

# A Study to Assess Adverse Events and Change in Disease Activity of Multiple Treatment Combinations With Intravenous Mirvetuximab Soravtansine in Adult Participants With Ovarian Cancer

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

Substudy 1 \* Participants must be willing to provide an archival tumor tissue block or slides or must undergo a procedure to obtain a new tumor biopsy using a low-risk, medically routine procedure for immunohistochemistry (IHC) confirmation of FR $\alpha$  expression as defined by the central VENTANA FOLR1 (FOLR1-2.1) assay. Tumors must have FR $\alpha$ -expression in  $\geq$  50% of viable tumor cells with  $\geq$  2+ staining intensity. \* Participants must have an Eastern Cooperative Oncology Group performance status of 0 or 1. \* 1L participants must have a confirmed diagnosis of Federation of Gynecology and Obstetrics (FIGO) Stage III or IV high-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancer. 2L participants must have platinum-sensitive high-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancer. Participants must have platinum-sensitive disease defined as radiographic progression greater than 183 days from the last dose of most recent platinum-based chemotherapy. Note: Progression should be calculated from the date of the last administered dose of platinum therapy to the date of the radiographic imaging showing progression. \* Participant has a local homologous recombination deficient (HRD) or breast cancer susceptibility gene (BRCA) test result available. Participants with BRCA wild-type will need to have a local HRD test result available. Substudy 2 \* Participants must be willing to provide an archival tumor tissue block or slides or must undergo a procedure to obtain a new tumor biopsy using a low-risk, medically routine procedure for immunohistochemistry (IHC) confirmation of FR $\alpha$  expression as defined by the central VENTANA FOLR1 (FOLR1-2.1) assay. Tumors must have FR $\alpha$ -expression in  $\geq$  50% of viable tumor cells with  $\geq$  2+ staining intensity. \* Participants must have an Eastern Cooperative Oncology Group performance status of 0 or 1. \* Participants must have a confirmed diagnosis of high-grade serous ovarian, primary peritoneal, or fallopian tube cancer. \* Participants must have relapsed after 1 or 2 prior lines of platinum-based chemotherapy. \* Participants must have platinum-sensitive disease defined as radiographic progression greater than 183 days from the last dose of platinum-based chemotherapy. \* Participants must have measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 (assessed by the investigator) at baseline. Substudy 3 \* Participants must be willing to provide an archival tumor tissue block or slides or must undergo a procedure to obtain a new tumor biopsy using a low-risk, medically routine procedure for immunohistochemistry (IHC) confirmation of FR $\alpha$  expression as defined by the central VENTANA FOLR1 (FOLR1-2.1) assay. Tumors must have FR $\alpha$ -expression in  $\geq$  50% of viable tumor cells with  $\geq$  2+ staining intensity. \* Participants must have an Eastern Cooperative Oncology Group performance status of 0 or 1. \* Participants must have a confirmed diagnosis of high-grade serous ovarian, primary peritoneal, or fallopian tube cancer. \* Participants must have relapsed after 1 or 2 prior lines of platinum-based chemotherapy. \* Participants must have platinum-sensitive disease defined as radiographic progression greater than 183 days from the last dose of platinum-based chemotherapy. \* Participants must have measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 (assessed by the investigator) at baseline.

### Exclusion Criteria:

Substudy 1 \* Participants with progressive disease (PD) while on triplet therapy or after the first day of their last triplet therapy cycle and before randomization. \* Participants who receive an intervening dose of bevacizumab after the first day of their last triplet therapy cycle and before randomization. \* Participants who received prior treatment with mirvetuximab soravtansine (MIRV), any FR $\alpha$ -targeting agent, or Poly(ADP-ribose) polymerase inhibitor (PARPi). Substudy 2 \* More than 2 prior lines of chemotherapy. Lines of prior anticancer therapy are counted with the following considerations: \* Neoadjuvant +/- adjuvant therapies are considered 1 line of therapy if the neoadjuvant and adjuvant correspond to 1 fully predefined regimen; otherwise, they are counted as 2 prior regimens. \* Maintenance therapy (e.g., bevacizumab, PARPi) will be considered part of the preceding line of therapy (i.e., not counted independently). \* If a chemotherapeutic agent in a regimen is substituted with another during a course of treatment due to toxicity, it will be considered part of the same line of therapy \* Prior hormonal therapy will not be counted as a separate line of chemotherapy (it will be counted as part of the prior systemic therapy regimen) \* Participants who received prior treatment with mirvetuximab soravtansine or other FR $\alpha$ -targeting agents. Substudy 3 \* More than 2 prior lines of chemotherapy. Lines of prior anticancer therapy are counted with the following considerations: \* Neoadjuvant +/- adjuvant therapies are considered 1 line of therapy if the neoadjuvant and adjuvant correspond to 1 fully predefined regimen; otherwise, they are counted as 2 prior regimens. \* Maintenance therapy (e.g., bevacizumab, PARPi) will be considered part of the preceding line of therapy (i.e., not counted independently). \* If a chemotherapeutic agent in a regimen is substituted with another during a course of treatment due to toxicity, it will be considered part of the same line of therapy \* Prior hormonal therapy will not be counted as a separate line of chemotherapy (it will be counted as part of the prior systemic therapy regimen) \* Participants who received prior treatment with mirvetuximab soravtansine or other FR $\alpha$ -targeting agents.

## Conditions & Interventions

### Interventions:

DRUG: Mirvetuximab Soravtansine, DRUG: Bevacizumab, DRUG: Carboplatin

### Conditions:

Ovarian Cancer

### Keywords:

Ovarian Cancer, Mirvetuximab Soravtansine, Bevacizumab, Carboplatin

## More Information

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**Number:**

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