Conclusion The MTD of the triple combination was established and the study met its secondary endpoint of initial efficacy; however, significant cytopenias were noted with this regimen, which may limit further development.

Abstracts

LONG-TERM RESPONDERS (LTR) TO RUCAPARIB IN RECURRENT OVARIAN CANCER: A SUB-GROUP ANALYSIS FROM THE RUCAPARIB ACCESS (RAP) PROGRAM IN SPAIN BY GEICO

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Introduction/Background Rucaparib is a PARPi approved as maintenance (MTN) for platinum (Pt)-sensitive recurrent HGOC, and as treatment (Tx) for BRCA-mutated recurrent HGOC patients. Real-world data about LTR patients from the RAP is analyzed here.

Methodology A retrospective GEICO study was performed at 22 hospitals that treated patients within the RAP. Women with HGOC received rucaparib (600 mg BID) in the MTN, Tx Pt-sensitive or Tx Pt-resistant setting. In this subanalysis, long-term response was defined as progression-free survival (PFS) ≥12 months for the MTN group and ≥6 months for the Tx group.

Results In the study 51 patients were recruited: 18 received rucaparib as MTN and 33 as Tx. In the MTN group, 6 patients (33.3%) were LTR. Of them, 2 patients (33.3%) harbored BRCA or RADS1/C mutations. The median number of prior lines was 3 (2–6), being ≥5 in 33.2%, 66.6% had measurable disease and 50.0% achieved PR to prior Pt-based chemotherapy. In the Tx group, 10 patients (30.3%) were LTR. All of them harbored BRCA and/or RADS1/C mutations. The median number of prior lines was 6 (2–9), with 60.0% receiving ≥5 prior lines, 60.0% were Pt-resistant and 60.0% had measurable disease. The median PFS of LTR was not achieved in the MTN group and was 10.9 months (95% CI: 7.0–16.7) in the Tx group. Adverse events (AE) of any grade were reported in 66.6% of LTR within the MTN group and in 100.0% within the Tx group, while AE of grade ≥3 occurred in 16.6% and 50.0%, respectively. No new safety signals were detected. At present, 3 and 1 patients are still receiving rucaparib as MTN and Tx, respectively.

Conclusion A durable response was achieved in a notable proportion of patients, despite their unfavorable conditions at treatment initiation. The safety profile of rucaparib in this real-world setting is consistent with that previously reported.

THE GENEVA HRD TEST: CLINICAL VALIDATION ON 469 SAMPLES FROM THE PAOLA-1 TRIAL

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Introduction/Background The efficacy of the Myriad myChoice® Homologous Recombination Deficiency (HRD) test to guide use of PARP inhibitors has been demonstrated in several phase III trials. However, its high failure rate and limited accessibility establish a need for a clinically validated laboratory developed test.

Methodology As part of the ENGOT HRD European Initiative, a subset of the PAOLA-1/ENGOT-ov25 phase 3 trial was analyzed in the Geneva University Hospitals with the OncoScan™ CNV Assay and an in-house algorithm developed using TCGA data. Results were compared to Myriad myChoice Genomic Instability Score (GIS) with respect to the progression-free survival in the Olaparib + Bev and placebo + Bev arms.

Results The analysis of the TCGA cohort revealed that a normalization of the number of LST (large-scale state transitions) by the number of whole-genome doubling events allows a better separation and classification of HRD samples than the Myriad GIS. On the 469 PAOLA-1 samples, the Geneva test yielded a lower failure rate than Myriad (10/469 vs 59/469 inconclusive results) and positive and negative agreement values of 96% (204/213) and, respectively, 81% (159/197). In Geneva HRD-positive samples, the hazard ratio (HR) was 0.40 (95% CI: 0.28–0.57; figure 1). For Myriad, the HR was 0.35. In BRCA wild-type and Geneva HRD-positive samples, the HR was 0.53 (Myriad: 0.41). Of note, in this subpopulation the Geneva test and the Myriad test yielded a similar 1-year PFS (87% and 88%) but a different 2-year PFS (52% vs 60%).

Abstract 2022-RA-567-ESGO Figure 1