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

1Ignace Vergote, 2Mansoor Mirza, 3Javid Sebouli, 4Domenica Lorusso, 5Fatih Köse, 6David Cobula, 7Anneke Westermann, 8Dearniall Collins, 9Susana Banerjee, 10Anna Oackchin, 11Ibrahima Soumaoro, 12Shweta Jain, 13Bradley Monk*. 14Leuven Cancer Institute and BGOG (Belgium and Luxembourg Gynaecological Oncology Group), University Hospitals Leuven, Leuven, Belgium; 15Rigshospitalet, Copenhagen University Hospital, Department of Cancer Treatment, Copenhagen, Denmark; 16Charité University Hospital Campus Virchow Klinikum, Gynecology and Gynaecological Oncology, Berlin, Germany; 17Fondazione Policlinico Universitario A.Gemelli IRCCS, Gynecologic Oncology, Rome, Italy; 18Baskent University, Department of Medical Oncology, Yâneğir/Adana, Turkey; 19First Faculty of Medicine, Charles University and General University Hospital, Department of Obstetrics and Gynaecology, Prague, Czech Republic; 20Dutch Gynaecological Oncology Group (DGOG) and Amsterdam University Medical Centers, Department of Medical Oncology, Amsterdam, Netherlands; 21Cork University Hospital, Department of Medical Oncology, Cork, Ireland; 22The Royal Marsden NHS Foundation Trust and Institute of Cancer Research, Gynaecology Unit, London, UK; 23Vall d’Hebron Institute of Oncology (VHIO), Hospital Universitari Vall d’Hebron, Vall d’Hebron Barcelona Hospital Campus, and GEICO, Gynaecologic Cancer Programme, Barcelona, Spain; 24Genmab US, Inc., Oncology, Plainsboro, USA; 25Seagen Inc., Late Stage Development, Bothell, USA; 26Director, Principal Investigator, Community Research Development, HonorHealth Research Institute, Division of Gynecologic Oncology, Phoenix, USA

10.1136/ijgc-2022-igcs.513

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 adenosquamous carcinoma 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.