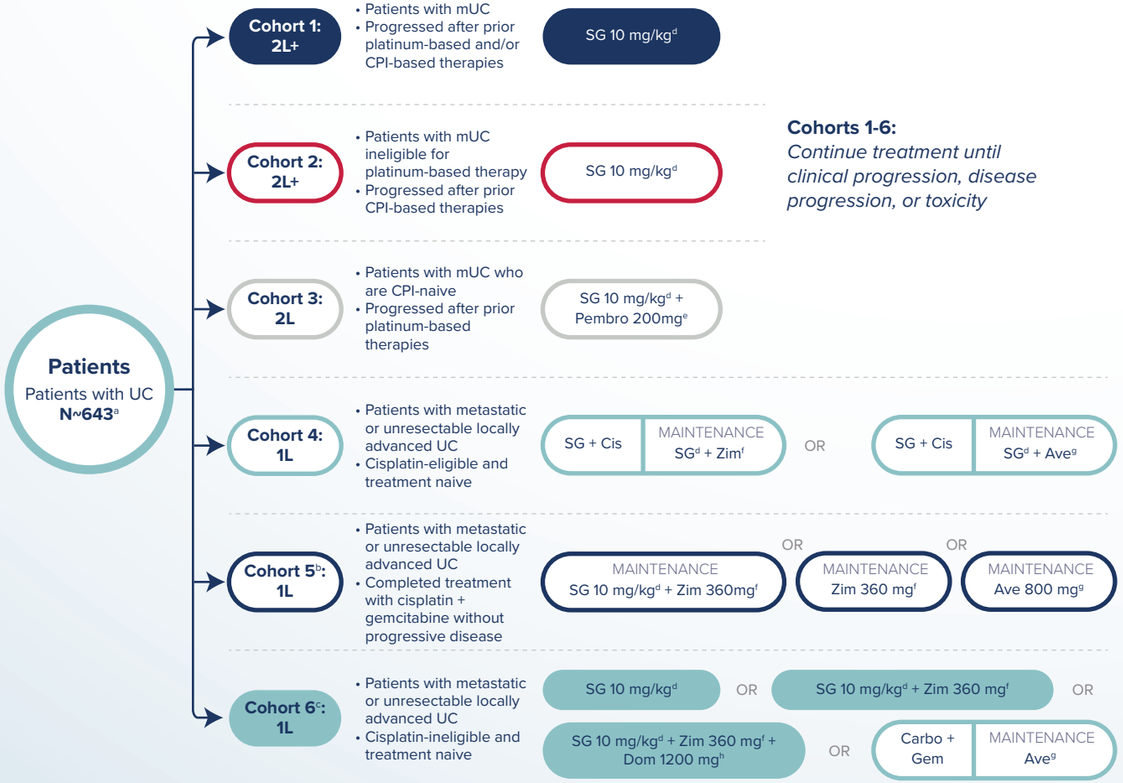
ClinicalTrials.gov Identifier: NCT03547973

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

Study Design[1,2]



Cohorts 1-6:
Continue treatment until clinical progression, disease progression, or toxicity

Key Eligibility Criteria[1,2]

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 central nervous system metastases and/or carcinomatous meningitis
- Active Hepatitis B or C

Endpoints[1,2]

Primary Endpoints

- Cohorts 1-4, 6: ORR[i]
- Cohort 5: PFS[j]

Key Secondary Endpoints

- Safety/tolerability
- ORR[i,j]
- CBR[i,j]
- DOR[i,j]
- PFS[i,j]
- OS

[a]Approximate enrollment. Actual enrollment numbers may vary. [b]Cohort 5 will begin with a 6-8 pt safety lead-in of SG + zimberelimab. [c]Cohort 6 will begin with two separate 6-8 patient safety lead-ins of SG+ zimberelimab and SG + zimberelimab + domvanalimab. [d]SG 10 mg/kg intravenously on Days 1 and 8 of a 21-day cycle. [e]Pembro 200 mg only on Day 1 of a 21-day cycle. [f]Zim 360 mg every 3 weeks on Day 1 of a 21-day cycle. [g]Ave 800 mg every 2 weeks beginning on Cycle 1, Day 1 and every 2 weeks thereafter. [h]Dom 1200 mg IV every 3 weeks on Day 1 of a 21-day cycle. [i]Per RECIST v1.1. [j]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; 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 v1.1, Response Evaluation Criteria in Solid Tumors, version 1.1; SG, sacituzumab govitecan; UC, urothelial cancer; Zim, zimberelimab.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT03547973
2. Data on file. Gilead Sciences, Inc. 2022.

The safety and efficacy of these investigational agents and/or uses have not been established. There is no guarantee that they will become commercially available. Visit clinicaltrials.gov for more information. Clinicaltrials.gov: NCT03547973