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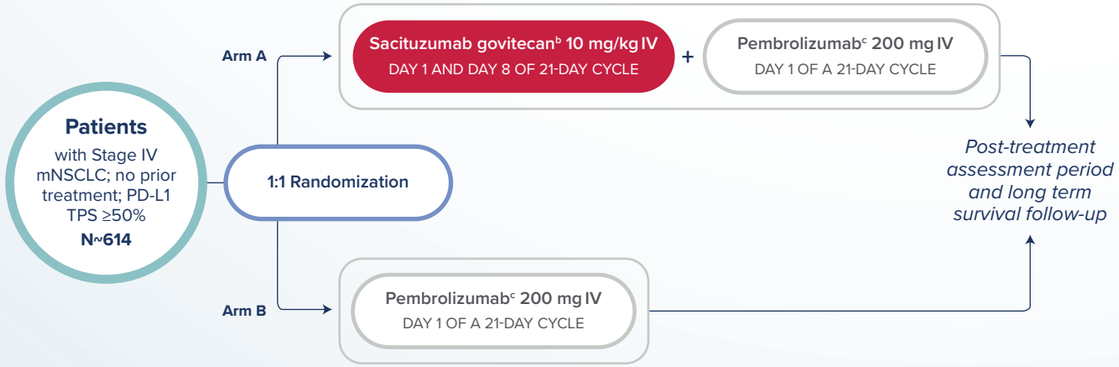
EVOKE-03: An Open-label, Multicenter, Phase 3 Randomized, Active-Comparator-Controlled Clinical Study of Pembrolizumab (MK-3475) in Combination With Sacituzumab Govitecan Versus MK-3475 Monotherapy as First-line Treatment in Participants With PD-L1 TPS ≥50% Metastatic Non-small Cell Lung Cancer[a]

Study Design[1-3]



[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]One gray (Gy) is the international system of units (SI) equivalent of 100 rads, which is equal to an absorbed dose of 1 Joule/kilogram. [e]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[1-3]

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[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[1-3]

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 February 6, 2024. https://clinicaltrials.gov/ct2/show/NCT05609968
2. Data on File. Merck Sharp & Dohme LLC, 2022.
3. Clinicaltrialsregister.eu website

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.