GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Combination With Pembrolizumab for 1L mNSCLC: EVOKE-03 Study

This document is in response to your request for information regarding Trodelvy® (sacituzumab govitecan-hziy [SG]) and data from the EVOKE-03 study on SG use with pembrolizumab (pembro) as first-line (1L) treatment for patients with metastatic non-small cell lung cancer (mNSCLC) with programmed death-ligand 1 (PD-L1) tumor proportion score (TPS) ≥50%.

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Trodelvy is not indicated for use in patients with mNSCLC. The full indication, important safety information, and boxed warnings for neutropenia and diarrhea are available at: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Clinical Data on 1L SG Use With Pembro in EVOKE-03

Study Design

The EVOKE-03 study (NCT05609968) is a randomized, open-label, multicenter, active-comparator–controlled phase 3 study investigating the efficacy and safety of SG plus pembro vs pembro monotherapy in the 1L treatment of patients with mNSCLC (estimated N=620).[1,2] Eligible patients had previously untreated mNSCLC; ≥1 measurable lesion per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1; an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 or 1; a PD-L1 TPS ≥50% by immunohistochemistry; no interstitial lung disease; no untreated or unstable brain metastasis; and no sensitizing epidermal growth factor receptor, anaplastic lymphoma kinase, or *ROS* proto-oncogene 1 alterations; and a life expectancy ≥3 months. Patients were stratified by ECOG PS (0 vs 1), predominant tumor histology (squamous vs nonsquamous), and geographic region (East Asia vs Western Europe, North America, and Australia vs rest of the world).[2]

Patients were randomly assigned 1:1 to receive SG (10 mg/kg IV on Days 1 and 8 of a 21-day cycle) plus pembro (200 mg IV on Day 1 of a 21-day cycle) or pembro monotherapy (200 mg IV on Day 1 of a 21-day cycle). SG was continued until disease progression, unacceptable toxicity, death, or another treatment discontinuation criterion was met and pembro will be continued for up to 35 cycles.[2]

The primary endpoints are progression-free survival (PFS) assessed by blinded independent central review (BICR) according to RECIST 1.1 criteria, and overall survival (OS).

Secondary endpoints include objective response rate and duration of response (per BICR according to RECIST v1.1 criteria), select patient reported outcomes (PROs), and safety.[3]

On June 8, 2026, Gilead announced the discontinuation of the EVOKE-03 study. The decision is based on the recommendation from the external Data Monitoring Committee following their review of the data from the prespecified final analysis of PFS and interim analysis of OS. A numerical improvement in PFS was observed but did not reach statistical significance. The probability of achieving statistically significant OS is unlikely at the planned final analysis. The safety profile for SG + pembro was consistent with the known safety of each agent. No new safety signals were identified with the combination. Detailed results from this study will be presented at an upcoming medical conference.[1]

References

1. Gilead Sciences, Inc. Merck and Gilead provide update on phase 3 KEYNOTE-D46/EVOKE-03 study. [press release]. 8 June 2026.
2. Moskovittz M, Okamoto I, Chen P, et al. Pembrolizumab with and without sacituzumab govitecan as first-line treatment for metastatic non-small-cell lung cancer (NSCLC) witht PD-L1 tumor proportion score >/=50%: phase 3 KEYNOTE-D46/EVOKE-03 study. Paper presented at: American Association for Cancer Research (AACR); April 14-19, 2023, 2023; Orlando, FL.
3. ClinicalTrials.gov. Study of pembrolizumab (MK-3475) monotherapy versus sacituzumab govitecan in combination with pembrolizumab for participants with metastatic non-small cell lung cancer (NSCLC) with programmed cell death ligand 1 (PD-L1) tumor proportion score (TPS) ≥50% (MK-3475-D46), ClinicalTrials.gov Identifier: NCT05609968. https://clinicaltrials.gov/study/NCT05609968. Accessed 11 May 2026.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Trodelvy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Follow Up

For any additional questions, please contact Gilead Medical Information at:

☎1-888-983-4668 or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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