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-Sirolioms is a nano-particle injectable form of mTORi approved for malignant perivascular epithelioid cell tumor. Preclinical data with nab-sirolioms demonstrated improved tumor accumulation, mTOR inhibition, and tumor growth suppression compared with conventional mTORi. We hypothesize that nab-sirolioms 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-sirolioms (100 mg/m², 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, EOCG 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.

AS11. Ovarian cancer

Introduction Oregovomab, a murine IgGx1 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 ≥ 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 6-18 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 enrollment Cohort 1 (378) and Cohort 2 (240) was achieved.

TP015/#1539

A DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE II CHEMIIMMUNOTHERAPY (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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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 IgGk monoclonal antibody binds to tumor-associated antigen, CA125, rendering tumor antigen immunogenic through 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 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 center clinical trial. Patients with FIGO III/IV EOC and serum CA125 ≥ 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 enrollment target of the study, 31 patients have been enrolled from 14 centers at the time of submission.