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Second progression-free survival (PFS2) and subsequent treatment in patients (pts) with folate receptor alpha (FR□)-positive platinum-resistant ovarian cancer (PROC) treated with mirvetuximab soravtansine (MIRV) vs investigator's choice chemotherapy (ICC): Phase III MIRASOL trial

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Background

In MIRASOL, MIRV showed superior progression-free survival (PFS) and overall survival (OS) vs ICC in pts with FR□-positive PROC. Here, we describe PFS2 and treatment sequencing in the intent-to-treat (ITT) population.

Methods

Adults with FRa-positive (≥75% of cells with ≥2+ membrane staining), high-grade serous PROC and 1–3 prior lines were randomized 1:1 to MIRV (6 mg/kg adjusted ideal body weight every 3 weeks) or single-agent ICC. Primary endpoint was PFS by investigator. PFS2 was assessed as a secondary endpoint.

Results

At MIRASOL final analysis, with 30.5 mo median follow-up (ITT, N=453: MIRV, n=227; ICC, n=226), median PFS (mPFS) of MIRV vs ICC was 5.6 mo (95% CI, 4.3–5.9) vs 4.0 (95% CI, 2.9–4.5), with a hazard ratio (HR) of 0.63 (95% CI, 0.51-0.79). The mPFS2 of MIRV vs ICC was 11.0 mo (95% CI, 9.3–12.0) vs 7.59 mo (6.6–8.84), with HR of 0.59 (95% CI, 0.48–0.73). In pts with prior PARPi maintenance (MIRV, n=124; ICC, n=128), mPFS2 of MIRV vs ICC was 11.5 mo (95% CI, 10.5–12.8) vs 7.2 mo (95% CI, 6.4–8.6), with HR of 0.49 (95% CI, 0.37-0.65). In pts with prior bevacizumab exposure (MIRV, n=138; ICC, n=143), mPFS2 of MIRV vs ICC was 9.3 mo (95% CI, 7.6–11.5) vs 6.9 mo (95% CI, 5.8–8.2), with HR of 0.61 (95% CI, 0.47–0.78). In the ITT, 152/227 (67%) MIRV pts vs 147/226 (65%) ICC pts went on to receive a new anticancer therapy, including, most commonly, taxanes (35% vs 26%), gemcitabine (24% vs 26%), platinum-based compounds (19% each), bevacizumab (19% vs 16%), and anthracyclines (25% vs 9%); 2 (<1%) vs 16 (7%) pts received MIRV. Reasons for treatment discontinuation in the MIRV arm were progressive disease (n=138 [91%]), adverse event (n=11 [7%]), investigator discretion (n=2 [1%]), and withdrawal of consent (n=1 [<1%]). Analyses of subsequent anticancer therapies per line of MIRV or ICC at study entry will be presented.

Conclusions

MIRV demonstrated favorable PFS2 vs ICC irrespective of prior PARPi or bevacizumab exposure. These results further strengthen MIRV as the standard of care with durable clinical benefit continuing beyond progression.

Clinical trial identification

NCT04209855.

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