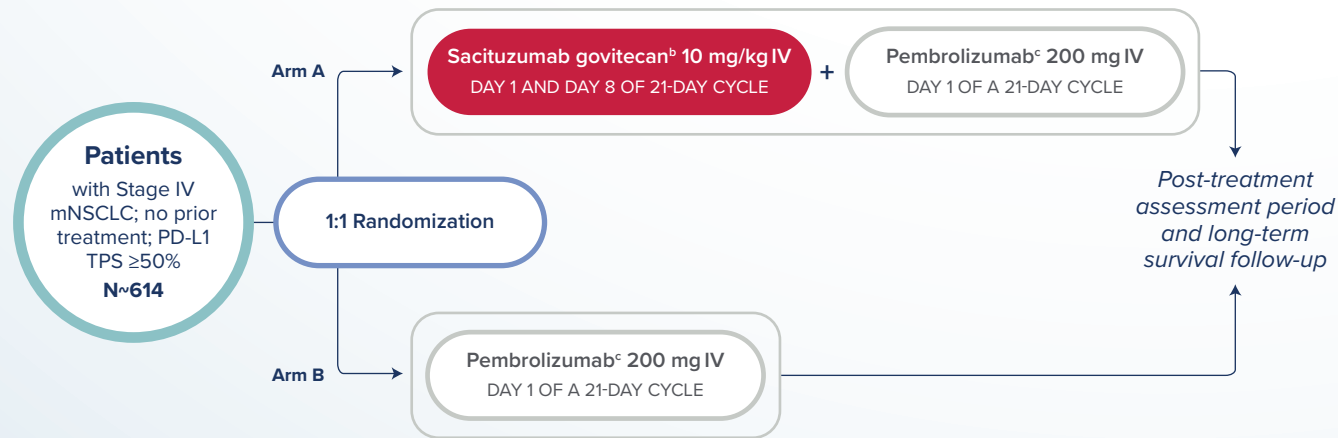


EVOKE-03: An Open-Label, Multicenter, Phase 3 Randomized, Active-Comparator-Controlled Clinical Study of Pembrolizumab (MK-3475) in Combination With Sacituzumab Govitecan Versus MK-3475 Monotherapy as First-Line Treatment in Participants With PD-L1 TPS ≥50% Metastatic Non-Small Cell Lung Cancer^a

Study Design^{1,2}



^aIn collaboration with Merck. ^bContinue sacituzumab govitecan treatment until disease progression, death, unacceptable toxicity, or another treatment discontinuation criterion is met. ^cContinue pembrolizumab treatment for up to 35 cycles. ^dOne gray (Gy) is the international system of units (SI) equivalent of 100 rads, which is equal to an absorbed dose of 1 Joule/kilogram. ^ePatients 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 v8
- ≥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 mNSCLC
- 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^d 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^e

Endpoints^{1,2}

Primary Endpoints

- 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; ALK, anaplastic lymphoma kinase; BICR, blinded independent central review; CNS, central nervous system; CTLA-4, cytotoxic T-lymphocyte associated protein 4; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; IHC, immunohistochemistry; IV, intravenous; m, metastatic; NSCLC, non-small cell lung cancer; ORR, overall response rate; 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; ROS-1, ROS proto-oncogene 1; TPS, tumor proportion score; v, version.

References

1. ClinicalTrials.gov website. Accessed May 3, 2024. <https://clinicaltrials.gov/ct2/show/NCT05609968>
2. Data on File. Merck Sharp & Dohme LLC, 2022.

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: NCT05609968