Upifitamab Rilsodotin Maintenance in Platinum-Sensitive Recurrent Ovarian Cancer (UP-NEXT)

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Participant must have a histological diagnosis of high grade serous ovarian cancer, which includes fallopian tube and primary peritoneal cancer, that is metastatic or recurrent. 2. Participant must have platinum-sensitive recurrent disease, defined as having achieved either a partial or complete response to 4 or more cycles in their penultimate platinum- containing regimen and their disease progressing more than 6 months after completion of the last dose of platinum containing therapy in the penultimate regimen. 3. Participant must have had 4 to 8 cycles of platinum-based chemotherapy in 2nd to 4th line setting in their most recent treatment regimen as defined below: 1. Platinum-based chemotherapy regimens allowed immediately preceding enrollment to the study: carboplatin or cisplatin ±: paclitaxel, docetaxel, pegylated liposomal doxorubicin or gemcitabine. 2. Participant must receive first study treatment infusion between 4 and 12 weeks after completing final dose of platinum in the most recent platinum-based regimen. 4. Participant must have had as their best response to last line of treatment one of the following: No Evidence of Disease (NED); Complete Response (CR); Partial Response (PR); OR Stable Disease (SD) 5. Participants with NED, CR, or PR as their best response to most recent line of treatment and who have not received treatment with a prior PARP inhibitor must have definitive BRCA1 and BRCA2 testing results that demonstrate no evidence of a deleterious BRCA1 or BRCA2 mutation. Somatic BRCA mutation testing is required for participants who are classified as not having a deleterious mutation by germline testing alone. 6. Participant must provide either a tumor tissue block or fresh cut slides for measurement of NaPi2b expression by a central laboratory. If sufficient archival tumor tissue is not available, then a tumor tissue block or slides must be obtained from a fresh biopsy and provided to the central laboratory. Confirmation of a NaPi2b-H/positive tumor by the central laboratory is required prior to randomization.

Exclusion Criteria:

1. Participant has received prior treatment with mirvetuximab soravtansine or another ADC containing an auristatin or maytansinoid payload. 2. Participant has received bevacizumab in combination with last platinum-based regiment or plans to receive maintenance therapy outside the study intervention. 3. Participant has clinical signs or symptoms of gastrointestinal obstruction and/or requirement for parenteral hydration or nutrition. 4. Participant has ascites or pleural effusion managed with therapeutic paracentesis or thoracentesis within 28 days prior to signing the principal study consent form. 5. Participant has history of cirrhosis, hepatic fibrosis, esophageal or gastric varices, or other clinically significant liver disease. Testing beyond laboratory studies otherwise defined in the eligibility criteria, to diagnose potentially clinically significant liver disease based on risk factors such as hepatic steatosis or history of excessive alcohol intake, will be based on clinical judgement of the investigator. 6. Participant has history of or suspected pneumonitis or interstitial lung disease. 7. Participant has untreated CNS metastases (including new and progressive brain metastases), history of leptomeningeal metastasis, or carcinomatous meningitis.

Conditions & Interventions

Interventions:
Drug: Upifitimab rilsodotin, Other: Placebo
Conditions:
High Grade Serous Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer
Keywords:
Ovarian Cancer, Serous, Maintenance, Antibody Drug Conjugate, Recurrent, Platinum-Sensitive, ADC, Fallopian Tube Cancer, Primary Peritoneal Cancer

More Information

Contact(s): Rita Lemming - medicalinformation@mersana.com
Principal Investigator:
Phase: Phase 3
IRB
Number:
System ID: NCT05329545
