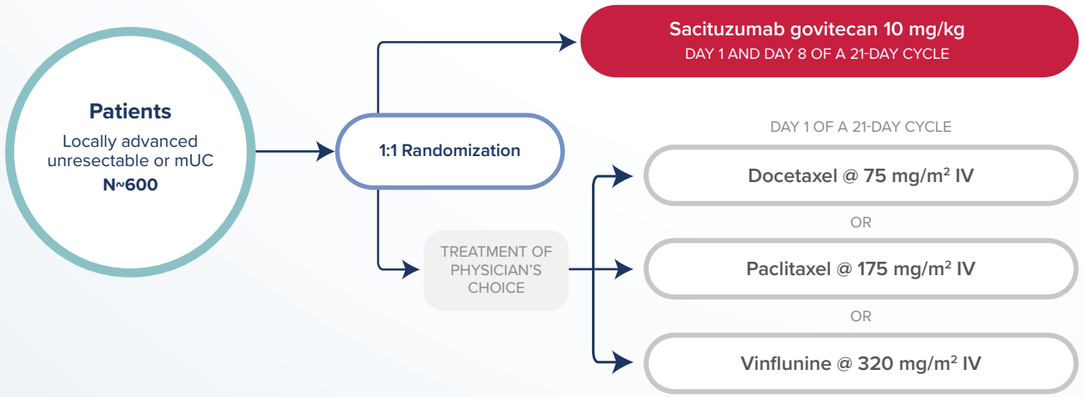
ClinicalTrials.gov Identifier: NCT04527991

TROPiCS-04: A Randomized Open-Label Phase III Study of Sacituzumab Govitecan vs Treatment of Physician's Choice (TPC) in Patients with Metastatic or Locally Advanced Unresectable Urothelial Carcinoma

Study Design[1,2]



TROPiCS-04

TROPiCS-04 is active, not recruiting.

Key Eligibility Criteria[1,2]

Key Inclusion Criteria

- ≥18 years of age
- ECOG PS of 0 or 1
- Locally advanced unresectable or mUC
- Patients with previously treated brain metastases with stable CNS disease for at least 4 weeks prior to C1D1
- Adequate organ function and eligible to receive SG or TPC at protocol specified doses
- Subjects who have progressed after receiving enfortumab vedotin in prior lines of therapy, and subjects who are either ineligible or unable to tolerate enfortumab vedotin therapy, are eligible to enroll in the study

Key Exclusion Criteria

- Have had a prior anti-cancer mAb/ADC within 4 weeks prior to C1D1 or have had prior chemotherapy, targeted small molecule therapy, or radiation therapy within 2 weeks prior to C1D1
- Have an active second malignancy
- Have received prior chemotherapy for UC with any available SOC therapies in the control arm
- A history of active interstitial lung disease or noninfectious pneumonitis

Endpoints[1,2]

Primary Endpoints

- OS

Secondary Endpoints

- ORR[a]
- DOR[a]
- PFS[a]
- CBR[a]
- Safety & Tolerability
- EORTC QLQ-C30 and Euro QOL EQ-5D-5L QOL Questionnaires

[a]By PI Assessment & BICR using RECIST v1.1

ADC, antibody-drug conjugate; BICR, blinded independent committee review; C1D1, day 1 of chemotherapy treatment cycle 1; CBR, clinical benefit rate; CNS, central nervous system; CPI, checkpoint inhibitor; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EORTC, European Organization for Research and Treatment of Cancer; mAb, monoclonal antibody; m, metastatic; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QoL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors, version 1.1; SOC, standard of care; UC; urothelial carcinoma.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://www.clinicaltrials.gov/ct2/show/NCT04527991
2. Gilead Sciences Data on File.

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: NCT04527991

US-UNBP-2431 11/23