Recruitment began April 2021; 252 of ~350 patients have been randomized globally (132 sites) (NCT04729608).

**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

**Objective**

**TP024/#446** UPGRADE: PHASE 1 COMBINATION TRIAL OF THE NAPI2B-DIRECTED ANTIBODY DRUG CONJUGATE (ADC) UPITITAMAB RILSODOTIN (UPRI; XMT-1536) IN PATIENTS WITH OVARIAN CANCER

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**Objectives**

UpRi is a first-in-class NaPi2b ADC with a novel scaffold-linker-payload that enables high drug-to-antibody ratio and controlled bystander effect. NaPi2b is a sodium-dependent phosphate transporter protein broadly expressed in high-grade serous ovarian cancer (HGSOC), with limited expression in healthy tissues. Interim data from the Phase 1b study of heavily pretreated HGSOC patients reported clinical activity, notably in patients with NaPi2b-high tumors (TPS ≥75). Based on the emerging single-agent safety and efficacy data, we hypothesize that UpRi in combination with other therapies may provide additional clinical benefit, offer improved tolerability over current approaches, and may provide patients with an option for earlier lines of treatment. UPGRADE was designed as a Ph1 dose escalation (DES) and expansion (EXP) umbrella study to evaluate UpRi combinations in recurrent OC. UPGRADE-A is the first cohort evaluating UpRi in combination with carboplatin in patients with PSO who have received 1–2 prior lines of therapy.

**Methods**

UPGRADE-A is enrolling patients with recurrent PSO. The trial consists of a DES and EXP portion. Participants will be treated with the carboplatin combination IV every 28 days for 6 cycles, followed by UpRi monotherapy until disease progression. 18 patients will be enrolled in the DES; the primary endpoint is to identify the MTD and to assess the feasibility of the combination. 30 patients will be enrolled in the expansion portion. Secondary endpoints include safety, pharmacokinetics, and preliminary activity. Patients are not selected by NaPi2b status, but baseline tumor samples (fresh or archived) are collected for central lab analysis. NCT04907968

**Results**

Trial in progress

**Conclusions**

Trial in progress

**ARTISTRY-7: PHASE 3 MULTICENTER STUDY OF NEMVALEUKIN ALFA PLUS PembroliZumab Versus Chemotherapy in Patients With Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer**

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**Objectives**

ARTISTRY-7 is evaluating the novel engineered cytokine nemvaleukin alfa (nemvaleukin, ALKS 4230) in patients with gynecological cancers. Nemvaleukin was designed to selectively bind to the intermediate-affinity interleukin-2 receptor, preferentially activating antitumor CD8+ T and NK cells, with minimal regulatory T cell expansion. This selectivity may provide enhanced tumor killing and improved safety/tolerability versus high-dose interleukin-2. In ARTISTRY-1, 4 responses (2 complete, 2 partial) were observed with nemvaleukin+pembrolizumab in patients with platinum-resistant ovarian cancer.

**Methods**

ARTISTRY-7 (NCT05092360) is a currently enrolling phase 3, multicenter, randomized study of nemvaleukin and/or pembrolizumab versus chemotherapy. Eligible patients have histologically confirmed epithelial ovarian (high-grade serous, endometrioid, clear cell), fallopian tube, or primary peritoneal cancer. Patients must have had ≥1 prior line of systemic therapy (platinum-sensitive setting), ≤5 prior lines (platinum-resistant setting), and prior bevacizumab, with radiographic progression on most recent therapy. Patients with primary platinum-refractory disease (progression on first-line platinum therapy) or primary platinum resistance (progression <3 months after first-line platinum therapy completion) are excluded. Approximately 376 patients are being randomized (3:1:1:3) to receive nemvaleukin 6 μg/kg intravenously (days 1–5) + pembrolizumab 200 mg intravenously (day 1) in 21-day cycles, pembrolizumab or nemvaleukin monotherapy, or chemotherapy. Primary endpoint is investigator-assessed progression-free survival (RECIST v1.1) in nemvaleukin+pembrolizumab versus chemotherapy arms. Secondary/exploratory endpoints include overall survival, other antitumor measures, safety, health-related quality of life, and pharmacokinetic/pharmacodynamic effects.

**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

**Abstracts**