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Title: Phase II OVARIO Study of niraparib + bevacizumab therapy in advanced ovarian cancer following front-line platinum-based chemotherapy with bevacizumab

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Objectives: Niraparib improves progression-free survival (PFS) in newly diagnosed, recurrent, and heavily pretreated ovarian cancer (OC) in patients (pts) after platinum-based chemotherapy in all biomarker-defined subgroups. Bevacizumab-induced hypoxia can drive genomic instability by altering DNA damage repair pathways, including homologous recombination (HR), and it is hypothesized to sensitize tumors to poly(ADP-ribose) polymerase inhibition. OVARIO (NCT03326193) is a single-arm, open-label study evaluating niraparib + bevacizumab treatment in advanced OC after response to first-line (1L) platinum-based chemotherapy + bevacizumab.

Methods: All pts with newly diagnosed high-grade serous or endometrioid stage IIIB-IV OC who had a complete response (CR), partial response, or no evidence of disease (NED) after 1L platinum-based chemotherapy + bevacizumab were eligible. Pts receiving neoadjuvant chemotherapy (NACT) or primary debulking surgery were eligible. All pts underwent tissue testing for HR deficiency (HRd) or proficiency (HRp) at enrollment. Bevacizumab dosage was 15 mg/kg q3w up to 22 cycles, including time on 1L chemotherapy. Niraparib, 300 or 200 mg qd, based on baseline body weight and platelet count, was started within 12 weeks of completing 1L treatment and continued for 3 years or until progressive disease or unacceptable toxicity. The primary endpoint was PFS rate at 18 months from treatment initiation of niraparib + bevacizumab maintenance.

Results: The study completed enrollment at 105 pts. Most pts were stage III (79%), had serous histology (95%), received NACT (63%), and had CR/NED at the completion of 1L (63%). Overall, 47% of pts were HRd, including HRd-BRCA mutated and HRd-BRCA wild-type. The niraparib starting dose was 200 mg in 78% of pts. At 6 and 12 months, PFS rates were 90% and 75%, respectively. At 12 months, the most common grade >=3 related treatment-emergent adverse events were thrombocytopenia, anemia, and hypertension (49% of pts had pre-existing hypertension). Further safety data and PFS rates at 18 months will be presented at the meeting.

Conclusions: Safety of the niraparib + bevacizumab combination was consistent with the known side effects of each drug as monotherapy, and the preliminary data suggest that the combination is efficacious.ClinicalTrials.gov number: NCT03326193