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

Methods This Phase 2, 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- 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.

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

Methods This is a phase 2, double-blind, placebo-controlled, multi centered clinical trial. Patients with FIGO III/IV EOC and serum CA125 ≥ 50 U/ml receiving neoadjuvant chemotherapy did not delay timing of cytoreductive surgery. The chemotherapy will be randomized. In each arm patients will receive oregovomab/placebo at cycles 1 and 3 in combination with platinum sensitive chemotherapy and serum CA125. 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 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

TP012/#1530

Introduction Oregovomab, a murine IgGκ monoclonal antibody binds to tumor-associated antigen, CA125, rendering the 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 ≥ 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 chemoinmunotherapy 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.