

progression or unacceptable toxicity or for up to 35 cycles. The primary endpoint will be PFS. An exploratory analysis on tumor biopsies before and after NAD will be performed, to identify immunogenic and genetic markers of responsiveness or resistance to NAD treatment.

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission.

TP004/#1457

TRIAL IN PROGRESS OF ENGOT-CX8/GOG-3024/INNOVATV 205: ADDITION OF A NEW COHORT USING FIRST-LINE TISOTUMAB VEDOTIN + PEMBROLIZUMAB + CARBOPLATIN ± BEVACIZUMAB IN RECURRENT/METASTATIC CERVICAL CANCER

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Objectives A 2-part, multicohort, phase 1b/2 trial, ENGOT-cx8/GOG-3024/innovaTV 205 (NCT03786081), established the recommended phase 2 dose (RP2D) and feasibility of tisotumab vedotin (TV) in combination with bevacizumab, pembrolizumab, or carboplatin (Monk et al, IGCS 2021). The current report details a new, ongoing, innovaTV 205 dose-expansion cohort evaluating combinations of TV, pembrolizumab, and carboplatin ± bevacizumab.

Methods The new cohort will include adult patients with recurrent or stage IVB squamous, adenosquamous, or adenocarcinoma of the cervix who received no prior systemic therapy and had an ECOG PS of 0 or 1. Patients will be treated with the RP2D of TV (2.0 mg/kg) + carboplatin (AUC 5 mg/mL), pembrolizumab (200 mg), and bevacizumab (15 mg/kg), or with TV + carboplatin (AUC 5 mg/mL) and pembrolizumab (200 mg), every 3 weeks. To assess the regimen's initial tolerability, a dose-limiting toxicity evaluation period will consist of completion of 1 treatment cycle of 21 days for 6

patients to receive the quadruplet combination. The primary end point is confirmed objective response per RECIST v1.1; secondary end points are duration of response, time to response, progression-free survival, overall survival, and safety. Enrollment is ongoing in the US and Europe, with additional sites planned globally.

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission. ©2022 American Society of Clinical Oncology, Inc. Reused with permission. This abstract was accepted and previously presented at the 2022 ASCO Annual Meeting. All rights reserved.

TP005/#272

CONTESSA/NEOCON-F TRIAL: NEOADJUVANT CHEMOTHERAPY FOLLOWED BY FERTILITY-SPARING SURGERY IN FIGO 2018 STAGE IB2 CERVICAL CANCER

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Objectives The primary objective of the CONTESSA/NEOCON-F trial (NCT04016389) is to assess the feasibility of preserving fertility in women with FIGO 2018 stage IB2 cervical cancer by administering neo-adjuvant chemotherapy (NACT) followed by fertility sparing surgery (FSS).

Methods This ongoing multi-center, phase II clinical trial will accrue 90 premenopausal women, aged between 18 and 40 years, who are diagnosed with lymph-node negative, FIGO 2018 stage IB2 cervical cancer and who have a desire to preserve fertility. Patients will receive three cycles paclitaxel and platinum-based chemotherapy. Following NACT the response will be evaluated by clinical examination and MRI. Patients with complete or partial response (residual lesion <2 cm) will be eligible for FSS: a conization or simple trachelectomy. Patients with suboptimal response (residual lesion ≥2 cm) will go off-study and receive definitive treatment as per local protocol. The follow-up is three years. The primary outcome is the rate of functional uterus defined as successful FSS and no adjuvant therapy. Secondary outcomes include the safety of NACT and FSS, the response rate to NACT, and the recurrence-free and overall