with documented platinum allergy require only one prior line of platinum. PICCOLO will enroll 75 patients who will receive intravenous mirvetuximab soravtansine at a dose of 6 mg/kg, calculated using adjusted ideal body weight, on Day 1 of a 21-day cycle. The primary efficacy endpoint is objective response rate (ORR; by investigator) and secondary endpoints include duration of response, progression-free survival, overall survival, CA-125 response, safety and tolerability. PICCOLO is a global study that opened for enrollment in August 2021.

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.

**TP021/#1521**

**FLORA-5/GOG3035: CHEMO-IMMUNOTHERAPY (PACLITAXEL AND CARBOPLATIN ± OREGOVOMAB) AS FRONT-LINE TREATMENT FOR PATIENTS WITH OVARIAN CANCER. A PHASE III DOUBLE BLIND PLACEBO CONTROLLED, GLOBAL MULTICENTER STUDY**


Objective Oregovomab (O), a murine IgG1 monoclonal antibody binds to tumor-associated antigen, CA125, rendering target 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 in combination with paclitaxel and carboplatin (PC) demonstrated significant improvement in PFS (median 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. FLORA-5/GOG-3035 is the confirmatory global registration trial.

Methods Optimally debulked patients with FIGO III/IV epithelial ovarian cancer and serum CA125 > 50 U/ml randomized to PC ± oregovomab. Patients with BRCA1/2 mutations are excluded. Chemotherapy will be administered every 3 weeks in two cohorts. In Cohort 1 (adjuvant), oregovomab/placebo is administered at cycles 1, 3, and 5 of chemotherapy and at 12 weeks following cycle 5. In Cohort 2 (neoadjuvant), oregovomab/placebo will be administered at cycles 4 and 6 of chemotherapy, and at 6- and 18-weeks following cycle 6. No other post front-line maintenance therapy is permitted. The primary objective is PFS by RECIST 1.1 criteria. Cohort 1 will recruit 372 patients and Cohort 2 will recruit 230 patients. Secondary objectives include OS, frequency and severity of adverse events, and quality of life. 137 sites in US, Canada Asia, Europe and South American are actively enrolling. 324 patients have been randomized.

**Objectives**

Hyperthermic intraperitoneal chemotherapy (HIPEC) improves survival in women with stage III ovarian cancer when added to interval cytoreductive surgery (CRS). Two established strategies for dosing of cisplatin for HIPEC exist, which follow either a body surface area (BSA)-based or concentration-based approach. Systemic administration of oncology drugs traditionally uses BSA to minimize inter-patient variability in drug exposure. With intraperitoneal administration, however, a BSA-based approach may actually increase inter-patient variability in drug concentration due to the weak correlation between BSA and intra-abdominal volume. Concentration-based dosing might lead to more standardized drug exposure leading to higher intratumoral platinum concentrations and improved efficacy. Therefore, this study aims to compare both strategies, focusing on pharmacological differences and treatment-related toxicity.

**Methods**

This single-center, phase II, randomized trial will enroll 40 patients with FIGO stage III high grade serous ovarian cancer, treated with optimal or complete interval CRS and serum CA125 > 50 U/ml randomized to PC ± oregovomab. Patients with BRCA1/2 mutations are excluded. Chemotherapy will be administered every 3 weeks in two cohorts. In Cohort 1 (adjuvant), oregovomab/placebo is administered at cycles 1, 3, and 5 of chemotherapy and at 12 weeks following cycle 5. In Cohort 2 (neoadjuvant), oregovomab/placebo will be administered at cycles 4 and 6 of chemotherapy, and at 6- and 18-weeks following cycle 6. No other post front-line maintenance therapy is permitted. The primary objective is PFS by RECIST 1.1 criteria. Cohort 1 will recruit 372 patients and Cohort 2 will recruit 230 patients. Secondary objectives include OS, frequency and severity of adverse events, and quality of life. 137 sites in US, Canada Asia, Europe and South American are actively enrolling. 324 patients have been randomized.

**TP020/#162**

**BODY SURFACE AREA-BASED VS CONCENTRATION-BASED DOSING OF CISPLATIN FOR HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY (HIPEC) IN WOMEN WITH ADVANCED OVARIAN CANCER**

1. Willemien Van Driel, 2. Lot Aronson*, 3. Alicia Léon-Castillo, 4. Karolina Sikorska, 5. Alwin Huitema, 6. Gabe Sonke, 7. Leeuwenhoek, Department of Biometrics, Amsterdam, Netherlands; 8. Netherlands Cancer Institute – Antoni van Leeuwenhoek, Department of Gynecologic Oncology, Amsterdam, Netherlands; 9. Netherlands Cancer Institute – Antoni van Leeuwenhoek, Department of Biometrics, Amsterdam, Netherlands; 10. Netherlands Cancer Institute – Antoni van Leeuwenhoek, Department of Pathology, Amsterdam, Netherlands; 11. Netherlands Cancer Institute – Antoni van Leeuwenhoek, Department of Gynecologic Oncology, Amsterdam, Netherlands; 12. Netherlands Cancer Institute – Antoni van Leeuwenhoek, Department of Pharmacy and Pharmacology, Amsterdam, Netherlands; 13. The Netherlands Cancer Institute – Antoni van Leeuwenhoek, Department of Medical Oncology, Amsterdam, Netherlands

**Methods**

This single-center, phase II, randomized trial will enroll 40 patients with FIGO stage III high grade serous ovarian cancer, treated with optimal or complete interval CRS and eligible for HIPEC. Patients are randomized to receive either BSA-based (cisplatin 100 mg/m²) or concentration-based (cisplatin 40 mg/L) HIPEC. Biopsies of tumor and normal tissue will be collected before, during, and after HIPEC. Also, perfusate samples are taken during perfusion. Primary endpoint is intratumoral platinum concentration at the end of HIPEC using inductively coupled plasma-mass spectrometry (ICP-MS). Secondary endpoints are pharmacokinetic parameters (Cmax, tmax, t½, AUC, clearance from perfusate), platinum concentration in normal tissue, 30-day toxicity (CTCAE 5.0), and overall survival. A modified intention-to-treat will be used for primary analysis. The trial started in July 2022 and primary analyses are anticipated in 2024.

**Results**

Trial in progress

**Conclusions**

Trial in progress
TP022/#1424 A PHASE I/II STUDY EVALUATING INTRAPERITONEAL GEN-1 IN COMBINATION WITH NEOADJUVANT CHEMOTHERAPY IN PATIENTS NEWLY DIAGNOSED WITH ADVANCED EPITHELIAL OVARIAN CANCER

1Premen Thaker, 2Debra Richardson, 3William Bradley, 4Lindsay Kuroki, 5Robert Holloway, 6Stephen DePascuale, 7Mark Reed, 8Amy Brezgar, 9Jennifer Scalici, 10Melanie Bergman, 11Charles Leah II, 12Maria Bell, 13Christopher Darus, 14Karen Finkelstein, 15Bhavana Poturi, 16David Wanshal, 17Nicholas Borns. 1Washington University School of Medicine, Department of Gynecologic Oncology, St Louis, USA; 2Stephenson Cancer Center/ Sarah Cannon Research Institute, University of Oklahoma Health Sciences Center, Gynecologic Oncology, Oklahoma City, USA; 3Medical College of Wisconsin, Cancer Center – Froedtert Hospital, Milwaukee, USA; 4AdventHealth Orlando, Gynecologic Oncology, Orlando, USA; 5Erlanger Womens Oncology, Gynecologic Oncology, Chattanooga, USA; 6West Cancer Center and Research Institute, Oncology, Germantown, USA; 7Massachusetts General Cancer Center, Gynecologic Oncology, Boston, USA; 8University of South Alabama Mitchell Cancer Institute, Gynecologic Oncology, Mobile, USA; 9Providence Sacred Heart, Providence Medical Research Center, Spokane, USA; 10The University of Alabama, Gynecologic Oncology, Birmingham, USA; 11Sanford Cancer Center, Gynecologic Oncology, Sioux Falls, USA; 12Providence Cancer Institute, Gynecologic Oncology, Portland, USA; 13Southwest Women’s Oncology, Gynecologic Oncology, Albuquerque, USA; 14NYU Langone Health, Department of Obstetrics and Gynecology, New York, USA; 15Cooper Health MD Anderson, Gynecologic Oncology, Camden, USA; 16Celgene Corporation, Clinical Development, Lawrenceville, USA

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Objectives GEN-1, an IL-12 DNA plasmid formulated with a synthetic carrier is being evaluated with neoadjuvant platinum-taxane chemotherapy (NACT) in patients with advanced epithelial ovarian cancer. OVATION 2 is a multi-center, randomized, open-label phase I/II study evaluating the safety, anti-tumor activity, and immunological response to GEN-1 at a dose of 100 mg/m2 intraperitoneal (IP) actively enrolling at 20 centers in USA and Canada.

Methods Up to 130 patients will be randomized 1:1 to receive either NACT plus GEN-1 or NACT alone. The phase 1 portion will evaluate safety in at least 6 patients administered in 8 weekly infusions starting at cycle 1 week 2 in combination with three 21-day cycles of carboplatin AUC 6 with paclitaxel 175 mg/m2 (PC). Following interval cytoreductive surgery an additional 9 weekly GEN-1 IP infusions starting at cycle 4 week 1 with three 21-day cycles of PC. If no dose limiting toxicities are found, then the study will continue into the phase II portion. To evaluate biological activity a subgroup of patients will have tumor tissue at initial biopsy/laparoscopy collected and at interval cytoreductive surgery. Tissue will be analyzed for the density of CD8, FoxP3, IDO-1, PD-1, and PDL-1 cells. Blood, peritoneal fluid/wash will be collected before and after treatment in a subgroup of patients to quantify for levels of IFN-g. The primary endpoint is PFS.

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.

TP023/#1560 A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO/PACLITAXEL-CONTROLLED STUDY OF BATIRAXCEPT IN COMBINATION WITH WEEKLY PACLITAXEL IN PATIENTS WITH PLATINUM-RESISTANT RECURRENT OVARIAN CANCER (GOG-3059/ENGOT OV-66)

1Katherine Fuh*, 2Kathleen Moore, 3Thais Baert, 4Thomas Herzog, 5David Cibula, 6Joyce Liu, 7Laurianne Ebert, 8Sharon Levin, 9Aneilese Alvarez Secord, 10Jalid Sehouli, 11Tashanna Myers, 12Aristotelis Bamias, 13BJ Rimel, 14Nicoletta Colombo, 15Amy Franke, 16Dipti Shipp, 17Ugo De Giorgi, 18Joanna Pikel, 19Rebecca Bowen, 20Antonio Gonzalez-Martín, 21University of California, San Francisco, Ob/Gyn, San Francisco, USA; 22Stephenson Cancer Center, Division of Obstetrics and Gynecology, Department of Gynecologic Oncology, University of Oklahoma Health Science Center, Oklahoma City, USA; 23UO Leuven, Ob/Gyn, Leuven, Belgium; 24University of Cincinnati Cancer Center, Obstetrics and Gynecology, Cincinnati, USA; 25First Faculty of Medicine, Charles University and General University Hospital, Department of Obstetrics and Gynecology, Prague, Czech Republic; 26Dana Farber Cancer Institute, Department of Medicine, Boston, USA; 27Insitut de cancerologia Strasbourg Europe, Oncology, Lyon, France; 28HolyName Patricia Lynch Cancer Center, Gynecologic Oncology, Teaneck, USA; 29Duke, Ob/Gyn, Durham, USA; 30Charité-Universitätsmedizin Berlin, Department of Gynecology With Center For Oncological Surgery, Campus Virchow Klinikum, Berlin, Germany; 31Baystate Medical Center, Obstetrics and Gynecology-Division Gynecologic Oncology, Springfield, USA; 32Atuzik General University Hospital of Athens, Oncology, Athens, Greece; 33Cedar-Sinai Medical Center, Gynecologic Oncology, Los Angeles, USA; 34University of Milan-Bicocca, European Institute of Oncology IRCCS, Gynecologic Oncology Department, Milan, Italy; 35Ariava, Oncology, Houston, USA; 36Ariava, Biologics, Houston, USA; 37Istituto Romagnolo per lo Studio dei Tumori (IRST) Dino Amadori, Uro-gynecology, Meldola, Italy; 38Regional Center of Oncology, Department of Gynecology, Gdansk, Poland; 39Royal United Hospital Bath, Oncology, Bath, UK; 40Clinica Universidad de Navarra, Medical Oncology, Madrid, Spain

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Objectives Introduction: The AXL receptor and its sole activating ligand, GAS6, are important drivers of metastasis and therapeutic resistance in human cancers. This signaling axis represents an attractive target for therapeutic intervention. The strong picomolar binding affinity between endogenous GAS6 and AXL and the promiscuity of small molecule AXL inhibitors have presented a barrier to specific and potent inhibition of AXL. Batiraxcept (AVB-S650) is a recombinant fusion protein with ~200-fold higher affinity for GAS6 than wild-type (WT) AXL. Batiraxcept binds GAS6, inhibiting its interaction with AXL thereby dramatically reducing AXL signaled invasion and migration of highly metastatic cells in vitro and inhibiting metastatic disease in nonclinical models of aggressive human cancers. The Phase 1b study showed no DLTs and established a RP2D of 15 mg/kg IV every 2 weeks with PAC/PLD. Longer PFS and OS times were observed in patients who had not been previously treated with bevacizumab (bev-naïve).

Methods High-grade serous PROC, who received 1–4 prior lines randomized (1:1) batiraxcept/PAC or placebo/PAC; stratified by last platinum regimen, prior lines, and prior bevacizu-mab. The primary endpoint is PFS by RECIST v1.1 assessed by the investigator with OS a secondary endpoint. The primary PFS analysis will be triggered when 130 PFS events occur in the bev-naïve; with an interim analysis of OS.