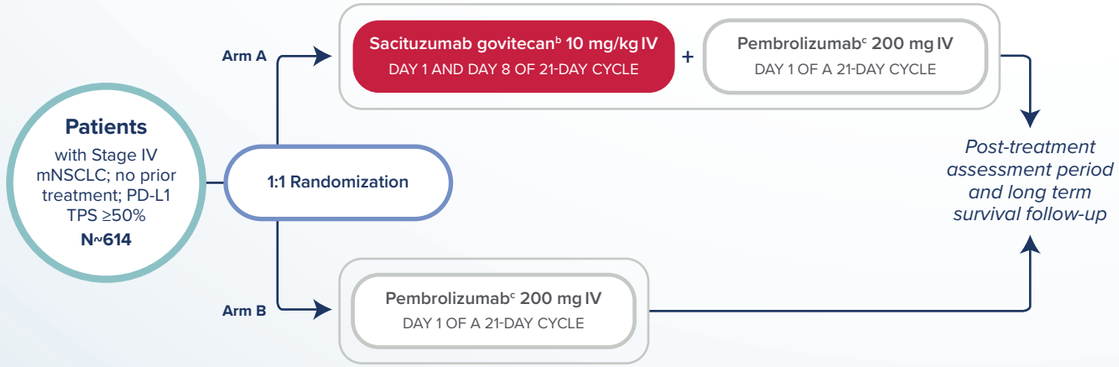
ClinicalTrials.gov Identifier: NCT05609968

EVOKE-03: An Open-label, Multicenter, Phase 3 Randomized, Active-Comparator-Controlled Clinical Study of Pembrolizumab (MK-3475) in Combination With Sacituzumab Govitecan Versus MK-3475 Monotherapy as First-line Treatment in Participants With PD-L1 TPS ≥50% Metastatic Non-small Cell Lung Cancer[a]

Study Design[1,2]



[a]EVOKE-03/KEYNOTE D46 is being operationalized by Merck. [b]Continue sacituzumab govitecan treatment until disease progression, death, unacceptable toxicity, or another treatment discontinuation criterion is met. [c]Continue pembrolizumab treatment for up to 35 cycles. [d]Patients with previously treated brain metastases may participate if radiologically stable for ≥4 wk and clinically stable without need for steroid treatment for ≥14 d before starting study treatment.

Key Eligibility Criteria[1,2]

Key Inclusion Criteria

- ≥18 years of age
- Histologically or cytologically confirmed stage IV NSCLC per AJCC Staging Manual version 8
- ≥1 measurable lesion per RECIST v1.1
- ECOG PS of 0 or 1 within 7 days before randomization
- PD-L1 TPS ≥50% as assessed by IHC at a central laboratory
- No sensitizing EGFR, ALK, or ROS-1 alterations
- Adequate organ function
- Life expectancy ≥3 months

Key Exclusion Criteria

- History of second malignancy, unless potentially curative treatment has been completed with no evidence of malignancy for 3 years
- Previous systemic chemotherapy or other targeted or biological antineoplastic therapy for metastatic NSCLC
- Previous receipt of any agent targeting topoisomerase 1, Trop-2, PD-1, PD-L1, PD-L2, or another stimulatory or coinhibitory T-cell receptor (eg, CTLA-4, OX-40, CD137)
- Radiotherapy within 2 weeks of starting study treatment or radiation-related toxicities requiring corticosteroids
- Radiation therapy to the lung >30 Gy within 6 months of starting study treatment
- Active chronic inflammatory bowel disease or gastrointestinal perforation within 6 months of enrollment
- Known active CNS metastases and/or carcinomatous meningitis[d]

Endpoints[1,2]

Primary Endpoint

- PFS per RECIST v1.1 by BICR
- OS

Secondary Endpoints

- ORR and DOR per RECIST v1.1 by BICR
- Safety
- PROs

AJCC, American Joint Committee on Cancer; BICR, blinded independent central review; CNS, central nervous system; CTLA-4, cytotoxic T-lymphocyte associated protein 4; ECOG PS, Eastern Cooperative Oncology Group performance status; IHC, immunohistochemistry; IV, intravenous; mNSCLC, metastatic non-small cell lung cancer; OS, overall survival; PD-L1, programmed cell death ligand 1; PFS, progression free survival; PROs, patient-reported outcomes; RECIST, Response Evaluation Criteria in Solid Tumors; TPS, tumor proportion score; v, version.

References

1. ClinicalTrials.gov website. Accessed October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT05609968
2. Data on File. Merck Sharp & Dohme LLC, 2022.

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: NCT05609968

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