the first-line maintenance setting via Early Access Programmes (Italy, UK), Temporary Use Authorization (France) or reimbursement following regulatory approval (Italy, UK). Main study endpoint is real-world PFS. Secondary endpoints include overall survival and response rates. The study will also describe surrogate measures of response and tolerability, including time to discontinuation, dose modifications (with reasons) and time to first and second subsequent treatment. Outcomes will be described by key subgroup status pre-index, including performance status, FIGO stage, BRCA status, debulking surgery outcome and clinical response to chemotherapy. The study aims to include 350 patients. Retrospective data collection began in December 2020 and is planned to end by Q3 2023. As of April 2021, 69 patients have participated.

**UPLIFT (ENGOT-OV67/GOG-3048) A PIVOTAL COHORT OF UPFITAMAB RILSODOTIN, A NAPI2B-DIRECTED ADC IN PLATINUM-RESISTANT OVARIAN CANCER**

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**Introduction/Background** Upfitamab rilsodotin (XMT-1536; UpRi), is a first-in-class Dolaflexin antibody-drug conjugate targeting NaPi2b, a sodium-dependent phosphate transport protein broadly expressed in solid tumors including high-grade serous epithelial ovarian cancer (OC). UpRi’s safety and efficacy are being evaluated in a Phase I study (NCT03319628). Preliminary antitumor activity from an expansion cohort of heavily-pretreated OC patients has been reported (Hamilton et al, ESMO 2020). A data-cut of December 2020 demonstrated an ORR of 39% including 2 CRs and DCR of 81% in 26 OC patients with high NaPi2b expression (TPS ≥75). The 2 patients achieving CR had previously been treated with bevacizumab and PARPi (Richardson et al, ASCO 2021, TPS5607). The prevalence of a TPS ≥75 is greater than 60%.

PROC remains a serious unmet medical need as available treatment options provide modest benefit of no more than 12% ORR and median OS less than 12 months. Based on encouraging anti-tumor activity of UpRi, UPLIFT was designed as a Phase 2 single-arm registration strategy for PROC as part of the ongoing study.

**Methodology** 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. UPLIFT will enroll approximately 180 patients globally for 100 patients with high NaPi2b expression. UpRi is dosed intravenously at 43 mg/m2 every 4 weeks. Patients may enroll regardless of NaPi2b expression and regardless of baseline peripheral neuropathy. Baseline tumor samples (fresh or archived) will be collected for retrospective tumor tissue evaluation of NaPi2b expression.

**Result** The primary objective is assessment of objective response rate in patients with high NaPi2b expression. The cut-off for high NaPi2b expression is TPS ≥75 and was based on data from the expansion cohort. Secondary endpoints include objective response rate in the overall population, duration of response, and adverse events.

**Conclusion** This study is being conducted in collaboration with ENGOT and GOG. Patients will be enrolled globally. (NCT03319628).