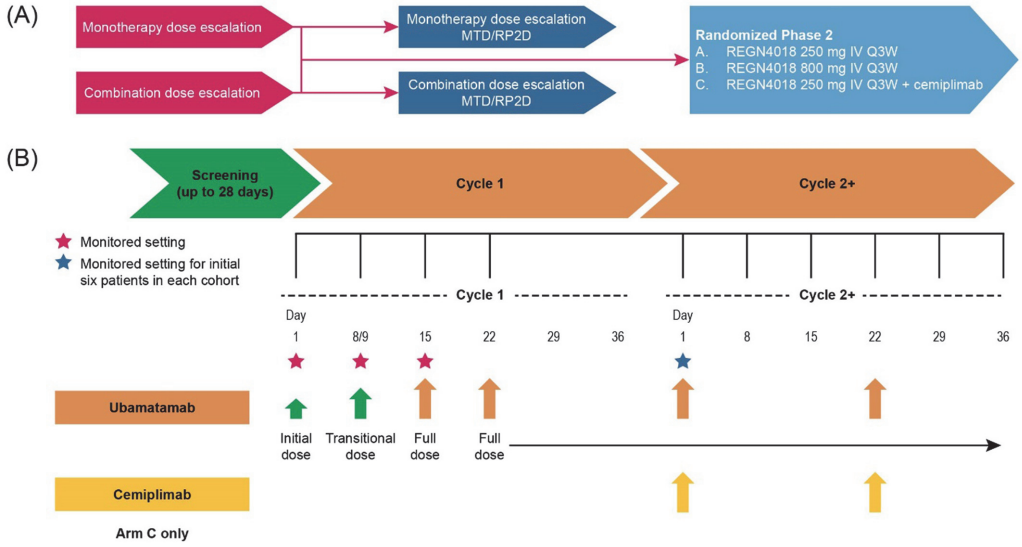

Abstract TP020/#1513 Figure 1 (A) Phase 1 dose escalation and Phase 2 dose expansion including randomized Phase 2 cohort and (B) study schema for randomized Phase 2 cohort

cytokine release syndrome before proceeding to Q3W dosing. Expansion cohorts will use a Simon 2-stage study design, with interim analysis after 20 patients. Any arm with ≥3 objective responses will be expanded to 50 patients. The primary endpoint for each treatment arm is ORR per RECIST 1.1 criteria. Secondary endpoints include DOR, PFS, safety, and pharmacokinetics of ubamatamab with/without cemiplimab. Exploratory endpoints include evaluation of baseline tumor MUC16 expression and other biomarkers as predictors of response. The impact of ubamatamab on QOL and physical functioning will be assessed.

Current Trial Status The study is currently recruiting patients to combination dose escalation, monotherapy dose expansion, and the randomized Phase 2 cohort.

TP021/#1540

REFRAME-O1/ENGOT-OV79/GOG-3086: A PHASE 2/3 OPEN-LABEL STUDY EVALUATING THE EFFICACY AND SAFETY OF LUVELTAMAB TAZEVIBULIN VERSUS INVESTIGATOR'S CHOICE CHEMOTHERAPY IN RELAPSED PLATINUM-RESISTANT EOC EXPRESSING FOLATE RECEPTOR-ALPHA

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Introduction Folate receptor alpha (FolRα) is a validated target in the treatment of platinum resistant ovarian cancer (PROC) expressing high-FolRα. There remains a high unmet need to treat PROC with low to moderate FolRα expression. Luveltamab tazevibulin (luvelta), a novel FolRα-targeting ADC with a hemiasterlin warhead (DAR4), is designed using site-specific conjugation technology to target a broad range of FolRα-expressing cancers. Luvelta demonstrated preliminary efficacy data (ORR of 37.5%; mDOR of 5.5 months; mPFS of 6.1 months) in 32 patients with advanced/relapsed EOC with FolRα expression of >25% (any intensity) in a Ph1 study (NCT03748186). ORR was higher at 5.2 mg/kg (43.8% versus 31.3%, n=32) compared to 4.3 mg/kg. Luvelta showed a manageable safety profile, with the most common grade 3+ adverse events of neutropenia, arthralgia, and anemia. This data forms the basis for a pivotal study of luvelta in patients with PROC with broad FolRα expression levels.

Methods REFRaME-O1/ENGOT-Ov79/GOG-3086 is a 2-part Phase 2/3 study of luvelta in subjects with relapsed PROC expressing FolRα. Part 1 is the dose-optimization stage, with ~50 subjects randomized 1:1 at 4.3 mg/kg Q3W or 5.2 mg/kg Q3W + prophylactic pegfilgrastim for 2 cycles followed by 4.3 mg/kg Q3W. Part 2 will commence with the selected optimized dose versus investigator's choice chemotherapy, with a 2:1 randomization schedule. Key inclusion criteria: progressive PROC, up to 3 prior regimens, TPS of ≥25% for FolRα expression, and measurable disease. Key exclusion criteria: primary platinum refractory disease and prior treatment with a FolRα ADC or ADC-containing tubulin inhibitor.

Current Trial Status Currently enrolling