**Forward I: a Phase III study of mirvetuximab soravtansine versus chemotherapy in platinum-resistant ovarian cancer**

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**Primary objective/rationale**

**Primary objective**
Compare PFS in patients randomized to mirvetuximab soravtansine versus IC chemotherapy, as assessed by a blinded independent review committee, in all randomized patients as well as in the high FRα subgroup (≥75% of tumor staining at ≥2+ intensity)

**Secondary objectives**
Compare ORR as assessed by a blinded independent review committee, OS, and primary patient-reported outcome end point in patients randomized to mirvetuximab soravtansine versus IC chemotherapy

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**Study design and treatment including planned sample size, planned study period and study procedures**

Arm 1 receives mirvetuximab soravtansine infusion at 6 mg/kg (AIBW) every 3 weeks.
Arm 2 receives IC chemotherapy: weekly infusion of paclitaxel at 80 mg/m² or PLD infusion at 40 mg/m² every 4 weeks, or topotecan infusion 4 mg/m² in a 4 week cycle or 1.25 mg/m² in a 3 week cycle

Stratified by number of prior lines of therapy (1 or 2 vs 3), FRα levels (high vs medium) and IC chemotherapy (paclitaxel vs PLD vs topotecan). Investigators will specify the chemotherapy of choice before randomization

Treatment is given until disease progression per RECIST v1.1 as assessed by the blinded independent review committee, development of unacceptable toxicity or withdrawal of consent

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**Key eligibility criteria**

**Age**
≥18 years of age

**Histologically confirmed diagnosis of EOC, primary peritoneal cancer or fallopian tube cancer**

**Platinum resistant disease defined as progression within 6 months from completion of a minimum of 4 cycles of platinum-containing therapy. Patient cannot have primary platinum-refractory disease defined as progression during or within 4 weeks of completion of first platinum-based chemotherapy**

**Measureable disease by RECIST v1.1**

**Patients must have received >1 or ≤ 3 prior systemic lines of anti-cancer therapy**

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**Outcome measures/end points**

**Primary end points:**
PFS in:
1. All randomized patients
2. Patients with high FRα levels (≥75% of tumor staining at ≥2+ intensity)

**Secondary end points:**
ORR per RECIST 1.1 criteria as assessed by blinded independent review committee, OS, and primary PRO endpoints

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**Glossary**

AIBW: Adjusted ideal body weight; IC: Investigator’s choice; EOC: Epithelial ovarian cancer; ORR: Objective response rate; OS: Overall survival; PLD: Pegylated liposomal doxorubicin; PFS: Progression-free survival; PRO: Patient-reported outcome; RECIST: Response Evaluation Criteria in Solid Tumors