TROPiCS-03 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^{1,2} Patients N~165 2L+ mNSCLC (SCC and adenocarcinoma) Treatment s/p IO and platinum-based regimen until PD or unacceptable toxicity 2L-4L mHNSCC s/p IO and platinum-based regimen^a ELIGIBILITY **EFFICACY** SIGNAL Sacituzumab govitecan 10 mg/kg IV Continue 2L-4L mEC Survival enrollment to DAYS 1 AND 8 OF 21-DAY CYCLE follow-up s/p IO and platinum-based regimen^a total N ~ 30-40/COHORT N ~ 165/cohort Signal seeking for POC 2L mSCLC Expansion stage planned only s/p IO and platinum-based regimen^b for HNSCC. EC. and SCLC cohorts (if efficacy sianal met in the POC stage)

^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

OS

DOR^c

Safety

CBR^{b,c}

PK & ADA

PFSb,c

^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.









