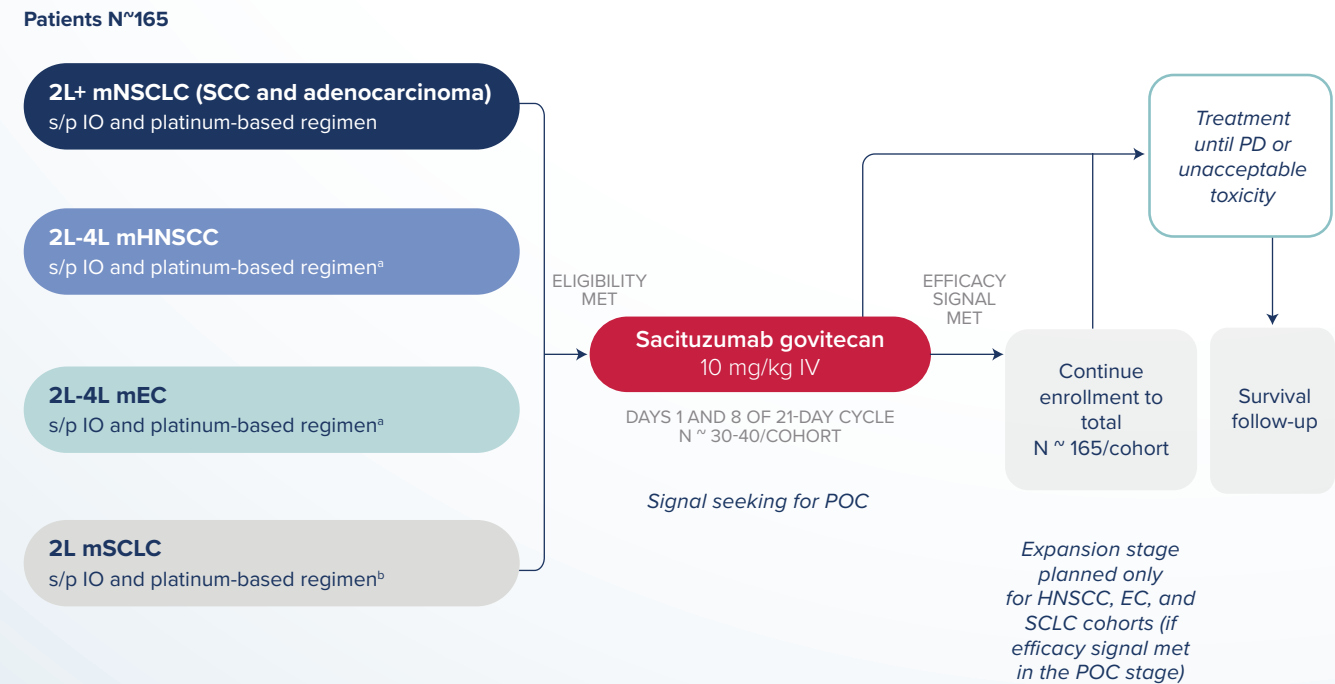


TROPiCS-03: A Phase 2 Open-Label Study of Sacituzumab Govitecan in Subjects With Metastatic Solid Tumors



TROPiCS-03 is active,
not recruiting.

Study Design^{1,2}



^aNo more than 3 prior lines of systemic treatment is allowed. ^bNo more than one prior line of systemic treatment is allowed (re-challenge with the same initial regimen is not allowed).

EC, endometrial cancer; HNSCC, head and neck squamous cell carcinoma; IO, immuno-oncology; IV, intravenous; m, metastatic; NSCLC, non-small cell lung carcinoma; POC, proof of concept; PD, progressive disease; SCLC, small cell lung cancer.

Key Eligibility Criteria^{1,2}

Key Inclusion Criteria

- ≥18 years of age
- ECOG PS of 0 or 1
- Documented metastatic or locally advanced solid tumors (NSCLC, HNSCC, EC, 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^{1,2}

Primary Endpoint

- ORR^b

Secondary Endpoints

- ORR^c
- DOR^c
- CBR^{b,c}
- PFS^{b,c}
- OS
- Safety
- PK & ADA

^bAs assessed by Investigator per RECIST v1.1. ^cAs assessed by BICR per RECIST v1.1.

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; MRI, magnetic resonance imaging; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; RECIST, Response Evaluation Criteria in Solid Tumors; SCC, squamous cell carcinoma; s/p, status post; v, version.

References

1. Clinicaltrials.gov website. Accessed July 8, 2024. <https://www.clinicaltrials.gov/study/NCT03964727>
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.

