**BACKGROUND**

- Despite advances with PARP inhibitors and anti-angiogenic agents in newly diagnosed ovarian cancer, unmet need remains for additional active and well-tolerated therapies in recurrent disease

- Elevated FRA expression is a characteristic of several solid tumors, including epithelial ovarian cancer (EOC), thereby providing an attractive candidate for targeted therapeutic approaches

- Mirvetuximab soravtansine (MIRV) is an antibody-drug conjugate (ADC) comprising a FRα binding antibody, cleavable linker, and the maytansinoid DM4, a potent tubulin-targeting agent that has shown consistent and meaningful single agent clinical activity, along with favorable tolerability, in patients with high FRA expressing ovarian cancer

- Mirvetuximab soravtansine has encouraging activity as a monotherapy in platinum resistant ovarian cancer (PROC) in patients whose tumors express medium and high levels of FRα

**MECHANISM OF ACTION**

1. The fully humanized antibody portion of MIRV binds to FRα receptor found on the surface of epithelial ovarian cancer cells
2. MIRV is internalized via endocytosis
3. MIRV is degraded within the lysosome to release its cytotoxic payload (DM4)
4. DM4, a second-generation maytansin derivative disrupts tubulin resulting in mitotic arrest and apoptosis—100-1000 fold more potent than vinca alkaloids
5. DM4 also diffuses through the cell membrane allowing bystander killing on adjacent tumor cells

**MECHANISM OF ACTION**

1. Monotherapy: 24% to 47% confirmed overall response rate (ORR) in FRα-positive ovarian cancer (EOC), thereby providing an attractive candidate for targeted therapeutic approaches

2. Mirvetuximab soravtansine (MIRV) is an antibody-drug conjugate (ADC) comprising a FRα binding antibody, cleavable linker, and the maytansinoid DM4, a potent tubulin-targeting agent that has shown consistent and meaningful single agent clinical activity, along with favorable tolerability, in patients with high FRA expressing ovarian cancer

3. Mirvetuximab soravtansine has encouraging activity as a monotherapy in platinum resistant ovarian cancer (PROC) in patients whose tumors express medium and high levels of FRα

**REFERENCES**

1. Moore et al ASCO 2017
2. Moore et al ESMO 2019

**STUDY DESIGN**

- Mirvasol is a randomized phase 3 study designed to evaluate the efficacy of MIRV compared with that of standard-of-care chemotherapy in adult patients with platinum-resistant EOC, primary peritoneal cancer, or fallopian tube cancers

- Confirmation of high FRA positivity by immunohistochemistry (high expression; ≥ 75% of cells with PS2+ staining intensity) and ≥ 3 prior lines of therapy

- Mirvasol is designed to randomize 430 patients, 1:1 to Arm 1 (MIRV at a dose of 6 mg/kg, calculated using adjusted ideal body weight, administered IV on Day 1 of a 21-day cycle) or Arm 2 (investigators’ choice chemotherapy (IC Chemo): paclitaxel, pegylated liposomal doxorubicin, or topotecan)

**TRIAL ENDPOINTS**

- Primary Endpoint
  - FFS, defined as the time from date of randomization until investigator-assessed progressive disease (PD) or death, whichever occurs first

- Secondary Objectives
  - To compare the PBR of patients randomized to MIRV vs. IC Chemo
  - To compare overall survival (OS) of patients randomized to MIRV vs. IC Chemo
  - To compare the primary patient-reported outcome (PRO) using the EORTC QLQ-OV28 (abdominal/GI symptom scale) assessment from patients randomized to MIRV vs. IC Chemo

**FUTURE DIRECTIONS FOR RESEARCH**

The trial is open and enrolling at centers in the US and Europe. This study is registered at clinicaltrials.gov: NCT04209855

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