AGO-OVAR 2.34 / MIROVA: A randomized phase II trial of Mirvetuximab soravtansine (IMGN853) in folate receptor alpha (FRα) high recurrent ovarian cancer eligible for platinum-based chemotherapy

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Background

Despite radical primary surgery and carboplatin/paclitaxel-based chemotherapy in combination with anti-angiogenic bevacizumab and/or PARP inhibitors (PARPi), most patients (pts) with advanced ovarian cancer (OC) will relapse. The antibody-drug conjugate Mirvetuximab soravtansine (MIRV) is comprised of a folate receptor alpha (FRα)-binding antibody, cleavable linker, and the maytansinoid DM4, a potent tubulin-targeting agent. Recent trials revealed that pts with high FRα expression had significant progression-free survival (PFS) improvements and high activity was most recently confirmed in the SORAYA trial with an overall response rate (ORR) of 32.4%.

Preliminary data for the combination of MIRV with carboplatin (Phase 1b FORWARD II trial) showed an ORR of 80% in the FRα medium/high subset of 10 pts.

In-/Exclusion Criteria

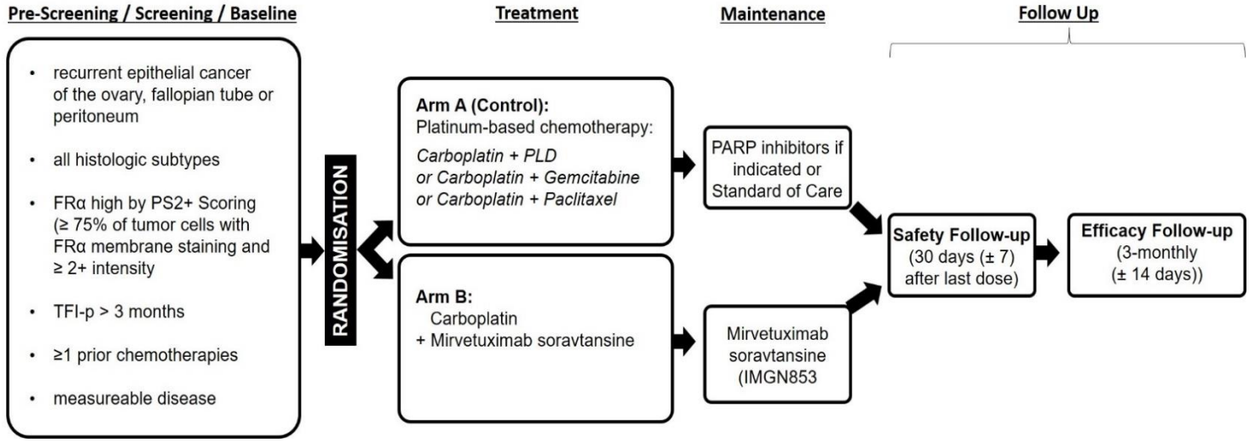
Main Inclusion Criteria

- Patients with relapse of ovarian, fallopian tube, or peritoneal cancer and measurable disease
- Patients with FRα high status by PS2+ scoring (Ventana FOLR1 (FOLR1 2.1) CDx assay)
- Patients with 1 or more prior therapies and platinum-free interval of >3 months.
- Patients with wildtype BRCA1/2 mutation status or a BRCA1/2 mutation if they underwent PARPi therapy previously.

Main Exclusion Criteria

- Patients planned to receive Bevacizumab
- Active or chronic corneal disorders.
- Required use of folate-containing supplements (e.g. folate deficiency)

Study Design



Recruitment Duration: approximately 18 months
Total Study Duration: approximately 5.5 years
Recruitment Start: September 2021

Study Objectives

Objective: Progression free survival (PFS)

Secondary Endpoints:

- OS, ORR
- Efficacy regarding PFS, OS and ORR depending on histologic subtype
- Time to serological PD according to GCIG criteria
- Time to first and second subsequent treatment
- Quality of Life (EORTC C-30, OV28)
- Safety and tolerability

Statistical Analysis

Sample Size	136	Drop-Out Rate	10 %
Randomization	1:1	Events	95
alpha	0.10 for PFS	Duration	18 months accrual
Hazard Ratio	0.60 for PFS	Follow-Up	12 months after inclusion of last pt

Contact Information

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