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

[1]Linda Duska, [2]Debra Richardson, [3]Srinivasa Rao Jada, [3]Sunil Gupta, [3]Tl Raj Teja, [4]Angeles Alvarez Secord*. *[1]University of Virginia, -, Charlottesville, USA; [2]Stephenson Cancer Center, University of Oklahoma Health Sciences Center, Department of Oncology, Oklahoma City, USA; [3]CanariaBio Inc, Clinical Development, Seoul, Korea, Republic of; [4]Duke University, Gynecologic Oncology, Durham, USA*

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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

[1]Niraj Bhatt, [2]Rajesh Korant, [3]Mahesh Kalloli, [4]Anita Ramesh, [5]Vijay Kumar, [6]TS Ganesan, [7]B Ravishankar, [8]K Pavithran, [9]Shilpa Kandipalli, [10]Evelyn (Ye Ran) Yoon, [10]Ben (Byung Hak) Yoon, [10]Tl Raj Teja, [10]Sunil Gupta, [10]Srinivasa Rao Jada*. *[1]Kailash cancer Hospital and Research Centre, Medical Oncology, Vadodara, India; [2]Himalaya Cancer Hospital and Research Institute, Radiation Oncology, Vadodara, India; [3]KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Surgical Oncology, Belagavi, India; [4]Saveetha Medical College and Hospital, Medical Oncology, Chennai, India; [5]King Georges Medical University, Surgical Oncology, Lucknow, India; [6]Sri Ramchandra Medical Centre, Medical Oncology, Chennai, India; [7]Omega Hospitals, Medical Oncology, Visakhapatnam, India; [8]Amrita Institute of Medical Sciences, Medical Oncology, Kochi, India; [9]King George Hospital, Medical Oncology, Visakhapatnam, India; [10]CanariaBio Inc, Clinical Development, Seoul, Korea, Republic of*

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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.