Poster Number 14 | UPLIFT (ENGOT-ov67/GOG-3048) A Pivotal Cohort of Upifitamab Rilsodotin (XMT-1536; UpRi), a NaPi2b-directed Antibody Drug Conjugate (ADC) in Platinum-Resistant Ovarian Cancer

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Topic: Ovarian

Objectives

Upifitamab rilsodotin (UpRi), is a first-in-class antibody drug conjugate targeting NaPi2b, a sodium-dependent phosphate transporter protein broadly expressed in solid tumors including high-grade serous epithelial ovarian, fallopian tube and primary peritoneal cancers (OC), and limited expression in healthy tissues. Preliminary antitumor activity from the Phase 1b expansion cohort of heavily pretreated patients with OC has been reported (Richardson et al., SGO 2022). Data through June 2021 demonstrated clinically meaningful activity in patients with recurrent ovarian cancer, with notable activity in patients with NaPi2b-high tumors (TPS≥75) treated at the optimized dose of 36 mg/m2. Effective and well-tolerated treatments for platinum-resistant ovarian cancer (PROC) remain a substantial unmet medical need. Single agent chemotherapy, which is the standard of care, has limited efficacy (response rate ≤12%) and short duration of response. Based on the encouraging anti-tumor activity of UpRi, UPLIFT was designed to be a single-arm Phase 2 registrational trial for UpRi in PROC.

Methods

The UPLIFT cohort is enrolling patients with platinum-resistant high grade serous ovarian, fallopian tube and primary peritoneal cancer with up to 4 prior lines of therapy. Prior bevacizumab is required for patients with 1 or 2 prior lines of therapy but is not required for patients with 3-4 prior lines of therapy. Patients may enroll regardless of NaPi2b expression; â‰¤ Grade 2 peripheral neuropathy is permitted. Primary platinum refractory patients are excluded. UPLIFT will enroll approximately 180 patients globally, including approximately 100 patients with high NaPi2b expression. UpRi will be dosed intravenously at 36 mg/m2 up to a maximum dose of ~80 mg every 4 weeks. Baseline tumor samples (fresh or archived) will be collected for central analysis of NaPi2b expression. The primary endpoint is ORR in patients with high NaPi2b expression. The cut-off for high NaPi2b expression is Tumor Proportion Score (TPS) ≥75, which was based on data from the Phase 1 expansion cohort. Secondary endpoints include ORR in the overall population, duration of response, and safety. This study is being conducted in collaboration with ENGOT (ENGOT-ov67) and GOG (GOG-3048). Patients will be enrolled globally. NCT03319628

Results

This is a Trial in Progress; therefore, we do not have results/conclusions at this time.

Conclusions

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