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Efficacy and safety of sofetabart mipitecan (Sofe-M), a folate receptor alpha (FR α) targeting antibody drug conjugate (ADC), plus bevacizumab (bev) in recurrent platinum (plat) sensitive ovarian cancer (PSOC)

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Background

Sofe-M is a FR α -targeting ADC composed of an Fc-silent humanized IgG1 with a hydrophilic polysarcosine linker (PSAR10) and exatecan payload. Sofe-M showed efficacy in PROC pts regardless of FR α level. Published data suggest that PARPi-exposed PSOC pts have reduced response to plat-doublet chemotherapy, identifying an unmet need.

Methods

In a phase 1 study (NCT06400472), in pts with advanced solid tumors, a cohort of PSOC pts received Sofe-M (4 mg/kg) + bev (15 mg/kg). Key inclusion criteria: ECOG 0-1; no limit on prior therapies, and prior MIRV allowed. Key endpoints: Safety and anti-tumor activity.

Results

As of 5 Mar 2026, 33 pts received Sofe-M+bev. Median age 67 (41–83); median prior therapies 3 (1–6); 70% prior bev and 67% prior PARPi. Common TEAEs were nausea (73%), epistaxis (67%), fatigue (64%), anemia (58%), neutropenia (55%); grade ≥ 3 neutropenia (39.4%), including G3 febrile neutropenia (3%). No keratopathies/high-grade peripheral neuropathy; 1 pt (3%) discontinued LY and Bev due to TEAE. The rate of interstitial lung disease was low at 6.1% (n=2, G2). At median follow-up of 6 months, ORR was 64% (95%CI, 45-80; 3 CR, 16 PR, 2uPR) and disease control rate was 100% (95% CI, 89-100) with 18/21 (86%) responders remaining on treatment. mDOR has not been reached. Response rates were consistent across FR α expression levels and prior PARPi exposure (Table).

Conclusions

Sofe-M + bev demonstrated 64% ORR in a heavily pre-treated population with favorable tolerability, including in PARPi-pretreated and FR α <75% pts. These data support the ongoing registrational three-part phase 3 FRamework-01 study (NCT07213804), actively enrolling PSOC pts in two parts based on prior PARPi exposure.

	FR α expression 0-24% n=4	FR α expression 25-49% n=1	FR α expression 50-74% n=7	FR α expression 0-74% n=12	FR α expression 75-100% n=18	FR α expression Unknown n=3	Prior PARPi n=22	No prior PARPi n=11
ORR, % (n)	50% (2)	100% (1)	71% (5)	67% (8)	67% (12)	33% (1)	59% (13)	73% (8)

Clinical trial identification

NCT06400472.

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Eli Lilly.

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