Introduction/Background Standard of care chemotherapy in patients (pts) with advanced ovarian cancer (AOC) is the combination of carboplatin and paclitaxel (C/P). Data from the PRIMA trial has shown a significant benefit in pts by the addition of a maintenance treatment (MT) with niraparib irrespective of BRCA or HRD-status in high-grade AOC. The PAOLA-1 trial evaluated MT in pts with AOC with the combination of olaparib and bevacizumab and has also shown a significant benefit compared to bevacizumab monotherapy. However, the role/benefit of bevacizumab in addition to PARP-inhibitor (PARPi) in MT is unclear. Therefore, we investigate, if the treatment strategy of carboplatin/paclitaxel/bevacizumab/PARPi is superior to the treatment of carboplatin/paclitaxel/PARPi in a population regardless of biomarker status.

Methodology AGO-OVAR 28/ENGOT-ov57 (NCT05009082; EuDrugCT-Number: 2021-001271-16) is a multicenter, randomized, prospective phase III trial. The trial population is composed of adult pts with newly diagnosed, high-grade epithelial AOC, primary peritoneal cancer or fallopian tube cancer FIGO III/IV (except FIGO IIIA2 without nodal involvement). All pts should have completed cycle 1 of chemotherapy (C/P) as part of Study-Run-In-Period. Prior to day 1 of cycle 2, pts with a valid central tumor BRCA (tBRCA) test result will be randomized 1:1 into either Arm1 and will receive 5 additional cycles of C/P q21d followed by niraparib for up to 3 years; or into Arm2 where pts will receive 5 additional cycles of C/P plus bevacizumab q21d followed by bevacizumab q21d (for up to 1 year) and niraparib for up to 3 years. Patients who are scheduled for neoadjuvant chemotherapy and interval debulking surgery can also be enrolled. The primary objective is progression-free-survival (PFS). Secondary objectives include but are not limited to: PFS according to tBRCA-status, overall survival, PFS2, safety/tolerability, and quality of life. First-Patient-First-Visit is expected in August 2022. Target recruitment is 970 patients.

Results Trial-In-Progress.

Conclusion Trial-In-Progress.