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Final overall survival (OS) from the phase III ATALANTE/ENGOT-ov29 trial evaluating atezolizumab (Atz) versus placebo with standard chemotherapy (Cx) plus bevacizumab (bev) in ovarian cancer (OC) patients (pts) with platinum-sensitive relapse (PSR)

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Background

In the ATALANTE trial, adding Atz to standard therapy for PSR pts modestly increased median PFS in the ITT (13.5 vs 11.2 months [m]); HR 0.83, 95% CI, 0.69-0.99) and PD-L1-positive pts (15.2 vs 13.1 m; HR 0.86, 95% CI, 0.63 to 1.16), without reaching statistical significance. We report the exploratory final OS analysis at 5 years.

Methods

PSR OC pts were randomised 2:1 to Atz (1200 mg, d1, q3w or 800 mg, d1&15, q4w or placebo (Pbo) with carboplatin and PLD, gemcitabine or paclitaxel at investigator-choice (6 cycles) plus bev (15 mg/kg, d1, q3w or 10 mg/kg, d1&15, q4w), followed by Atz/Pbo plus bev maintenance for up to 24 months. OS analysis required at least 60% data maturity and it was performed two years after the primary endpoint completion date.

Results

614 pts were randomized to Atz (n=410) or Pbo (n=204). Median follow-up and OS data maturity were 60.1 m and 72.8%. In the ITT population, the median OS in the Atz and Pbo arms were 35.8 m (95% CI, 32.9-41.0) and 30.6 m (95% CI, 27.8-33.2) (HR, 0.79; 95% CI, 0.65 to 0.96) respectively. The 5-year OS rate favoured Atz: 27% (95% CI, 23-32) vs Pbo: 17% (95% CI, 12-23). In the PD-L1 positive population (>1% IC;38% of pts in both arms) the median OS in Atz and Pbo arms respectively were 43.0 m (95% CI, 38.1-50.2) vs 33.7 m (95% CI, 30.6-50.8) (HR, 0.84; 95% CI, 0.60 to 1.17) in Pbo. The 5-year OS rates were: Atz: 36% (95% CI, 29-45): 28% (95% CI, 19-42). There was no significant difference between both arms regarding the percentage of patients receiving first subsequent therapy (83.0 vs 86.8%) with Cx (74.4 vs 74.5%) including platinum (52.2 vs 52.9%), and/or PARP inhibitor (23.9 vs 22.1%), and/or bev (3.4 vs 3.4%) and/or immunotherapy (0 vs 1.9%).

Conclusions

In this exploratory analysis of the ATALANTE trial, with a 5-year follow-up, the median OS was prolonged by 5+ months in PSR OC pts when

Atz is added to standard therapy. First subsequent therapy was similar in both arms. PD-L1 status was not predictive of Atz efficacy. More research is needed to better identify patients who benefit from this extended survival.

Clinical trial identification

EudraCT 2015-005471-24; NCT02891824 (last update 14 December 2023).

Legal entity responsible for the study

ARCAGY-GINECO.

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Disclosure

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