Abstracts

TP036/#426 UPLIFT (ENGOT-OV67/GOG-3048) A PIVOTAL COHORT OF THE XMT-1536–1 TRIAL OF UPFICITAMAB RILSODOTIN (XMT-1536; UPRI), A NAPI2B-DIRECTED ANTIBODY DRUG CONJUGATE (ADC) IN PLATINUM-RESISTANT OVARIAN CANCER

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Objectives
UpRi is a first-in-class NaPi2b-targeting 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. It’s estimated that about two-thirds of HGSOC patients are NaPi2b-high. Studies are ongoing to evaluate UpRi safety and efficacy in platinum-resistant ovarian cancer (PROC), but there remains an unmet need in the maintenance setting for patients with platinum-sensitive, recurrent ovarian cancer (PSOC), particularly patients who received standard-of-care treatment and are at high-risk of early relapse.

Methods
UpRI is an ADC in collaboration with GOG (GOG-3048) and ENGOT (ENGOT-OV67) for the treatment of platinum-resistant ovarian cancer. The primary endpoint is PFS assessed by investigator. Secondary endpoints include ORR in the overall population, duration of response, and safety. UPLIFT is a Phase 1b expansion cohort trial in collaboration with ENGOT (ENGOT-OV67) and GOG (GOG-3048). NCT03319628

Results
trialinprogress

Conclusions
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TP037/#453 UP-NEXT (GOG-3049/ENGOT-OV71-NSGO-CTU): A STUDY OF UPFICITAMAB RILSODOTIN (UPRI), A NAPI2B-DIRECTED ANTIBODY DRUG CONJUGATE (ADC) IN PLATINUM-SENSITIVE RECURRENT OVARIAN CANCER

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Objectives
UpRI is a first-in-class NaPi2b-targeting 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. It’s estimated that about two-thirds of HGSOC patients are NaPi2b-high. Studies are being conducted to evaluate UpRI safety and efficacy in platinum-resistant ovarian cancer (PROC), but there remains an unmet need in the maintenance setting for patients with platinum-sensitive, recurrent ovarian cancer (PSOC), particularly patients who received standard-of-care treatment and are at high-risk of early relapse.

Methods
Up-NEXT is a Ph3 study evaluating UpRI monotherapy as post-platinum maintenance therapy in recurrent PSOC, enrolling patients with NaPi2b-high tumours (defined as TPS ≥75). Patients must have received 2–4 prior lines of platinum containing chemotherapy, achieved a partial or complete response in their penultimate platinum regimen, and progressed >6mo after completion of the last dose of platinum. Patients may be enrolled if their best response to the last line of treatment is no evidence of disease, complete or partial response, or stable disease. If patients have a known BRCA mutation, prior PARPi treatment is required. Patients who received bevacizumab in combination with their last platinum containing regimen are excluded. Patients are randomized 2:1 to UpRI or placebo, given IV Q4W. The primary endpoint is PFS assessed by BICR, with key secondary endpoint of OS. UP-NEXT is conducted in collaboration with GOG(3049) and ENGOT (Ov71-NSGO-CTU). NCT03329545

Results
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Conclusions
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