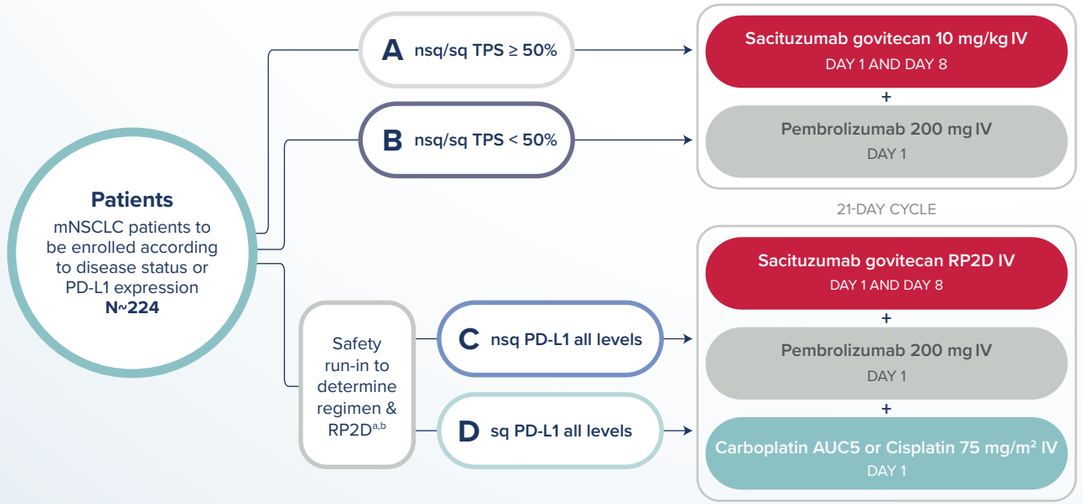
EVOKE-02: An Open-Label, Multicenter, Phase 2 Study of Sacituzumab Govitecan Combinations in First-line Treatment of Patients With Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) Without Actionable Genomic Alterations

Study Design[1-3]



[a]Participants will receive SG (de-escalating dose levels: 10.0 mg/kg, 7.5 mg/kg, or 5.0 mg/kg) on Days 1 and 8 of a 21-day cycle + pembrolizumab 200 mg on Day 1 of a 21-day cycle + carboplatin area under the concentration versus time curve AUC5 on Day 1 of a 21-day cycle.
[b]Participants will receive SG (either 10 mg/kg or 7.5 mg/kg) on Days 1 and 8 of a 21-day cycle + pembrolizumab 200 mg on Day 1 of a 21-day cycle + cisplatin 75 mg/m^2 on Day 1 of a 21-day cycle.
[c]By the IRC per RECIST Version 1.1.

EVOKE-02 is active, not recruiting.

Key Eligibility Criteria[1-3]

Key Inclusion Criteria

- Pathologically documented stage IV NSCLC
- No prior systemic treatment for mNSCLC
- ECOG PS score of 0 or 1
- Has no known genomic alterations in actionable driver oncogenes with approved therapies for frontline treatments
- Adequate renal and hepatic function as well as hematologic counts

Key Exclusion Criteria

- Mixed SCLC and NSCLC histology
- Active secondary malignancy
- Have previously received treatment with Topoisomerase 1 inhibitors, Trop-2–targeted therapy
- Active CNS metastases or carcinomatous meningitis
- Currently participating in a clinical trial

Endpoints[1-3]

Primary Endpoint

- ORR[c]
- Percentage of patients experiencing DLTs per dose level in the safety run-in cohort

Secondary Endpoints

- PFS[c]
- OS
- DOR[c]
- DCR[c]
- Safety & tolerability

AUC5, area under the concentration versus time curve; CNS, central nervous system; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IRC, independent review committee; IV, intravenous; m, metastatic; NSCLC, non-small cell lung cancer; nsq, nonsquamous histology; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PD-L1, programmed cell death ligand 1; RECIST, Response Evaluation Criteria in Solid Tumors, version 1.1; RP2D, recommended Phase 2 dose; SCLC, small-cell lung cancer; sq, squamous histology; TPS, tumor proportion score; Trop-2, tumor-associated calcium signal transducer 2.

References

1. Clinicaltrials.gov website. Accessed February 6, 2024. https://clinicaltrials.gov/ct2/show/NCT05186974
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.