



Lilly presents first clinical data in platinum-sensitive ovarian cancer for its investigational, next-generation, FR α -targeting ADC at ESMO 2026

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Sofetabart mipitecan (Sofe-M) in combination with bevacizumab demonstrated a 79% confirmed objective response rate and 100% disease control rate, with similar activity observed across FR α expression levels

Clinical activity with Sofe-M was maintained even in patients with prior PARP inhibitor exposure, patients who typically experience poor outcomes with platinum-based chemotherapy

Sofe-M is currently being studied in both platinum-sensitive and platinum-resistant ovarian cancer in multiple Phase 3 studies as part of the FRAMework-01 master protocol

INDIANAPOLIS, Oct. 24, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced new Phase 1 data showing that its investigational folate receptor alpha (FR α) antibody-drug conjugate (ADC) sofetabart mipitecan (Sofe-M) plus bevacizumab achieved a confirmed objective response rate (cORR) of 79% and a disease control rate (DCR) of 100% in patients with platinum-sensitive ovarian cancer (PSOC). A cORR of 79% or higher was seen in both poly (ADP-ribose) polymerase inhibitor (PARPi)-treated and PARPi-naïve patients. These data will be shared in an oral presentation at the [European Society for Medical Oncology \(ESMO\) Annual Congress](#) in Madrid, Spain.

FR α is expressed in almost all ovarian cancers, at much higher levels than in healthy tissue, making it a target that can help direct treatment to tumor cells. Sofe-M is an FR α -targeting ADC composed of an Fc-silent, FR α -specific humanized monoclonal antibody linked to exatecan, a topoisomerase I inhibitor, via a proprietary cleavable polysarcosine linker. The antibody is designed to bind FR α on the surface of tumor cells, delivering exatecan directly into the tumor cell to disrupt DNA replication.

Jacob Van Naarden, Executive Vice President and President of Lilly Oncology: "The standard of care for platinum-sensitive ovarian cancer has remained unchanged for a decade and demands new treatment options. Results for Sofe-M show a promising efficacy and tolerability profile across both platinum-resistant and platinum-sensitive ovarian cancer, regardless of FR α expression levels or prior treatment. These data give us confidence as we continue to study Sofe-M in our Phase 3 FRAMework-01 program to bring this potential new medicine to the women who need it."

The Phase 1 study is evaluating Sofe-M plus bevacizumab in patients with advanced solid tumors, including a cohort of 33 women with PSOC who received Sofe-M (4 mg/kg) plus bevacizumab (15 mg/kg). Patients received a median of three prior systemic regimens (range 1–6), including prior PARPi (67%) and prior bevacizumab (70%). As of the July 6, 2026, data cutoff, the cORR among the 29 patients with measurable disease was 79.3% (23/29; 6 complete responses [CR, 20.7%] and 17 partial responses [PR, 58.6%]), and DCR was 100%. Responses were consistent across FR α expression levels and prior PARPi exposure. Median duration of response (DOR) and median progression-free survival (PFS) were not reached at median follow-ups of 6.2 and 10.2 months, respectively.

Chrisann Kyi, MD, Gynecologic Medical Oncologist & Early Drug Development Specialist at Memorial Sloan Kettering Cancer Center: "The durable and robust responses we've seen in patients with platinum-sensitive ovarian cancer are important, particularly in a PARPi pretreated population, where the response rate seen with Sofe-M exceeds what has been reported in published platinum re-challenge studies. The observed safety profile and low discontinuation rates, combined with early efficacy results, support the continued investigation of Sofe-M as a potentially meaningful new option for patients."

Sofe-M plus bevacizumab demonstrated a safety profile consistent with the known profiles of each medicine. No new safety signals were observed. The most common treatment-emergent adverse events (TEAEs) across all patients included epistaxis (73%), nausea (73%), anemia (58%), neutropenia (55%), and fatigue (52%). The most common Grade ≥ 3 TEAEs were neutropenia (42%) and anemia (24%); febrile neutropenia occurred in 3% of patients, and G-CSF prophylaxis was not mandated. Any-grade neuropathy occurred in 9% of patients, with no Grade ≥ 3 events. Dose reductions occurred in 42% of patients, and 6% discontinued treatment due to an adverse event.

The FRAMework-01 program is evaluating Sofe-M in three global Phase 3 trials across both platinum-resistant and platinum-sensitive ovarian cancer: Part A tests Sofe-M as monotherapy in platinum-resistant disease; Part B tests Sofe-M plus bevacizumab in platinum-sensitive disease that progressed on or within six months of completing a PARPi; and Part C tests Sofe-M plus bevacizumab in PARPi-naïve platinum-sensitive disease. The study is being conducted in partnership with the European Network for Gynaecological Oncological Trial groups (ENGOT - lead groups GINECO/NOGGO e.V.), the GOG Foundation (GOG), and the Asia-Pacific Gynecologic Oncology Trials Group (APGOT).

For more information on Lilly's oncology pipeline, click [here](#).

Frequently Asked Questions

1. What is sofetabart mipitecan (Sofe-M)?

Sofetabart mipitecan (Sofe-M) is an investigational folate receptor alpha (FR α)-targeting antibody-drug conjugate (ADC) being studied for the treatment of ovarian cancer and other solid tumors. It is designed to selectively bind to cancer cells expressing FR α and deliver a topoisomerase I inhibitor payload directly to those cells.

2. What is an antibody-drug conjugate?

An antibody-drug conjugate (ADC) is a type of medicine that pairs an antibody with a cell-killing payload. The antibody is designed to recognize and bind to a specific protein found on the surface of cancer cells, and the payload is released once the ADC reaches its target, allowing the medicine to attack cancer cells while limiting exposure to healthy tissue.¹

3. How is Sofe-M different from other FRα-targeted ADCs?

Sofe-M is designed to target FRα across a broad range of expression levels, including in tumors with lower FRα expression. In this Phase 1 study, Sofe-M plus bevacizumab showed a confirmed objective response rate of 79.3% in platinum-sensitive ovarian cancer (PSOC), with consistent activity across FRα expression levels and regardless of prior PARP inhibitor exposure. Earlier studies in platinum-resistant ovarian cancer (PROC) also demonstrated responses observed across all FRα expression levels and in patients previously treated with mirvetuximab soravtansine (MIRV).² These results are being further evaluated in Lilly's ongoing Phase 3 FRamework-01 program, which is studying Sofe-M across both platinum-resistant and platinum-sensitive ovarian cancer.

4. What are the results with sofetabart mipitecan (Sofe-M) in the treatment of platinum-sensitive ovarian cancer (PSOC)?

The Phase 1 study demonstrated encouraging clinical activity, including a confirmed objective response rate (cORR) of 79.3% and a disease control rate (DCR) of 100%, in heavily pretreated patients with platinum-sensitive ovarian cancer. Activity was observed across FRα expression levels and regardless of prior PARP inhibitor exposure. Median duration of response (DOR) and median progression-free survival (PFS) were not reached at median follow-ups of 6.2 and 10.2 months, respectively. Sofetabart mipitecan (Sofe-M) plus bevacizumab demonstrated a safety profile consistent with the known profiles of each medicine, with no new safety signals observed and a low rate of discontinuation due to adverse events (6%). These findings support continued investigation of Sofe-M in the ongoing Phase 3 FRamework-01 trial.

5. In this study Sofe-M was dosed at 4 mg/kg. Why is it dosed at 3mg/kg in the Phase 3 FRamework-01 trial?

The 3 mg/kg dose of Sofe-M was selected as the recommended phase 3 dose (RP3D), based on analysis of the safety, efficacy and PK data as monotherapy. The ORR was comparable between the two doses, with ORRs of 59.0% (95% CI 42.1, 74.4) and 58.8% (95% CI 32.9, 81.6), at 4 mg/kg and 3mg/kg doses, respectively. Safety signals were higher at 4 mg/kg versus 3 mg/kg, with Grade ≥3 TRAEs at 56.4% vs 35.3% and dose reductions of 41.0% vs 23.5%.

6. What are historical clinical trial results for standard of care in platinum-sensitive ovarian cancer (PSOC)?

For patients who recur after platinum-based chemotherapy and PARP inhibitor (PARPi) maintenance, published real world data on subsequent platinum re-challenge have shown modest response rates, with an objective response rate (ORR) of 41.9%.³ Other studies of platinum-based regimens, such as OCEANS, were conducted prior to the routine use of PARPi maintenance and did not include patients previously treated with a PARPi,⁴ a population that now represents a majority of patients with recurrent PSOC, including those enrolled in Sofe-M's Phase 1 study.

7. What is platinum-sensitive ovarian cancer (PSOC)?

Platinum-sensitive ovarian cancer (PSOC) is characterized as ovarian cancer that comes back more than six months after platinum-based chemotherapy. While people with PSOC can often be treated with platinum again, the disease tends to return, and each recurrence can leave fewer treatment options and shorter remissions.⁵

8. What is the current unmet need in platinum-sensitive ovarian cancer (PSOC)?

The standard of care for PSOC has remained largely unchanged for more than a decade, even as understanding of which patients benefit from it has evolved. Approximately 50% of PSOC patients have HRD-positive tumors, meaning their tumors carry a specific DNA-repair deficiency.⁶ These patients tend to have longer progression-free survival with upfront platinum-based chemotherapy plus a PARP inhibitor (PARPi).⁶ However, when these patients do recur after PARPi maintenance, response rates to subsequent platinum-based treatment are modest.⁶ Patients with non-HRD-positive tumors see minimal benefit from PARPi to begin with and generally have a poorer prognosis overall.⁶ Despite these different outcomes between HRD-positive and HRD-negative patients, treatment approaches for PSOC have not meaningfully changed to reflect that distinction.

9. What is the difference between platinum-resistant (PROC) and platinum-sensitive ovarian cancer (PSOC)?

The difference comes down to timing. If ovarian cancer returns more than six months after platinum-based chemotherapy, it's considered platinum-sensitive, and patients often respond well to platinum treatment again. If the cancer returns within six months, or continues growing during treatment, it's considered platinum-resistant, and platinum-based chemotherapy is generally no longer effective. Because platinum resistance tends to develop gradually, each recurrence can bring a shorter remission, even while a patient's disease is still classified as platinum-sensitive.⁶

10. What is folate receptor alpha (FR α), and why is FR α expression level important in treating ovarian cancer?

FR α is expressed in almost all ovarian cancers, at much higher levels than in healthy tissue, making it a target that can help direct treatment to tumor cells.⁷ FR α expression level refers to the amount of the protein present on a tumor and may influence eligibility for or response to certain FR α -targeted therapies.⁷

11. How is the FRAMework-01 clinical trial designed?

FRAMework-01 is a global, three-part Phase 3 trial studying sofetabart mipitecan (Sofe-M) across both platinum-resistant and platinum-sensitive ovarian cancer in a single program: Part A tests Sofe-M as monotherapy in platinum-resistant disease; Part B tests Sofe-M plus bevacizumab in platinum-sensitive disease that progressed on or within six months of completing a PARPi; and Part C tests Sofe-M plus bevacizumab in PARPi-naïve platinum-sensitive disease.

The trial's main measure of success across all three parts is how long patients go without their cancer progressing. The study is being conducted in partnership with the European Network for Gynaecological Oncological Trial groups (ENGOT - lead groups GINECO/NOGGO e.V.), the GOG Foundation (GOG), and the Asia-Pacific Gynecologic Oncology Trials Group (APGOT). Enrollment is ongoing globally with first registrational dose in Q4 2025 for PROC and in Q1 2026 for PSOC.

About Ovarian Cancer

Ovarian cancer is the sixth leading cause of cancer death among women in the United States.⁸ While most patients initially respond to platinum-based chemotherapy, approximately 70% will experience recurrence, leading to progressively shorter remission periods with each subsequent treatment.⁶ When cancer recurs during or within six months of platinum therapy, known as platinum-resistant disease, patients face limited treatment options.^{6,9}

About Sofetabart Mipitecan

Sofetabart mipitecan (Sofe-M; LY4170156) is composed of an Fc-silent, folate receptor alpha (FR α) specific humanized monoclonal antibody linked to exatecan, a topoisomerase I inhibitor, via a proprietary cleavable polysarcosine linker (PSARlink). Sofe-M was designed to target FR α across all expression levels with improved therapeutic index. FR α is a cell-surface glycoprotein encoded by the gene FOLR1 that binds to the essential nutrients folic acid and reduced folates, bringing them into cells to facilitate cell division and growth. FR α is overexpressed in many solid tumors such as ovarian and endometrial cancers. Sofe-M has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for platinum-resistant ovarian cancer (PROC) and is currently being evaluated in the Phase 3 FRAMework-01 program. The study is being conducted in partnership with the European Network for Gynaecological Oncological Trial groups (ENGOT - lead groups GINECO/NOGGO e.V.), the GOG Foundation (GOG), and the Asia-Pacific Gynecologic Oncology Trials Group (APGOT).

About FRAMework-01

FRAMework-01 ([NCT07213804](#)) is a Phase 3, randomized, open-label, three-part study evaluating sofetabart mipitecan (Sofe-M; LY4170156) in patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. Part A tests Sofe-M as monotherapy in platinum-resistant disease; Part B tests Sofe-M plus bevacizumab in platinum-sensitive disease that progressed on or within six months of completing a PARPi; and Part C tests Sofe-M plus bevacizumab in PARPi-naïve platinum-sensitive disease. The primary endpoint is progression-free survival (PFS), assessed by the investigator in Part A and by blinded independent central review (BICR) in Parts B and C. Key secondary endpoints are overall survival, objective response rate, duration of response, and safety. The FRAMework-01 study is in partnership with the [European Network for Gynecological Oncological Trial groups](#) (ENGOT - lead groups [GINECO/NOGGO e.V.](#)), [the GOG Foundation \(GOG\)](#), and the [Asia-Pacific Gynecologic Oncology Trials Group \(APGOT\)](#).

More information on FRAMework-01 can be found on [clinicaltrials.gov](#).

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about sofetabart mipitecan plus bevacizumab and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, that any of these therapies will prove to be a safe and effective treatment or receive regulatory approval, or that Lilly will execute its strategy as expected. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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