Maintenance with Mirvetuximab Soravtansine plus Bevacizumab vs Bevacizumab in FRα-High Platinum-Sensitive Ovarian Cancer

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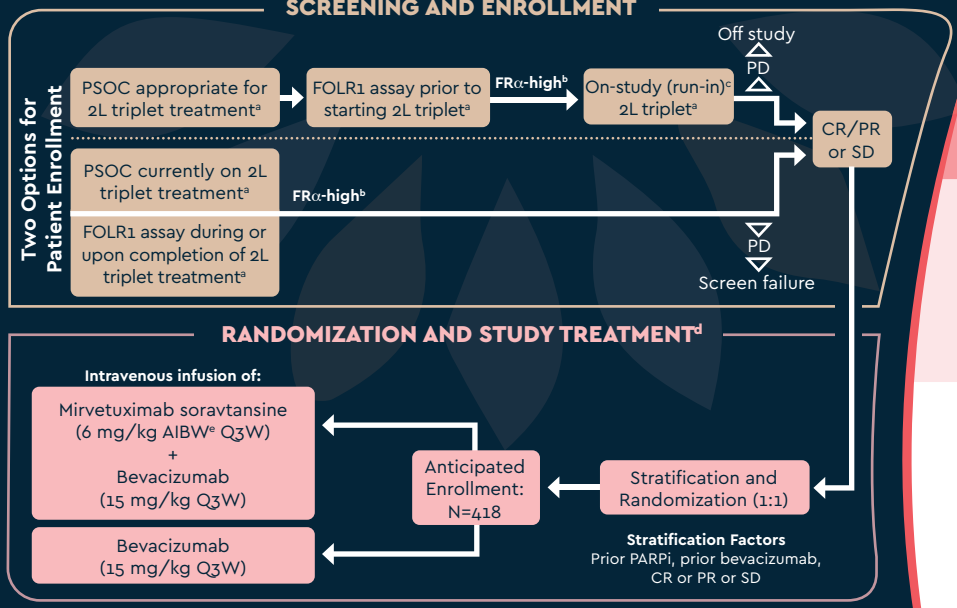
Rationale:

FRα — In ovarian cancer, 72% to 97% of patients have tumors that express FRα

MIRV — Mirvetuximab soravtansine-gynx (MIRV) is an FRα-targeting antibody-drug conjugate that received accelerated US FDA approval in November 2022 for the treatment of FRα-positive platinum-resistant ovarian cancer

MIRV + BEV — MIRV+bevacizumab demonstrated clinically meaningful activity in patients with platinum-sensitive and platinum-resistant ovarian cancer in the phase 1b/2 FORWARD II trial



[a]Triplet treatment consists of platinum plus chemotherapy plus bevacizumab for planned 6 cycles (minimum 4 and maximum 8 cycles), including at least 3 cycles of bevacizumab.
[b]FRα-high is defined by FRα positivity of ≥75% of tumor membrane staining at ≥2+ intensity (PS2+).
[c]FRα-high participants who desire to be treated and followed while on their run-in triplet therapy must sign a run-in consent as part of the main consent form if they meet eligibility criteria as assessed by the investigator.
[d]Maintenance treatment must begin ≤12 weeks from last dose of triplet therapy and within 30 days of randomization. Treatment continues until PD, unacceptable toxicity, withdrawal of consent, death, or study sponsor termination.
[e]AIBW, also known as AdjBW, is calculated as IBW (kg) + 0.4 (actual weight − IBW). IBW for females is calculated as 0.9 × height (cm) − 92.

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Key Eligibility Criteria

- ✓ High-grade serous epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer
- ✓ Platinum-sensitive disease (defined as progression >6 months from last dose of primary platinum therapy)
- ✓ Patients ≥18 years old
- ✓ FRα positivity detected by IHC with PS2+ intensity among ≥75% of viable tumor cells
- ✓ 1 prior systemic treatment
- ✓ Prior PARPi required if *BRCA*+
- ✓ CR, PR, or SD after treatment with platinum-based doublet + bevacizumab

Outcomes Assessed

Primary Endpoint: Investigator-assessed PFS

Key Secondary Endpoint: OS

Other Secondary Endpoints: Safety and tolerability, PFS2, ORR, DOR, DFS, CA-125 response, patient-reported outcomes

Abbreviations: 2L, second-line; AdjBW, adjusted body weight; AIBW, adjusted ideal body weight; BEV, bevacizumab; *BRCA*, BReast CAncer gene; CA-125, cancer antigen 125; CR, complete response; DFS, disease-free survival; DOR, duration of response; FDA, US Food and Drug Administration; FOLR1, folate receptor 1; FRα, folate receptor alpha; IBW, ideal body weight; IHC, immunohistochemistry; MIRV, mirvetuximab soravtansine-gynx; ORR, objective response rate; OS, overall survival; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitor; PD, progressive disease; PFS, progression-free survival; PFS2, time from date of randomization until second disease progression or death, whichever occurs first; PR, partial response; PS2+, positive staining 2+; PSOC, platinum-sensitive ovarian cancer; Q3W, 3 times per week; SD, stable disease.

Funding: This clinical trial is funded by ImmunoGen, Inc.

Additional Information
- This trial will be performed according to the principles of the Joint ENGOT and GOG Foundation requirements for trials with industry partners. A model C design will be utilized.

Trial Tracking Information
- ClinicalTrials.gov ID: NCT05445778
- ENGOT.ESGO.org ID: ENGOT-ov76
- GOG.org ID: GOG-3078

ENGOT European Network of Gynaecological Oncological Trial groups
GOG FOUNDATION