Objectives Albumin-bound (nab)-sirolimus, a novel mechanistic target of rapamycin inhibitor (mTORi) that utilizes nanoparticle technology to preferentially target tumors, is approved in the US for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa). In an exploratory analysis of the registrational trial of nab-sirolimus in advanced malignant PEComa (PMID: 34637337), 8/9 (89%) and 1/5 (20%) patients with TSC1 and TSC2 inactivating alterations, respectively, had confirmed response.

Methods PRECISION I (NCT05103358) is a phase 2, open-label, multi-institutional basket trial evaluating efficacy and safety of nab-sirolimus in patients with alterations in TSC1 (Arm A) and TSC2 (Arm B) (figure 1).

Patients ≥12 years old with malignant solid tumors harboring pathogenic inactivating alterations in TSC1 or TSC2 (confirmed by central review of next generation sequencing reports) who have progressed on standard therapies and are mTORi-naïve will be eligible. nab-Sirolimus will be administered IV at 100 mg/m² weekly on Days 1 and 8 of each 21-day cycle. The primary endpoint is overall response rate determined by independent review using RECIST v1.1; other endpoints are shown in figure 1. Enrollment is ongoing. The most frequent tumor types expected in this tissue-agnostic trial are lung, bladder, soft tissue sarcomas, uterine, colon, kidney, melanoma, liver, and esophageal, based on prevalence of TSC1 or TSC2 alterations (table 1).

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available results at the time of submission.

Objectives Elevated FRα expression is a characteristic of epithelial ovarian cancer (EOC), thereby an attractive candidate for targeted therapeutic approaches. Mirvetuximab soravtansine is an antibody-drug conjugate (ADC) comprising a FRα-binding antibody, cleavable linker, and maytansinoid DM4, a potent tubulin-targeting agent that has consistently shown clinically meaningful single agent activity, along with favorable tolerability, in patients with high FRα expressing tumors.

Methods PICCOLO is a single arm, phase 2 study designed to evaluate the efficacy of mirvetuximab soravtansine in patients with recurrent platinum-sensitive high-grade epithelial ovarian cancers with high FOLATE-ALPHA EXPRESSION.
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.

**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

**Abstracts**

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

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