



Abstract LB002/#1545 Figure 1 Kaplan-meier curves of progression-free survival and overall survival according to HIPEC (A,B). ICS, interval cytoreduction surgery

Objectives The aim of this study was to determine the effectiveness and safety of hyperthermic intraperitoneal chemotherapy (HIPEC) to interval cytoreductive surgery (ICS) in clinical practice

Methods This is a prospective, multicenter, cohort study, a total of 205 patients were enrolled. 9 patients were excluded, because they did not meet the inclusion criteria. We enrolled stage III/IV ovarian cancer who had at least three cycles of neoadjuvant chemotherapy followed by ICS either with or without HIPEC at seven Korean Gynecologic Oncology Group institutions between 2017 and 2021. The primary end point was progression-free survival (PFS). Overall survival (OS) and safety profile were key secondary endpoint.

Results 196 patients were included in this trial. 87 patients receive ICS without HIPEC and 109 patients receive ICS with HIPEC. The median duration of follow up was 28.2 months. 128 (65.3%) patients had disease recurrence and 30 (15.3%) patients had died. ICS with HIPEC was associated with significantly improved PFS (22.9 vs. 14.2 months; $p = 0.005$) and OS (not reached vs. 53.0; $p = 0.002$), compared with ICS without HIPEC. Grade III/IV postoperative complications were similar in the two groups ($p = 1.000$). Peritoneal recurrences were more common in ICS without HIPEC compared to the ICS with HIPEC (41/64 [64.1%] vs 21/64 [32.8%], $p = 0.001$).

Conclusions The incorporation of HIPEC to ICS resulted in longer PFS and OS than ICS alone without higher rates of side effects in advanced-stage ovarian cancer. Lower rate of peritoneal recurrence after HIPEC might have a prominent impact on OS.

0001/#504

DURVALUMAB, IN COMBINATION WITH AND FOLLOWING CHEMORADIOTHERAPY, IN LOCALLY ADVANCED CERVICAL CANCER: RESULTS FROM THE PHASE 3 INTERNATIONAL, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CALLA TRIAL

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10.1136/ijgc-2022-igcs.3

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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10.1136/ijgc-2022-igcs.4

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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10.1136/ijgc-2022-igcs.5

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.