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# Phase III MIRASOL trial: Updated overall survival results of mirvetuximab soravtansine (MIRV) vs. investigator's choice chemotherapy (ICC) in patients (pts) with platinum-resistant ovarian cancer (PROC) and high folate receptor-alpha (FRα) expression

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## Background

In the primary analysis of the MIRASOL trial, MIRV demonstrated superior progression-free survival (PFS), objective response rate, and overall survival (OS), over ICC in patients (pts) with high-grade serous PROC (Moore K et al. N Engl J Med 2023;389:2162-74) with a median follow-up time of 11.2 months. Here, we report updated nonanalytical results based on a median follow-up of 16.7 months.

## Methods

453 PROC pts with high FRα expression (VENTANA FOLR1 [FOLR1-2.1] RxDx Assay) with 1-3 prior therapies were randomized 1:1 to MIRV 6 mg/kg, adjusted ideal body weight, Day 1 of a 21-day cycle or ICC: paclitaxel (PAC), pegylated liposomal doxorubicin (PLD), or topotecan (Topo). The primary efficacy endpoint was PFS by an investigator, with key secondary endpoints ORR, OS, and patient-reported outcomes in hierarchical order; other endpoints included safety, tolerability, and duration of response.

## Results

With an extended data cutoff of October 27, 2023, the mPFS was 5.6 months (95% CI 4.3, 6.0) for MIRV vs 4.0 months (95% CI 2.9, 4.5) for ICC with a hazard ratio (HR) of 0.65 (95% CI 0.53, 0.80). The mOS was 16.5 months (95% CI 14.4, 19.9) for MIRV and 13.3 months (95% CI 11.4, 15.4) for ICC with a HR of 0.67 (95% CI 0.53, 0.85). The adverse event (AE) profile of MIRV was consistent with prior reports and included: blurred vision (MIRV 43% vs ICC 2%; grade 3+ 8% vs 0), keratopathy (MIRV 33% vs. ICC 0; grade 3+ 9% vs 0), abdominal pain (MIRV 31% vs ICC 15%; grade 3+ 3% vs 1%), fatigue (MIRV 30% vs ICC 25%; grade 3+ 2% vs 5%), diarrhea (MIRV 29% vs ICC 17%; grade 3+ 1% vs <1%). Compared with ICC, MIRV was associated with lower rates of grade 3+ treatment-emergent AEs (43% vs. 54%), serious AEs (25% vs. 33%), and discontinuations due to TEAEs (10% vs. 16%). 5% of pts on the MIRV arm remained on study drug vs <1% on the IC arm.

## Conclusions

With a median follow-up of 16.7 months, MIRV demonstrated improved efficacy vs ICC in pts with PROC. The efficacy data, along with the well-characterized safety profile, supports MIRV as the standard of care for pts with FRα positive PROC. Clinical Trial Information: NCT04209855.

## Clinical trial identification

NCT04209855.

## Legal entity responsible for the study

ImmunoGen, Inc.

## Funding

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## Disclosure

All authors have declared no conflicts of interest.