Poster 43: UP-NEXT (ENGOT-Ov71-NSGO-CTU/GOG-3049): A Study of Upitifamab Rilsodotin (UpRi), a NaPi2b-directed Antibody Drug Conjugate (ADC) in Platinum-Sensitive Recurrent Ovarian Cancer

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Topic: Ovarian

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 is estimated that the majority of HGSOCs have high NaPi2b expression. Studies are being conducted to evaluate UpRi safety and efficacy in platinum-resistant ovarian cancer (PROC), and data from the Ph1b study has demonstrated activity in PROC, but there remains an unmet need in the maintenance setting for patients with recurrent platinum-sensitive ovarian cancer (PSOC), particularly for patients who have received prior maintenance therapy, are at high-risk of early relapse, and where close monitoring after platinum-based therapy would generally be considered preferable.

Methods

UP-NEXT is a Phase 3 study evaluating UpRi monotherapy as post-platinum maintenance treatment in recurrent PSOC, enrolling patients with NaPi2b-positive tumors (defined as TPS ≥75). Patients must have received 4-8 cycles of platinum-based therapy in the 2nd to-4th line of therapy (not all lines need to be platinum-based). Patients must have progressed >6 months after completion of the last dose of platinum in the penultimate regimen. 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. Secondary debulking surgery is also permitted prior to enrollment. Prior PARPi treatment is required for patients with a BRCA mutation. Patients who received bevacizumab in combination with their most recent platinum containing regimen are excluded. Patients are randomized 2:1 to UpRi 30mg/m2 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) . Approximately 350 patients will be enrolled globally. NCT05329545

Results

N/A

Conclusions

N/A