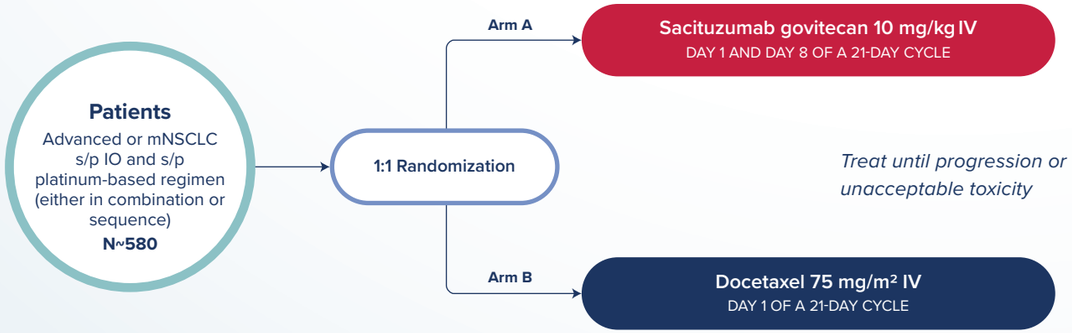
ClinicalTrials.gov Identifier: NCT05089734

EVOKE-01: An Open-Label, Global, Multicenter, Randomized, Phase 3 Study of Sacituzumab Govitecan Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) With Progression on or After Platinum-Based Chemotherapy and Anti-PD-1/PD-L1 Immunotherapy

Study Design[1,2]



Stratification Factors:

- Histology (squamous vs non-squamous)
- Response to last prior immune therapy received (best response PD/SD vs CR/PR on immune therapy)
- Received prior targeted therapy for actionable genomic alteration (yes vs no)

[a]Assessed by Investigator per RECIST v 1.1.

evoke-01

EVOKE-01 is active, not recruiting.

Key Eligibility Criteria[1,2]

Key Inclusion Criteria

- Female or male patients ≥18 years of age
- Must have progressed after platinum-based chemotherapy in combination with anti-PD-L1 antibody OR platinum-based chemotherapy and anti-PD-L1 antibody (in either order) sequentially
- ECOG PS score of 0 or 1
- Measurable disease by CT or MRI as per RECIST v 1.1
- CrCl ≥30 mL/min and adequate hepatic function
- Adequate hematologic counts without transfusion or growth factor support within 2 weeks of study drug initiation

Key Inclusion Criteria (cont'd)

- Individuals with *EGFR*, *ALK*, or any other known actionable genomic alterations must have also received treatment with at least 1 locally approved and available tyrosine kinase inhibitor 1 (TKI) appropriate to the genomic alteration

Key Exclusion Criteria

- Mixed small-cell lung cancer and NSCLC histology
- Previously received treatment with any of the following:
  - Topoisomerase 1 inhibitors. Any agent including an ADC containing a chemotherapeutic agent targeting topoisomerase 1
  - Trop-2–targeted therapy
  - Docetaxel as monotherapy or in combination with other agents
- Active secondary malignancy

Endpoints[1,2]

Primary Endpoint

- OS

Secondary Endpoints

- PFS[a]
- DOR[a]
- DCR[a]
- ORR[a]
- Safety
- PRO

ADC, antibody-drug conjugate; ALK, anaplastic lymphoma kinase; CNS, central nervous system; CrCl, creatinine clearance; CR, complete response; CT, computed tomography; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; IO, immuno-oncology; IV, intravenous; m, metastatic; NSCLC, non-small cell lung cancer; MRI, magnetic resonance imaging; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-L1, programmed cell death ligand 1; PFS, progression-free survival; PR, partial response; PRO, patient-reported outcomes; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SOC, standard of care; s/p, status post; Trop-2, tumor-associated calcium signal transducer 2; v, version; vs, versus.

References

1. Clinicaltrials.gov website. Accessed May 3, 2024. https://www.clinicaltrials.gov/ct2/show/NCT05089734
2. Data on file. Gilead Sciences, Inc; 2023.

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: NCT05089734