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AGO-OVAR 28/ENGOT-OV57: NIRAPARIB VS NIRAPARIB IN COMBINATION WITH BEVACIZUMAB IN PATIENTS WITH CARBOPLATIN-TAXANE BASED CHEMOTHERAPY IN ADVANCED OVARIAN CANCER (A MULTICENTRE RANDOMISED PHASE III TRIAL)

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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; EudraCT-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 cycle1 of chemotherapy (C/P) as part of Study-Run-In-Period. Prior to day1 of cycle2, 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.

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CLINICAL PERFORMANCE EVALUATION OF A NOVEL DEEP LEARNING SOLUTION FOR HOMOLOGOUS RECOMBINATION DEFICIENCY DETECTION

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Introduction/Background Comprehensive identification of ovarian cancer (OvCa) patients that can benefit from poly (ADP-ribose) polymerase inhibitors (PARPi) treatment is currently based on genome-wide enumeration of known Homologous Recombination Deficiency (HRD) biomarkers and requires deep sequence profiles (>30x). The cost and challenges of implementing available solutions currently hinders clinical adoption of HRD testing. We present the interim results for the ongoing multicenter evaluation study of SOPHiA DDM Dx HRD (SOPHiA GENETICS, SA), a novel deep learning-based solution that leverages the impact of HRD on the coverage profiles from low-pass whole-genome sequencing (lpWGS, 1x) data.

Methodology In this multicenter study, we processed and analyzed according to manufacturer's instructions, DNA from 319 formalin-fixed paraffin-embedded (FFPE) OvCa samples. We assessed the concordance between SOPHiA DDM Dx HRD solution and Myriad myChoice® CDx results. For the subset of our cohort (206 samples) included in the PAOLA-1 clinical trial, we carried out survival analysis to investigate differences in progression-free survival (PFS) in the olaparib and placebo arms of the study between patients, with HRD positive or non-positive tumors.

Results We found a high overall percentage agreement, 90.48% (95% confidence interval [CI], 86.58–93.33), between SOPHiA DDM Dx HRD and Myriad myChoice® CDx status. The median PFS time for patients with HRD positive tumors was 20.8 months higher in the olaparib arm (hazard ratio [HR], 0.44; 95% CI, 0.26–0.76, P=0.003). No significant