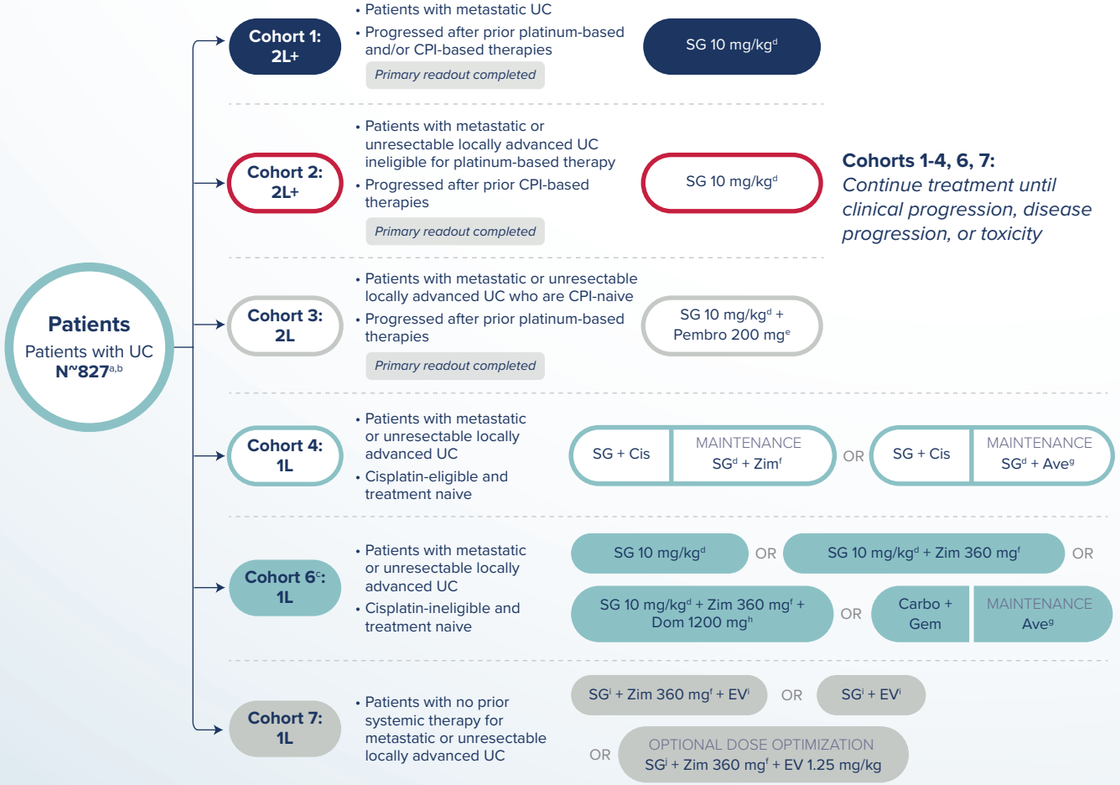
TROPHY U-01: A Phase 2 Open-Label Study of Sacituzumab Govitecan in Unresectable Locally Advanced/Metastatic Urothelial Cancer

Study Design[1,2]



Key Eligibility Criteria[1,2]

Key Inclusion Criteria

- ECOG PS 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[1,2]

Primary Endpoint

- Cohorts 1-4, 6, 7: ORR[k]
- Cohort 7: Safety/tolerability

Key Secondary Endpoints

Cohorts 1-4, 6, 7:

- Safety/tolerability
- ORR[k,l]
- CBR[k,l]
- DOR[k,l]
- PFS[k,l]
- 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]SG and EV doses determined in Phase 1b. [j]Arm 3 is optional dose optimization arm to evaluate SG at 1 dose level below the RP2D that may be enrolled based on the RP2D and the totality of emerging data from Cohort 7. [k]Per RECIST v1.1. [l]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 PS, Eastern Cooperative Oncology Group Performance Score; EV, enfortumab vedotin; 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; RP2D, recommended phase 2 dose; SG, sacituzumab govitecan; UC, urothelial cancer; v, version; Zim, zimberelimab.

References

1. Clinicaltrials.gov website. Accessed December 9, 2024. https://www.clinicaltrials.gov/study/NCT03547973
2. Data on file. Gilead Sciences, Inc. 2024.

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.