Long-Term Safety of Sacituzumab Govitecan + Pembrolizumab in Patients with Metastatic Non–Small Cell Lung Cancer from EVOKE-02

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EVOKE-02

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Conclusions

- After extended follow-up, the combination of SG plus pembro continued to show a manageable safety profile, which is consistent with the known safety profiles for each agent
- All participants experienced TEAEs, with the majority experiencing Grade ≥3 TEAEs; the most common were neutropenia, pneumonia, diarrhea, anemia, and dyspnea
  - Rate of serious infections secondary to neutropenia was low
- Despite longer follow-up (median, 29 months) and exposure to treatment, safety was manageable and no additional treatment-related TEAEs leading to death occurred beyond those reported approximately one year earlier[8]
- These safety results together with efficacy data from EVOKE-02 support further investigation of this combination as 1L treatment for patients with mNSCLC with PD-L1 ≥50% and no AGAs
- This combination was further evaluated in the Phase 3 EVOKE-03 clinical study (NCT05609968); primary results will be presented at the 2026 WCLC on Sunday, September 13, 2026 between 08:00 AM and 10:30 AM

Plain Language Summary

Many patients with non−small cell lung cancer (NSCLC) that has spread throughout their body are first treated with a drug called pembrolizumab, with or without chemotherapy, but often this treatment does not shrink their tumors. A new drug, sacituzumab govitecan, has been shown to be effective at shrinking tumor masses when added to pembrolizumab as a treatment for patients with NSCLC. It is important that a drug combination remains safe for patients over time. We report that sacituzumab govitecan plus pembrolizumab showed manageable safety over a median follow-up period of about 2.5 years (29 months) in patients with NSCLC that had no genetic changes that could guide treatment. These safety results, together with data on how effective the treatment is, support further investigation of this drug combination as an initial therapy for patients with NSCLC.

References: **1.** Owen DH, et al. *J Clin Oncol.* 2025;43(24):e45−e58. **2.** Hendriks LEL, et al. *Ann Oncol.* 2025;36(10):1223−1227. **3.** Li H, et al. *Cancers* (Basel). 2024;16(4):744. **4.** Goldenberg DM, et al. *Oncotarget.* 2015;6:22496−512. **5.** ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT05186974. Accessed June 23, 2026. **6.** Patel J, et al. *J Thoracic Oncol.* 2024;19(7S):e6. **7.** Cappuzzo F, et al. Presented at the European Lung Cancer Congress; March 20−23, 2024; Prague, Czech Republic. **8.** Reck M, et al. *J Thorac Oncol.* 2026;21(3):103509

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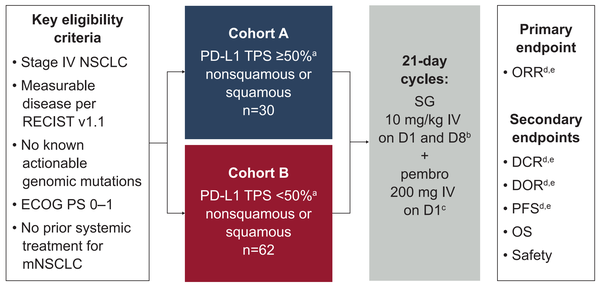
Introduction

- Pembrolizumab (pembro) ± chemotherapy is a current standard of care for first-line (1L) metastatic non–small cell lung cancer (mNSCLC) without actionable genomic alterations (AGAs).[1,2] However, many patients do not achieve a favorable response to initial treatment[3]
- Sacituzumab govitecan (SG) is a first-in-class trophoblast cell surface antigen 2–directed antibody-drug conjugate being evaluated in combination with pembro for the treatment of mNSCLC in the EVOKE-02 clinical study (NCT05186974) to address this unmet need[4,5]
- In a previous analysis of EVOKE-02, participants in Cohorts A and B exhibited encouraging response rates and durable activity across tumor histologies (squamous or nonsquamous), regardless of programmed cell death ligand 1 (PD-L1) expression[6,7,8]
  - For participants with PD-L1 tumor proportion score (TPS) ≥50% (Cohort A), the objective response rate (ORR) was 67%, the disease control rate (DCR) was 87%, and the median duration of response (DOR) was not reached (NR)
  - For participants with PD-L1 TPS <50% (Cohort B), the ORR was 29%, the DCR was 66%, and the median DOR (95% CI) was 11.9 (6.9–NR) months
- Here, we report the long-term safety data from Cohorts A and B of EVOKE-02 to provide further insights into the tolerability of SG + pembro in participants with mNSCLC

Methods

- EVOKE-02 is an ongoing, open-label, multicenter, multicohort, Phase 2 study investigating SG in combination with pembro as a 1L therapy in participants with mNSCLC (squamous or nonsquamous) without AGAs (**Figure 1**)
- Cohorts A and B comprised participants with PD-L1 TPS ≥50% and PD-L1 TPS <50%, respectively
- Participants received SG 10 mg/kg intravenously (IV) on days 1 and 8 plus pembro 200 mg IV on day 1 of 21-day cycles
- The percentage of participants experiencing treatment-emergent adverse events (TEAEs) was a secondary endpoint

Figure 1. EVOKE-02 Study Design (Cohorts A and B)



[a]PD-L1 status was determined locally or at the central laboratory by 22C3 assay before initiating treatment; [b]Until PD (as assessed by the investigator), death, unacceptable toxicity, or another treatment discontinuation criterion is met; [c]Up to 35 cycles; [d]By IRC; [e]Per RECIST v1.1.

D1, day 1; D8, day 8; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IRC, independent review committee; IV, intravenous; (m)NSCLC, (metastatic) non–small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-L1, programmed cell death ligand 1; pembro, pembrolizumab; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; SG, sacituzumab govitecan; TPS, tumor proportion score.

Results

Participant Baseline Characteristics

- This long-term safety follow-up analysis included 92 participants (Cohort A, n=30; Cohort B, n=62; **Table 1**)
- At data cutoff (June 16, 2025), median (range) follow-up was 29.0 (20.9–36.2) months
- Median (range) duration of treatment exposure was 5.4 (<0.1–35.1) months for SG and 4.9 (<0.1–28.3) months for pembro

Table 1. Baseline Characteristics

Characteristic	Overall (n=92)	Cohort A (n=30)	Cohort B (n=62)
Median age (range), years	68 (32–80)	67 (47–77)	68 (32–80)
Sex			
Male	67 (72.8)	24 (80.0)	43 (69.4)
Race			
Asian	24 (26.1)	6 (20.0)	18 (29.0)
Black	5 (5.4)	2 (6.7)	3 (4.8)
White	63 (68.5)	22 (73.3)	41 (66.1)
Ethnicity			
Hispanic or Lantino	4 (4.3)	2 (6.7)	2 (3.2)
Not Hispanic or Latino	88 (95.7)	28 (93.3)	60 (96.8)
ECOG PS			
0	27 (29.3)	6 (20.0)	21 (33.9)
1	65 (70.7)	24 (80.0)	41 (66.1)
Histology			
Squamous	38 (41.3)	12 (40.0)	26 (41.9)
Nonsquamous	54 (58.7)	18 (60.0)	36 (58.1)
Disease stage at diagnosis			
I–III	14 (15.2)	5 (16.7)	9 (14.5)
IV	76 (82.6)	24 (80.0)	52 (83.9)
Unknown	2 (2.2)	1 (3.3)	1 (1.6)

Data presented as n (%) unless otherwise stated.
ECOG PS, Eastern Cooperative Oncology Group performance status.

Long-Term Safety

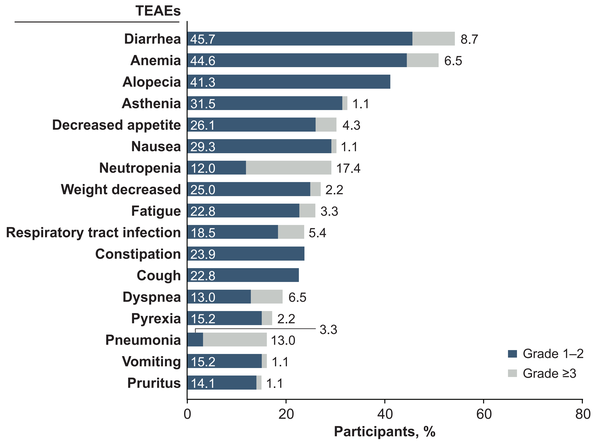
- Overall, the safety results for this population with an extended follow-up period resembled those reported approximately one year earlier[8]
- All participants experienced TEAEs, with 81.5% experiencing Grade ≥3 TEAEs (**Table 2**)
- The most common TEAEs occurring in ≥15% of participants are shown in **Figure 2**
- The most common Grade ≥3 TEAEs were neutropenia (17.4%), pneumonia (13.0%), decreased neutrophil count (9.8%), diarrhea (8.7%), anemia (6.5%), and dyspnea (6.5%)
  - The prevalence of TEAEs and Grade ≥3 TEAEs were similar in Cohorts A and B (**Table 3**)
- TEAEs of special interest for SG and pembro occurred in 53.3% and 26.1% of participants, respectively
- TEAEs led to discontinuation of any study drug in 28.3% of participants and discontinuation of SG in 25.0% of participants

Table 2. Summary of TEAEs in All Participants

TEAEs, n (%)	Overall (n=92)
Any grade	**92 (100)**
Grade ≥3	75 (81.5)
TEAEs related to any study drug	**84 (91.3)**
Grade ≥3	43 (46.7)
Serious TEAEs	**65 (70.7)**
Related to any study drug	19 (20.7)
TEAEs leading to discontinuation of any study drug	**26 (28.3)**
TEAEs leading to discontinuation of SG	23 (25.0)
TEAEs leading to discontinuation of pembro	21 (22.8)
TEAEs leading to dose reduction of SG	18 (19.6)
TEAEs leading to dose interruption of any study drug	**65 (70.7)**
TEAEs leading to dose interruption of SG	64 (69.6)
TEAEs leading to dose interruption of pembro	53 (57.6)
TEAEs leading to death	**9 (9.8)**
TEAEs related to any study drug leading to death	3 (3.3)

pembro, pembrolizumab; SG, sacituzumab govitecan; TEAE, treatment-emergent adverse event.

Figure 2. Most Common TEAEs Occurring in ≥15% of Participants



TEAE, treatment-emergent adverse event.

Table 3. TEAEs Occurring in ≥15% of the Overall Population by Cohort[a]

TEAE, n (%)	Cohort A (n=30)		Cohort B (n=62)	
	Total	Grade ≥3	Total	Grade ≥3
Any TEAE	**30 (100)**	**21 (70.0)**	**62 (100)**	**54 (87.1)**
Diarrhea	17 (56.7)	3 (10.0)	33 (53.2)	5 (8.1)
Anemia	15 (50.0)	0	32 (51.6)	6 (9.7)
Alopecia	15 (50.0)	0	23 (37.1)	0
Asthenia	15 (50.0)	0	15 (24.2)	1 (1.6)
Nausea	14 (46.7)	1 (3.3)	14 (22.6)	0
Decreased appetite	11 (36.7)	0	17 (27.4)	4 (6.5)
Constipation	11 (36.7)	0	11 (17.7)	0
Neutropenia	10 (33.3)	5 (16.7)	17 (27.4)	11 (17.7)
Dyspnea	10 (33.3)	2 (6.7)	8 (12.9)	4 (6.5)
Weight decreased	9 (30.0)	2 (6.7)	16 (25.8)	0
Fatigue	9 (30.0)	0	15 (24.2)	3 (4.8)
Respiratory tract infection	9 (30.0)	0	13 (21.0)	5 (8.1)
Cough	9 (30.0)	0	12 (19.4)	0
Pyrexia	9 (30.0)	1 (3.3)	7 (11.3)	1 (1.6)
Vomiting	6 (20.0)	0	9 (14.5)	1 (1.6)
Pneumonia	3 (10.0)	2 (6.7)	12 (19.4)	10 (16.1)
Pruritus	2 (6.7)	0	12 (19.4)	1 (1.6)
TEAEs of special interest				
For SG[b]	14 (46.7)	7 (23.3)	35 (56.5)	22 (35.5)
For pembro[c]	9 (30.0)	3 (10.0)	15 (24.2)	7 (11.3)

[a]TEAEs occurring in ≥15% of participants in the overall population are shown; incidences are presented separately for Cohorts A and B. [b]TEAEs of special interest for SG occurring in ≥1 participant included hypersensitivity, neutropenia, serious infections secondary to neutropenia, and severe diarrhea. [c]TEAEs of special interest for pembro occurring in ≥1 participant included colitis, hyperthyroidism, hypothyroidism, infusion reactions, myocarditis, myositis, nephritis, pneumonitis, severe skin reactions, and vasculitis.

pembro, pembrolizumab; SG, sacituzumab govitecan; TEAE, treatment-emergent adverse event.