

**Objectives** In locally-advanced cervical cancer (LACC), platinum-based chemoradiotherapy (CRT) has been the standard-of-care treatment for >20 years. CALLA is the first global Phase 3 study evaluating immune checkpoint inhibition (durvalumab) versus placebo in combination with and following CRT in LACC (NCT03830866).

**Methods** Newly-diagnosed, untreated patients with LACC (FIGO 2009 stages IB2-IIB node positive, IIIA-IVA with any node status) were randomized 1:1 to durvalumab (1500 mg IV) or placebo Q4W, for a total of up to 24 months, in combination with and following CRT. CRT comprised concurrent weekly IV cisplatin with EBRT and brachytherapy. RT quality was monitored, with variations evaluated for clinical significance. The primary endpoint is PFS; secondary endpoints include OS, objective response rate, local/distant disease progression incidence, and safety.

**Results** 770 patients were randomized (N=385 per arm) at 120 sites in 15 countries. Median age was 49 years; median follow-up was 18.5 months. Durvalumab+CRT did not show a statistically significant improvement in PFS vs placebo+CRT (HR 0.84 [95% CI, 0.65–1.08]; P=0.174); there was no detriment to OS, although data were immature and not formally tested. Adverse events of grade 3–4 occurred in 51.7% and 51.0% of patients in the durvalumab+CRT and placebo+CRT arms, respectively; 12.5% and 9.6% of patients discontinued treatment due to AEs possibly related to study drug.

**Conclusions** Durvalumab in combination with and following CRT did not significantly improve PFS in patients with LACC. Safety of durvalumab+CRT was generally comparable to CRT alone, with no new or unexpected toxicity. Funding: AstraZeneca.

0002/#185

## UTERINE TRANSPOSITION: FEASIBILITY STUDY

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**Objectives** To evaluate the feasibility of uterine transposition (UT) as a method of preserving ovarian and uterine function after pelvic radiation.

**Methods** This was a prospective, non-randomized feasibility study of UT for patients with non-gynecologic pelvic cancers, who require radiation. UT to the upper abdomen was performed 7 to 14 days prior radiation. Frequent clinical examinations and doppler ultrasound were used to evaluate the gonadal vessels vasculature after surgery. The uterus was placed back to the pelvis 2 to 4 weeks after radiation and patients were followed with clinical examinations, pelvic ultrasound and laboratory tests to evaluate hormonal function. Menses were systematically recorded. Cancer treatment and follow-up were performed according to the standard guidelines and no modification were allowed.

**Results** From June 2017 to June 2019, eleven patients were selected for the study. Eight patients were submitted to UT (median age of 30.5 yo). There were no transoperative complications. Cervical stenosis was the most common postoperative complication. One patient had uterine necrosis 4 days after surgery, but the right ovary was preserved and kept normal hormonal function. One patient died from carcinomatosis

4 months after UT. All patients who preserved the uterus have normal hormonal levels, menses and sexual activity after treatment. Two patients have had spontaneous pregnancies, one baby was born at 37 weeks and the other patient is 20 weeks pregnant. One patient tried to get pregnant but did not succeed.

**Conclusions** Uterine transposition is a feasible procedure to preserve the uterus and gonadal function. Spontaneous and healthy pregnancy is also possible.

0003/#557

## OVERALL SURVIVAL RESULTS FROM ARIEL3: A PHASE 3 RANDOMIZED, DOUBLE-BLIND STUDY OF RUCAPARIB VS PLACEBO FOLLOWING RESPONSE TO PLATINUM-BASED CHEMOTHERAPY FOR RECURRENT OVARIAN CARCINOMA

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**Objectives** In ARIEL3 (NCT01968213), rucaparib maintenance treatment significantly improved progression-free survival (PFS) vs placebo. We present updated PFS2 and preplanned final overall survival (OS) analyses.

**Methods** Patients were randomized to receive rucaparib 600 mg BID or placebo. Efficacy was analyzed across the 3 protocol-defined nested cohorts (BRCA-mutant, homologous recombination deficient [HRD], and intent-to-treat [ITT]). PFS2 was an exploratory endpoint, defined as time from randomization to second event of investigator-assessed disease progression, or death due to any cause. OS was a secondary endpoint with analysis planned after 70% of death events. The data cutoff was April 4, 2022, for efficacy and December 31, 2019, for safety. Patients were followed after treatment discontinuation for incidence of myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML); MDS/AML are reported as of April 12, 2022.

## Abstract 0003/#557 Table 1

	BRCA		HRD		ITT	
	Rucaparib (n=130)	Placebo (n=66)	Rucaparib (n=236)	Placebo (n=118)	Rucaparib (n=375)	Placebo (n=189)
PFS2 events, n (%)	98 (75.4)	54 (81.8)	183 (77.5)	99 (83.9)	302 (80.5)	162 (85.7)
Median PFS2, months (95% CI)	26.1 (22.8–32.8)	18.4 (15.7–24.4)	24.7 (21.9–26.8)	18.4 (15.8–22.1)	20.6 (18.7–23.5)	16.3 (14.6–17.9)
	HR 0.672 (95% CI 0.480–0.941) P=0.02		HR 0.718 (95% CI 0.558–0.923) P=0.01		HR 0.703 (95% CI 0.579–0.854) P<0.01	
OS events, n (%)	82 (63.1)	48 (72.7)	159 (67.4)	85 (72.0)	270 (72.0)	140 (74.1)
Median OS, months (95% CI)	45.9 (37.7–59.6)	47.8 (43.2–55.8)	40.5 (36.6–48.4)	47.8 (42.7–53.0)	36.0 (32.8–39.4)	43.2 (38.1–46.9)
	HR 0.832 (95% CI 0.581–1.192) P=0.32		HR 1.005 (95% CI 0.766–1.320) P=0.97		HR 0.995 (95% CI 0.809–1.223) P=0.96	

HRs and associated P values were calculated using a stratified log-rank test and stratified Cox-proportional model. P values are nominal with no adjustment for multiplicity. CI, confidence interval; HR, hazard ratio.

**Results** Median follow-up was 77.0 months as of the efficacy data cutoff. In the ITT population, death events had occurred in 410/564 (72.7%) patients. PFS2 and OS are presented in the table 1. Among placebo-arm patients, ≈45% received a PARP inhibitor as a subsequent treatment. Safety was consistent with prior reports; MDS/AML was reported in 14 (3.8%) rucaparib-arm and 6 (3.2%) placebo-arm patients (P=0.72) (reported post-study drug treatment in 8 cases in the rucaparib arm and 6 in the placebo arm).

**Conclusions** These data support the use of rucaparib as a maintenance treatment for recurrent ovarian carcinoma; although no OS benefit was seen, the PFS benefit for rucaparib was maintained through the subsequent line of therapy.

0004/#752

# SELECTION CRITERIA FOR OMITTING INTERVAL DEBULKING SURGERY AFTER NEOADJUVANT CHEMOTHERAPY FOR ADVANCED HIGH-GRADE SEROUS CARCINOMA OF THE OVARY: KGOV OVSURG-2016/SCORE STUDY

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**Objectives** This study investigates the selection criteria for omitting interval debulking surgery (IDS) after neoadjuvant chemotherapy (NACT) due to a higher response to chemotherapy for advanced ovarian cancer.

**Methods** We searched the ovarian, fallopian, or primary peritoneal cancer database registered between January 2000 and May 2021. We included patients with clinical stage III to IV high-grade serous carcinoma of the ovary (HGSC) who received NACT after serial measurement of serum levels of CA-125 regardless of IDS. We calculated the CA-125 ELIMination of Rate Constant K (KELIM) value during two cycles of NACT. Then, we calculated the cut-off values of KELIM for predicting platinum resistance and then evaluated the effect of IDS on progression-free survival (PFS) and overall survival (OS) based on the values.

**Results** Among 279 patients, 194 (76%) were treated with NACT/IDS, and 61 (24%) were treated with chemotherapy alone. Although NACT/IDS showed better PFS and OS than chemotherapy alone in patients with lower KELIM (<0.95), no difference in survival was shown in higher KELIM

(≥0.95). In multivariate analysis, IDS was associated with better OS in Low KELIM patients (hazard ratio [HR], 0.517, p=0.016), while IDS was not associated with better survival in High KELIM patients (HR, 0.739, p=0.390). Also, radiologic complete response (CR) and partial response (PR) were associated with better survival regardless of KELIM score.

**Conclusions** In conclusion, for stage III/IV HGSC patients presenting higher KELIM (≥0.95), IDS may be omitted when the radiologic CR or PR is accomplished during NACT.

0005/#638

# PROMISE-2: A ONE STEP DNA-BASED ENDOMETRIAL CANCER MOLECULAR CLASSIFIER

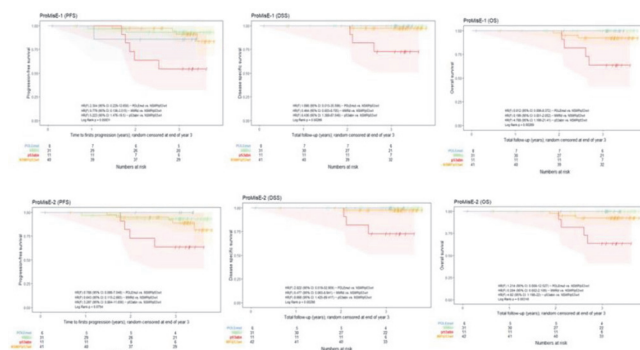
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**Objectives** Despite recommendations for the integration of molecular classification in endometrial cancers (EC) into pathology reporting and clinical management, uptake is inconsistent. To assign ProMisE subtype, all molecular components must be available (POLE mutation status, MMR and p53 immunohistochemistry (IHC)) and often components are performed at different stages of care and/or at different centers resulting in diagnostic delays. We assess the performance of a one step DNA-based molecular classifier (ProMisE-2) compared to ProMisE.

**Methods** DNA was extracted from ECs that had previously undergone molecular classification using ProMisE (POLE sequencing, IHC for p53 and MMR). ProMisE2 was derived using the Imagia Canexia Health Find It next-generation sequencing assay to assess mutations in POLE, TP53 and presence of microsatellite instability (MSI). Molecular subtypes assigned by ProMisE and ProMisE-2 were assessed for concordance metrics and the ability to recapitulate Kaplan-Meier survival curves.

**Results** ProMisE-2 was assessed in 91 ECs with 2 cases failing sequencing coverage thresholds. 85/89 of cases were concordant with a kappa statistic 0.93 and an overall accuracy of



**Abstract 0005/#638 Figure 1** Kaplan-Meier survival analyses demonstrating molecular subtype is associated with outcomes across progression free survival, disease specific survival, and overall survival in both ProMisE and ProMisE-2