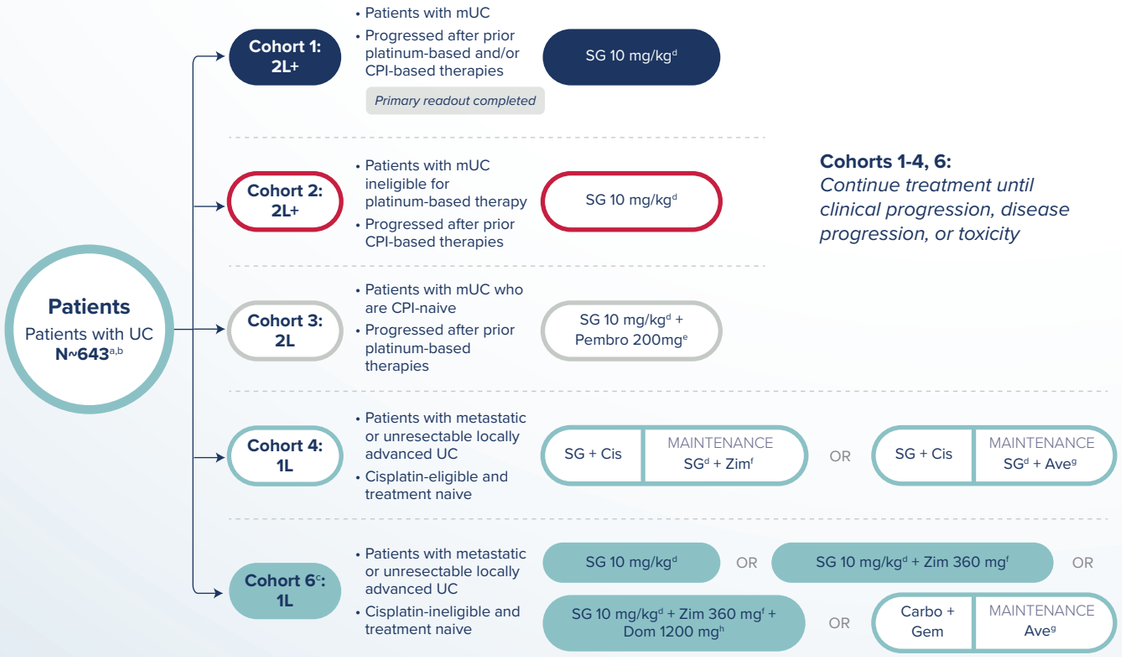
ClinicalTrials.gov Identifier: NCT03547973 • EudraCT Identifier: 2018-001167-23

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

Study Design[1-3]



Cohorts 1-4, 6:
Continue treatment until clinical progression, disease progression, or toxicity

Key Eligibility Criteria[1-3]

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[1-3]

Primary Endpoints

- Cohorts 1-4, 6: ORR[i]

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 has been canceled, effective December 2023. [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.
3. Clinicaltrialsregister.eu website

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.