with documented platinum allergy require only one prior line of platinum. PICCOLO will enroll 75 patients who will receive intravenous nirvutiximab soravansine 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.

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 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

Objectives Oregovomab (O), a murine IgG 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 America are actively enrolling. 324 patients have been randomized.