Abstracts

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)

1Florian Heitz*, 2Edgar Petru, 3Stéphanie Henry, 4Alexander Reuss, 5David Cibula, 6Lydia Gaba, 7Nicoletta Colombo, 8Sandra Polleis, 1Philipp Harter. 1AGO Study Group and Ev. Kliniken Essen-Mitte, Essen, Germany; 2AGO-Austria and Department of Obstetrics and Gynecology, Medical University of Graz, Graz, Austria; 3BGOG and CHU UCL. Namur Site Sainte Elisabeth, Namur, Belgium; 4AGO and KKS Marburg, Marburg, Germany; 5CEEGOG and Department of Obstetrics and Gynecology, General University Hospital in Prague, First Medical Faculty of the Charles University, Prague, Czech Republic; 6GEICO and Medical Oncology, Gynecological Cancer Unit, Hospital Clinic de Barcelona, Barcelona, Spain; 7MANGO and IDE, European Institute of Oncology, IRCCS, Milan and University of Milano-Bicocca, Milan, Italy; 8AGO Study Group, Wiesbaden, Germany

#259

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 IIIf2 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, 970 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. The trial is currently recruiting, the first patient was randomized in October 2022.

Results Trial-In-Progress

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.

Conclusion Frailty is a multidimensional, difficult quantifiable complex. To ensure a possible operationalization, we developed the two-step frailty assessment. This two-step frailty assessment identifies a significant proportion of non-frail patients and women who received optimization of their global health status to realize the standard operation.

Disclosures The authors declare no relevant conflict of interests.

Int J Gynecol Cancer 2023;33(Suppl 3):A1–A453

10.1136/ijgc-2023-ESGO.875