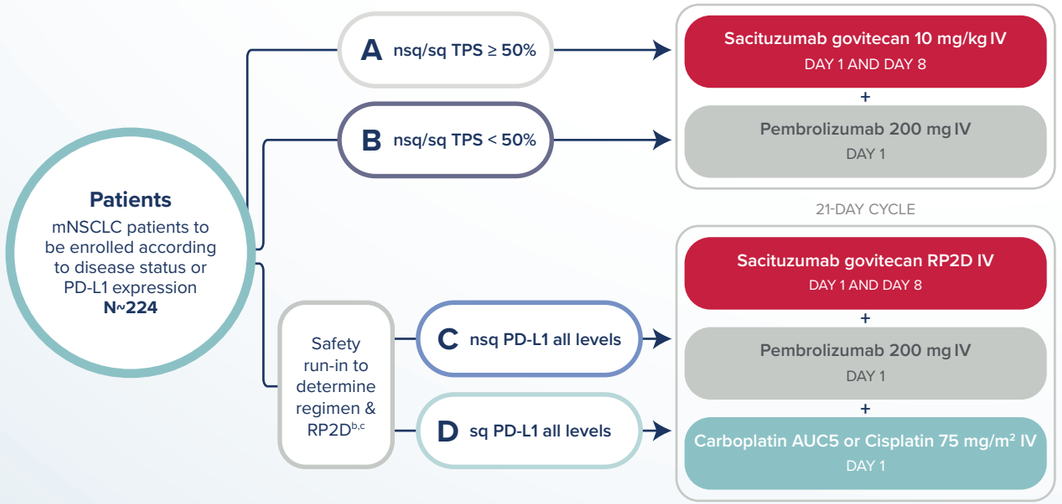
ClinicalTrials.gov Identifier: NCT05186974

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[a]

Study Design[1,2]



[a]EVOKE-01 is active, not recruiting.
[b]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.
[c]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.
[d]By the IRC per RECIST Version 1.1.

Key Eligibility Criteria[1,2]

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[1,2]

Primary Endpoint

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

Secondary Endpoints

- PFS[d]
- OS
- DOR[d]
- DCR[d]
- 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 October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT05186974
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: NCT05186974

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