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Primary results from IMagyn050/GOG 3015/ENGOT-OV39, a double-blind placebo (pbo)-controlled randomised phase III trial of bevacizumab (bev)-containing therapy +/- atezolizumab (atezo) for newly diagnosed stage III/IV ovarian cancer (OC)

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Background

Atezo, which targets PD-L1, is effective in several cancers. Blocking tumour-associated VEGF may promote T-cell infiltration into the tumour bed and boost anti-tumour immune response, justifying combination with bev. Dual VEGF-A and PD-L1 blockade is effective in lung and hepatocellular cancers.

Methods

IMagyn050 (NCT03038100) enrolled patients (pts) with newly diagnosed untreated stage III/IV OC who underwent either primary cytoreductive surgery (PCS) with gross residual disease or neoadjuvant chemotherapy (NACT) and interval surgery. Eligible pts were randomised 1:1 to atezo 1200 mg or pbo cycles 1–22, with paclitaxel 175 mg/m^2 + carboplatin AUC6 cycles 1–6 + bev 15 mg/kg cycles 2–22 (PCS pts), omitting peri-operative bev in NACT pts. Cycles were repeated q3w. Stratification factors were: stage (III vs IV), ECOG PS (0 vs 1/2), PD-L1 staining in immune cells (IC <1% vs ≥1% [PD-L1+]) and treatment strategy (PCS vs NACT). The co-primary endpoints were investigator-assessed progression-free survival (PFS; RECIST v1.1) and overall survival (OS) in the intent-to-treat (ITT) and PD-L1+ populations. PFS was tested in parallel in the two populations; OS was tested hierarchically.

Results

Of 1301 enrolled pts, ⊠25% received NACT. At the data cut-off (30 Mar 2020) median follow-up was ⊠20 months in both arms. There was no statistically significant PFS improvement in either the ITT population (HR 0.92 [95% CI 0.79–1.07]; median 18.4 months with pbo vs 19.5 months with atezo) or the PD-L1+ population (HR 0.80 [0.65–0.99], median 18.5 vs 20.8 months, respectively). Exploratory PFS analyses in the PD-L1 IC ≥5% subgroup showed a trend favouring atezo. Though immature, first interim OS results did not show significant benefit from atezo. Similar proportions discontinued any study treatment for AEs (22% pbo vs 26% atezo pts). The safety profile of atezo + bev + chemotherapy was consistent with expected AEs.

Conclusions

Atezo did not significantly improve PFS in the ITT or PD-L1+ population. The combination was generally well tolerated with manageable AEs. Exploratory biomarker subgroup analyses are ongoing.

Clinical trial identification

NCT03038100.

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