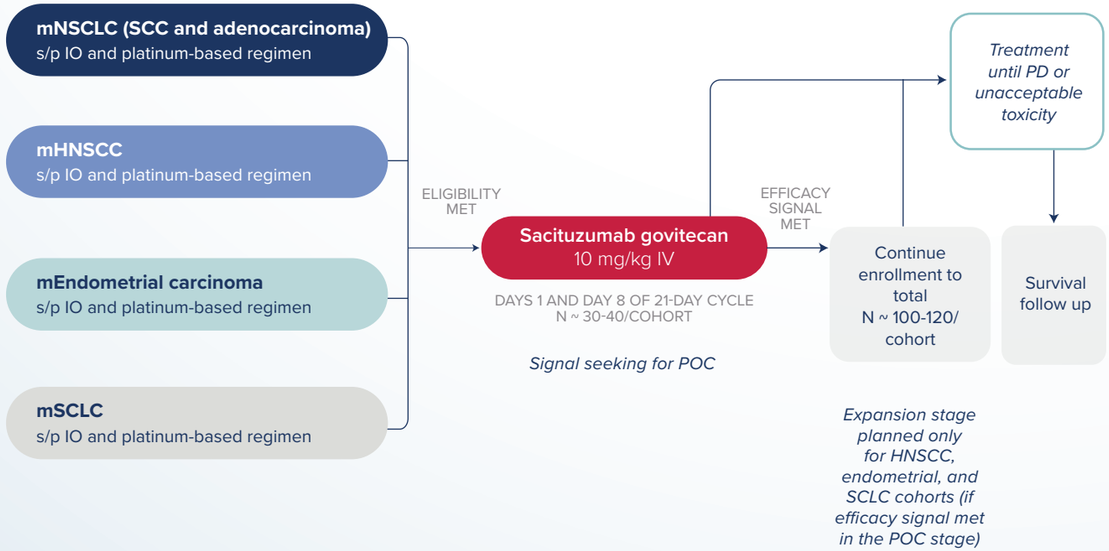
ClinicalTrials.gov Identifier: NCT03964727 • EudraCT Identifier: 2019-000579-18

TROPiCS-03 is active, not recruiting

TROPiCS-03: A Phase 2 Open-Label Study of Sacituzumab Govitecan in Subjects With Metastatic Solid Tumors

Study Design[1-3]



Key Eligibility Criteria[1-3]

Key Inclusion Criteria

- Female or male patients ≥18 years of age
- ECOG PS of 0 or 1
- Documented metastatic or locally advanced solid tumors (NSCLC, HNSCC, endometrial, and SCLC)
- Measurable disease by CT or MRI as per RECIST v1.1
- Adequate hepatic and renal function (CrCl ≥30mL/min)
- Adequate hematologic counts without transfusion or growth factor support within 2 weeks of study drug initiation

Endpoints[1-3]

Primary Endpoint

- ORR (by investigator-assessed RECIST v 1.1)

Secondary Endpoints

- ORR, DOR, CBR, PFS (by BICR RECIST v1.1)
- DOR, CBR, PFS (by Investigator-assessed RECIST v1.1)
- OS
- Safety
- PK & ADA

ADA, anti-drug antibodies; BICR, blinded independent central review; CBR, clinical benefit rate; CrCl, creatinine clearance; CT, computed tomography; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; HNSCC, head and neck squamous cell carcinoma; IO, immuno-oncology; IV, intravenous; m, metastatic; MRI, magnetic resonance imaging; NSCLC, non-small cell lung carcinoma; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PK, pharmacokinetics; POC, proof of concept; RECIST v 1.1, Response Evaluation Criteria in Solid Tumors Version 1.1; SCLC, small cell lung cancer; SCC, squamous cell carcinoma; s/p, status post.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://www.clinicaltrials.gov/ct2/show/NCT03964727
2. Gilead Sciences Data on File.
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.