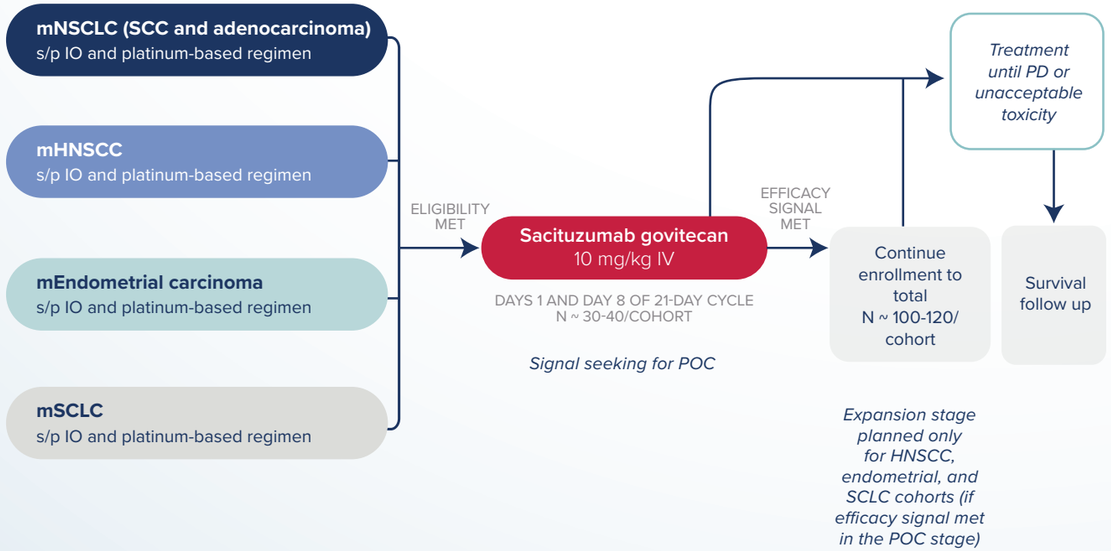
ClinicalTrials.gov Identifier: NCT03964727

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

## Study Design[1,2]




TROPiCS-03 Advanced Solid Tumors

*TROPiCS-03 is active, not recruiting.*

## Key Eligibility Criteria[1,2]

### 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[1,2]

### 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.


**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: NCT03964727