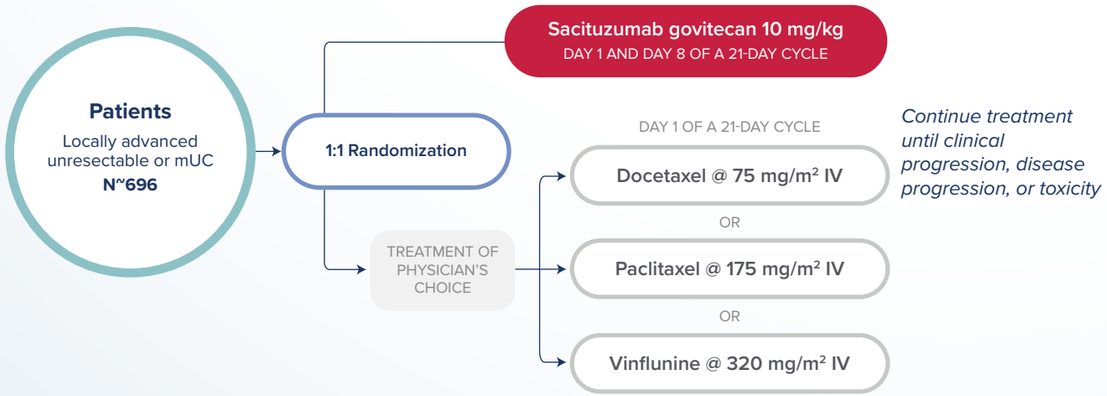
ClinicalTrials.gov Identifier: NCT04527991 EudraCT Identifier: 2020-002964-29

TROPiCS-04: A Randomized, Open-Label Phase 3 Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice (TPC) in Patients with Metastatic or Locally Advanced Unresectable Urothelial Carcinoma

Study Design[1,2]



Endpoints[1,2]

Primary Endpoint

- OS

Secondary Endpoints

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

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
- Subjects with progression or recurrence following receipt of platinum-containing regimen and PD-1/PD-L1 therapy for 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

[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 QLQ-C30, European Organization for Research and Treatment Core Quality of Life questionnaire; mAb, monoclonal antibody; m, metastatic; ORR, objective response rate; OS, overall survival; PD-1, anti programmed cell death protein 1; PD-L1, programmed death-ligand 1; PFS, progression-free survival; QoL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors; SG, sacituzumab govitecan-hziy; SOC, standard of care; TPC, treatment of physician's choice; UC; urothelial carcinoma; v, version.

References

1. Clinicaltrials.gov website. Accessed May 3, 2024. https://www.clinicaltrials.gov/ct2/show/NCT04527991
2. Gilead Sciences Data on File.

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 for more information. Clinicaltrials.gov: NCT04527991

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