**Abstracts**

**0016/#233**

**CLINICAL AND MOLECULAR CHARACTERISTICS OF ARIEL3 PATIENTS WHO DERIVED EXCEPTIONAL BENEFIT FROM RUCAPARIB MAINTENANCE TREATMENT FOR HIGH-GRADE OVARIAN CANCER (HGOC)**

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**Objectives** ARIEL3 is a placebo-controlled randomized trial of the PARP inhibitor (PARPi) rucaparib as maintenance treatment in HGOC patients who responded to the latest line of platinum therapy (NCT01968213). Rucaparib improved progression-free survival (PFS) across all predefined subgroups. Here, we present an exploratory analysis of characteristics associated with exceptional benefit from rucaparib.

**Methods** Patients were randomized 2:1 to rucaparib 600 mg BID or placebo. As of 31 Dec 2019 (data cutoff), 33/375 (9%) and 1/189 (0.5%) patients were still ongoing and receiving rucaparib or placebo. Molecular features (genomic alterations, BRCA1 promoter methylation) and baseline clinical characteristics were compared between patients who derived exceptional benefit (PFS ≥ 2 years), and those with disease progression on first scan (>12 wks; the short-term subgroup) within each treatment arm.

**Results** Of 564 patients, 79/375 (21%) in the rucaparib arm and 4/189 (2%) in the placebo arm showed exceptional benefit. Within the rucaparib arm, exceptional benefit patients had more favorable clinical prognostic factors at baseline versus the short-term subgroup (Table). Although BRCA mutations were enriched in the rucaparib exceptional benefit subgroup, 33/79 (42%) of these patients were BRCA wild type. Patterns of enrichment varied among other biomarkers. Overall trends were similar in the placebo arm.

**Conclusions** Exceptional benefit in ARIEL3 was more common in, but not exclusive to, patients with favorable clinical characteristics and known mechanisms of PARPi sensitivity. Our results suggest rucaparib can deliver exceptional benefit to a diverse set of patients with HGOC.

**0017/#15**

**Efficacy and Safety of Niraparib Maintenance Treatment in Platinum-Sensitive Recurrent Ovarian Cancer After Shorter or Longer Chemotherapy: A Post Hoc Subgroup Analysis**

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**Objectives** Traditionally ≥6 cycles of platinum-containing chemotherapy (Pt-chemo) are recommended for platinum-sensitive recurrent ovarian cancer (PSROC). PARP inhibitor maintenance treatment (MT) can be initiated upon clinical complete/clinical partial response (CR/PR) after ≥4 cycles of chemotherapy. Shorter chemotherapy may improve patient experience without compromising efficacy. This study aims to compare the efficacy and safety of niraparib to placebo as MT administered after ≤4 or >4 cycles of Pt-chemo.
Methods This is a post hoc analysis of the published NORA phase III study (NCT03705156). Adults with PSROC and CR/PR to most recent Pt-chemo were randomized 2:1 to niraparib or placebo. Primary endpoint was PFS by BICR. Subgroups comprised patients with ≤4 or >4 cycles of most recent Pt-chemo.

Results Table 1 summarizes key baseline characteristics which were overall balanced between groups. Median (95% CI) PFS was 18.37 months (8.54–not estimable [NE], ≤4-cycle/niraparib) versus 3.88 months (3.68–7.43, ≤4-cycle/placebo; HR=0.36 [p=0.0016]), and was 18.33 months (10.28–NE, >4-cycle/niraparib) versus 5.49 months (3.71–5.75, >4-cycle/placebo; HR=0.33 [p<0.0001]) (figure 1). Overall safety profiles were comparable between ≤4-cycle/niraparib and >4-cycle/niraparib, with similar percentages of patients experiencing neutrophil count decrease (60.4%; 58.1%), anemia (50.0%; 55.0%), and platelet count decrease (45.8%; 58.1%). Composition of grade ≥3 TEAEs was consistent with the overall NORA results.

Conclusions Similar niraparib-versus-placebo PFS benefits were observed after ≤4-cycle or >4-cycle Pt-chemo in CR/PR patients. The efficacy and safety of niraparib MT after shorter Pt-chemo remain to be verified in larger samples.

Oral Featured Posters

OP001/#162 SENTINEL LYMPH NODE MAPPING IN EARLY-STAGE CERVICAL CANCER – A NATIONAL PROSPECTIVE MULTICENTER STUDY (SENTIREC TRIAL)

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Objectives Sentinel lymph node (SLN) mapping may replace staging radical pelvic lymphadenectomy in women with early-stage cervical cancer. In a national multicenter setting, we evaluated SLN mapping in women with early-stage cervical cancer and investigated the accuracy of SLN mapping and FDG-PET/CT in tumors >20 mm.

Methods We prospectively included women with early-stage cervical cancer from March 2017-January 2021 to undergo SLN mapping. Women with tumors >20 mm underwent completion pelvic lymphadenectomy and removal of FDG-PET/CT positive nodes. We determined SLN detection rates, incidence of nodal disease, sensitivity and negative predictive value (NPV) of SLN mapping, and the sensitivity, specificity, NPV, and positive predictive value (PPV) of FDG-PET/CT.

Results We included 245 women, and 38 (15.5%) had nodal metastasis. The SLN detection rate was 96.3% (236/245), with 82.0% (201/245) bilateral detection. In a stratified analysis of 103 women with tumors >20 mm, 27 (26.2%) had nodal metastases. The sensitivity of SLN mapping adhering to the algorithm was 96.3% (95% CI 81.0–99.9%) and the NPV 98.7% (95% CI 93.0–100%). For FDG-PET/CT imaging the sensitivity was 14.8% (95% CI 4.2–33.7%), the specificity 85.5% (95% CI 75.6–92.5%), the NPV 73.9% (95% CI 63.4–82.7%), and the PPV 26.7% (95% CI 7.8–51.5%).

Conclusions Our results suggest that SLN mapping is a reliable method in women with early-stage cervical cancer. However, until the oncological safety is established, we recommend completion pelvic lymphadenectomy in women with tumors >20 mm. FDG-PET/CT seems redundant for nodal staging in women with early-stage cervical cancer.