endocrine resistance. GOG-3007 and other phase 2 studies have demonstrated that the combination of conventional mTOR inhibitors (mTORi) and endocrine therapy provides clinical benefit in patients with EC. nab-Sirolimus is a nanoparticle injectable form of mTORi approved for malignant perivascular epithelioid cell tumor. Preclinical data with nab-sirolimus demonstrated improved tumor accumulation, mTOR inhibition, and tumor growth suppression compared with conventional mTORi. We hypothesize that nab-sirolimus in combination with letrozole may produce synergistic antitumor activity in patients with recurrent EEC.

Methods In this phase 2, open-label, single-arm, multi-center study (NCT05997017), nab-sirolimus (100 mg/m^2, IV, days 1 and 8 of each 21-day cycle) and letrozole (2.5 mg, oral, daily) are administered to patients (~29 planned) with clinically confirmed, advanced or recurrent EEC. Eligibility criteria include age ≥18 years, 0–1 prior chemo-based regimens, ECOG 0–1, mTORi naïve, and RECIST-measurable disease. The primary endpoint is best ORR by RECIST v1.1; key secondary endpoints include duration of response, PFS, OS, and safety. The relationship between biomarkers and response outcomes is an exploratory endpoint.

Current Trial Status Open for enrollment.

TP010/#397

ENGOT-EN20/GOG-3083/XPORT-EC-042 A PHASE 3, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND, MULTICENTER TRIAL OF SELINEXOR IN MAINTENANCE THERAPY FOR PATIENTS WITH P53 WILD-TYPE, ADVANCED OR RECURRENT ENDOMETRIAL CARCINOMA

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Introduction Selinexor is FDA-approved for use in multiple myeloma and diffuse large B-cell lymphoma. In the ENGOT-EN5/GOG-3055/SIENDO study (NCT03555422), preliminary analysis of a pre-specified exploratory subgroup of patients with TP53wt EC showed a decrease in risk for progression or death with a median PFS of 13.7 months with selinexor vs 3.7 months with placebo. of the EC molecular subtypes, TP53 wild type (wt) tumors represent 50% of advanced and recurrent tumors.

Methods XPORT-EC-042 (NCT05611931) is a phase 3 randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of selinexor as maintenance therapy in patients with TP53wt primary stage IV or recurrent EC, who achieved a partial or complete response per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 after completing at least 12 weeks of platinum combination chemotherapy±immunotherapy. Among other inclusion/exclusion criteria, eligible patients must be ≥18 years of age, have histologically confirmed EC, and TP53wt tumor confirmed by NGS sequencing. Patients will be randomized 1:1 with selinexor 60 mg or placebo once-weekly in 28-day cycles until progressive disease, toxicity, or 3-years if in complete response. A total of 220 patients are estimated to be enrolled globally. The primary endpoint is PFS based on RECIST v1.1 criteria as assessed by the Investigator. The key secondary endpoint is overall survival. Select secondary endpoints include safety assessments and PFS assessed by a blinded independent central review.

Current Trial Status Patient enrollment is ongoing.

AS11. Ovarian cancer

TP011/#1536

A DOUBLE-BLIND PLACEBO-CONTROLLED PHASE III CHEMO-IMMUNOTHERAPY (PACLITAXEL-CARBOPLATIN-OREGOVOMAB [PCO]) VS CHEMOTHERAPY (PACLITAXEL-CARBOPLATIN-PLACEBO [PCP]) IN PATIENTS WITH NEWLY DIAGNOSED, ADVANCED EPITHELIAL OVARIAN CANCER (EOC): FLORA-5/GOG-3035 STUDY

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Introduction Oregovomab, a murine IgGκ1 MAb, binds to the circulating tumor associated antigen CA125, resulting in development of immunogenic complexes with CA125, which are subsequently processed by dendritic cells and macrophages leading to downstream CA125-specific antitumor activity by T and B lymphocytes. In a randomized Phase 2 study in previously untreated EOC patients, immunization with oregovomab with paclitaxel and carboplatin (PC) demonstrated significant improvement in mPFS (months) 41.8 for PCO and 12.2 for PC (p = 0.0027, HR 0.46) and mOS has not yet been

reached (NE) for PCO and was 43.2 months for PC (p = 0.043, HR 0.35).

Methods This Phase 3, double-blind, placebo-controlled, multicenter trial, has enrolled patients from 14 countries. Patients with optimally debulked with FIGO III/IV EOC and serum CA125 $\geq$ 50 U/ml receiving adjuvant (Cohort 1) or neoadjuvant (Cohort 2) chemotherapy were randomized post-surgery to PCO or PCP. Patients with germline BRCA1/2 mutations were excluded. Chemotherapy will be administered every 3 weeks in both cohorts. In cohort 1, oregovomab/placebo is administered simultaneously at cycles 1, 3, and 5 of chemotherapy with an additional dose at 12 weeks following cycle 5. In cohort 2, oregovomab/placebo is administered post interval debulking surgery at cycles 4 and 6 with an additional dose at 6- and 18-weeks following cycle 6. The primary objective is PFS determined by RECIST 1.1 criteria.

Current Trial Status At the time of abstract submission, 618 patients were enrolled and target enrolment Cohort 1 (378) and Cohort 2 (240) was achieved.

TP012/#1530 PHASE 2, SINGLE ARM CLINICAL TRIAL TO EVALUATE THE SAFETY AND ACTIVITY OF OREGOVOMAB AND NIRAPARIB IN SUBJECTS WITH PLATINUM SENSITIVE RECURRENT OVARIAN CANCER: FLORA-4

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Introduction Oregovomab, a murine IgGκ1 MAb, with high affinity binding (1.16 x $10^{10}/M^{-1}$) to the tumor associated antigen CA125, acts as a therapeutic vaccine inducing indirect immunization by cellular and humoral immune responses directed against CA125. In a randomized phase II study in patients with previously untreated EOC, immunization with oregovomab in a schedule-dependent combination with paclitaxel and carboplatin (PC) demonstrated significant improvement in mPFS (months) 41.8 for PCO and 12.2 for PC (p = 0.0027, HR 0.46) and mOS has not yet been reached (NE) for PCO and was 43.2 months for PC (p = 0.043, HR 0.35).

Methods This is a single arm Phase 2 evaluation of the combination of oregovomab and niraparib in subjects who have been previously treated with 1 to 3 lines of platinum-based chemotherapy and have platinum sensitive EOC. All subjects will receive the combination of niraparib and oregovomab. The daily dose of niraparib will be 300 mg taken orally from Day 1 Week 1 to at least the end of Week 12. For subjects whose baseline weight is <77 kg or baseline platelet count is <150,000 μL the daily dose of niraparib will be 200 mg. Oregovomab (2 mg) will be administered at Day 1 of Weeks 1, 4, 7, 12, and 20. This study will assess DCR, ORR, early humoral response, and safety of concomitant administration of oregovomab and niraparib.

Current Trial Status At the time of abstract submission, 10 subjects were enrolled, and the target enrollment was completed.

TP015/#1539 A DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE II CHEMOIMMUNOTHERAPY (PACLITAXEL-CARBOPLATIN-OREGOVOMAB) VS CHEMOTHERAPY (PACLITAXEL-CARBOPLATIN-PLACEBO) AS NEOADJUVANT THERAPY IN PATIENTS WITH ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PERITONEAL CARCINOMA

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Introduction Oregovomab, a murine IgGκ monoclonal antibody binds to tumor-associated antigen, CA125, rendering target antigen CA125 more immunogenic through enhanced antigen processing and presentation to specific T cells, bypassing tumor-associated suppression and resulting in enhanced efficacy of chemotherapy. In a randomized phase II study, oregovomab (O) in combination with paclitaxel and carboplatin (PC) demonstrated significant improvement in mPFS (months) 41.8 PCO vs 12.3 PC, HR=0.46, p=0.0027 and OS median N.E. PCO vs 43.2 PC, HR=0.35, p=0.043.

Methods This is a phase 2, double-blind, placebo-controlled, multi centered clinical trial. Patients with FIGO III/IV EOC and serum CA125 $\geq$ 50 U/ml receiving neoadjuvant chemotherapy will be randomized. In each arm patients will receive oregovomab/placebo at cycles 1 and 3 in combination with chemotherapy prior to interval debulking surgery, followed by oregovomab/placebo at cycles 4 and 6 in combination with chemotherapy, and oregovomab/placebo monotherapy at cycle 6 plus12 weeks. The objective of this study is to confirm that the presence of primary tumor and its immune suppressive biology does not interfere with chemoimmunotherapy when oregovomab is administered with initiation (Cycle 1) of chemotherapy did not delay timing of cytoreductive surgery. The primary objective of the study is to evaluate the PFS Rate at 12 months. Secondary objectives include investigator assessed ORR and DCR by RECIST v1.1, PFS, OS, Response to surgery, safety and tolerability.

Current Trial Status Of the 88 patients enrolment target of the study, 31 patients have been enrolled from 14 centers at the time of submission.