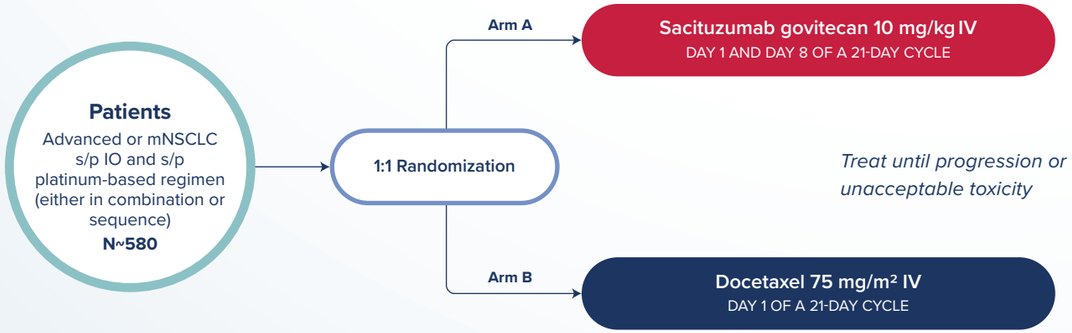
ClinicalTrials.gov Identifier: NCT05089734 EudraCT Identifier: 2021-003578-30

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 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. Visit clinicaltrials.gov for more information. Clinicaltrials.gov: NCT05089734