UP-NEXT (GOG-3049/ENGOT-ov71-NSGO-CTU): A Study of Upifitamab Rilsodotin (UpRi), a NaPi2b-directed Antibody-Drug Conjugate (ADC) in Platinum-Sensitive Recurrent Ovarian Cancer

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BACKGROUND

Unmet Medical Need in Platinum-Sensitive Recurrent High-Grade Serous Ovarian Cancer (HSOC)

- Standard of care for patients with platinum-sensitive recurrent HSOGC consists of platinum-based doublet chemotherapy, with or without bevacizumab, followed by bevacizumab monotherapy or PARPi maintenance1
- Recent changes in the treatment landscape with the use of PARP inhibitors in patients with platinum-sensitive recurrent ovarian cancer, and more recently in frontline setting, have created a new unmet need for patients who exhaust these options earlier in their disease course, either because they take them in combination or sequentially2-4
- In addition, many patients are not appropriate candidates for these agents due to tolerability concerns, particularly in patients with comorbidities
- PARPi maintenance is not indicated for patients who achieve only stable disease after platinum therapy

NaPi2b is a Sodium-Dependent Phosphate Transporter Broadly Expressed in Ovarian Cancer With Limited Expression in Healthy Tissues3

- It is believed that approximately two-thirds of patients with HSOGC have high NaPi2b expression based on an IHC tumor proportion score (TPS) of at least 75%4
- NaPi2b is a lineage antigen and not an oncogene; its expression remains consistent throughout the course of disease3

Upifitamab Rilsodotin (UpRi) – Investigational First-in-Class NaPi2b-targeting ADC With a Novel Scaffold-Linker-Payload4

- Antibody: Humanized monoclonal anti-SLC34A2 (NaPi2b)
- Linker: Fleximer polymer scaffold, cleavable ester linker stable in circulation
- Payload: AF-HPA (Auristatin F-hydroxypropylamide) conjugated with the NaPi2b-dependent Phosphate Transporter Broadly Expressed
- Drug-to-Antibody Ratio (DAR): ~10

METHODS

Study Design and Eligibility

- UP-NEXT is a global Phase 3, double-blind, randomized, placebo-controlled study of UpRi monotherapy maintenance in patients with NaPi2b-positive platinum-sensitive recurrent ovarian cancer

Key Enrollment Criteria

- Patients with platinum-sensitive recurrent HSOGC
- 2–4 prior platinum-containing chemotherapy regimens
- Best response to last line of treatment: MED, CR, PR, or SD
- ECOG PS 0/1
- NaPi2b expression (TPS ≥75%) tumor (archival or fresh biopsy)
- Prior PARPi required for patients with known deleterious BRCA mutations
- Patients who received bevacizumab in combination with their last platinum-containing regimen are excluded

Study Locations

NORTH AMERICA

EUROPE

ASIA PACIFIC

CONCLUSIONS

- Upifitamab rilsodotin (UpRi) is an investigational first-in-class NaPi2b-targeting ADC with a novel scaffold-linker-payload that is designed with high DAR and a controlled bystander effect
- UP-NEXT is a global Phase 3 study of UpRi monotherapy maintenance in patients with NaPi2b-positive platinum-sensitive recurrent ovarian cancer
- Primary endpoint is PFS by BICR. Secondary endpoints include PFS by investigator, ORR by investigator, OS, and safety
- Trial is currently open for enrollment and is being conducted in collaboration with GOG (GOG-3049) and ENGOT (ENGOT-ov71-NSGO-CTU)

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REFERENCES


ADDITIONAL INFORMATION

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For more information on UP-NEXT, visit ClinicalTrials.gov page NCT03329645 or QR code provided or contact medicalinformation@mersana.com