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-IIIB 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.

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 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 formed 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 follow-up was 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 transitory 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.