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Oral Abstract Session

Atezolizumab versus placebo in combination with bevacizumab and non-platinum-based chemotherapy in recurrent ovarian cancer: Final overall and progression-free survival results from the AGO-OVAR 2.29/ENGOT-ov34 study.

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Background: Paclitaxel or pegylated liposomal doxorubicin (PLD) in combination with bevacizumab (bev) are standard treatment options in patients with relapsed ovarian cancer not candidates for platinum, but responses are usually short-lived. Recently, two trials have reported a numerical but non-significant advantage from the addition of atezolizumab (atezo) to chemo plus bev in the recurrent setting (ATALANTE, Kurtz JE et al., J Clin Oncol & NRG GY009, O'Cearbhaill et al, IGCS 2023). AGO-OVAR 2.29 investigated the efficacy of atezo in combination with bev and non-platinum-based chemo. **Methods:** AGO-OVAR 2.29 is a randomized, double blind, phase III trial evaluating the efficacy and safety of atezo plus bev and chemo in patients (pts) with recurrent ovarian cancer. Eligible patients had a 1st/2nd relapse within 6 months after completing platinum-based chemo or a 3rd relapse regardless of treatment-free interval. A fresh biopsy for central PD-L1 testing (VENTANA SP142 assay) prior to randomization was mandatory. All pts received weekly paclitaxel or PLD and bev until disease progression or intolerable toxicity and were randomized 1:1 to either atezolizumab 840 mg q14 days or placebo until progression or for a maximum duration of 24 months. Number of prior lines, planned chemo, prior bev and PD-L1 status served as stratification factors. Overall survival (OS) and progression-free survival (PFS) in the intention to treat (ITT) population were primary endpoints, both to be analyzed after observation of 391 deaths. Data cut-off (DCO) occurred on 26/01/2024. OS and PFS analysis is based on a multiple Cox regression with treatment arm and stratification factors as covariates. Safety is reported for pts who received at least one dose of study treatment. **Results:** 574 pts were randomly assigned to atezo (285) or placebo (289). 45.1% received PLD and 53.7% paclitaxel. 7 pts did not start study treatment. 36.1% of pts had received 3 prior lines and 72.5% prior bev. 25.8% were PD-L1 positive. At DCO 418 OS and 505 PFS events have occurred. Median OS was 14.3 months (mos) in the atezo and 13.0 mos in the placebo arm (HR 0.83, 95% CI 0.68-1.01; p=0.06) and PFS 6.3 mos for atezo vs 6.6 mos for placebo arm (HR 0.88, 95% CI 0.73-1.05; p=0.15). Similar HR were observed in PD-L1 positive and negative pts. In total, 580 SAE and 141 AESI were reported. AEs of ≥ grade 3 were reported in 71.5% in the atezo and 68.9% in the placebo arm. 63.7% of pts in the atezo and 51.4% in the placebo arm experienced serious AEs. **Conclusions:** The addition of atezo to chemo plus bev did not significantly improve OS or PFS in pts. with recurrent ovarian cancer who are no candidates for platinum. Safety was within the expected range. Translational research is ongoing. Clinical trial information: NCT03353831. Research Sponsor: F. Hoffmann-La Roche ltd.