**Gloriosa Trial Design**

**Inclusion Criteria**
- Patients ≥18 years old
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Confirmed high-grade serous epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer
- FRα detected by IHC with ≥2% intensity among ≥75% of viable tumor cells
- Prior PARPi therapy if positive for BRCA mutation
- ≥1 prior platinum treatment
- Relapsed after 1L platinum-based chemotherapy
- Platinum-sensitive disease (PDI) >6 months
- Applicable for, currently on, or have completed ≥2L platinum-based tript therapy
- Received ≥4 cycles of ≥2 platinum-based tript therapy, which included ≥3 cycles of bevacizumab in combination with platinum-based chemotherapy
- CR, PR, or SD after prior treatment with platinum-based doublet + bevacizumab
- Randomized no later than 8 weeks from the last dose of platinum-based tript therapy in second line
- Stabilized or recovered (Grade 1 or baseline) from all prior therapy-related toxicities (except alopecia) and not had any major surgeries for at least 4 weeks prior to the first dose of maintenance therapy
- Adequate hematologic, liver, and kidney functions

**Exclusion Criteria**
- Endometrioid, clear cell, mucinous, or seromucous histology, mixed tumors containing any of the above histologies, or low-grade/borderline ovarian tumor
- ≥1 line of prior chemotherapy
- ≤3 prior platinum-based tript therapy
- Active or chronic bowel disorders, history of bowel transplantation, or active ocular conditions requiring ongoing treatment/monitoring
- Grade 1 peripheral neuropathy per CTCAE
- History of bowel obstruction related to underlying disease within 6 months before the start of maintenance study therapy
- Prior treatment with Mirvetuximab soravtansine or other FRα-targeting agents

**GLORIOSA: A randomized, open-label, phase 3 study of mirvetuximab soravtansine with bevacizumab vs. bevacizumab as maintenance in platinum-sensitive ovarian, fallopian tube or primary peritoneal cancer**

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**Trial Tracking Information**
- Clinical Trials.gov ID: NCT04545778
- ENCTG.ESGO.org ID: ENCTG2016/GOG.org ID: GOG-3078

**Overall Status and Enrollment**
- This is a global study that is currently open and enrolling

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**Abstract**

**GLORIOSA: A randomized, open-label, phase 3 study of mirvetuximab soravtansine with bevacizumab vs. bevacizumab as maintenance in platinum-sensitive ovarian, fallopian tube or primary peritoneal cancer**

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**Background**
- Epithelial ovarian cancer, primary peritoneal cancer, and fallopian tube cancer (together referred to as EOC) are a leading cause of death from gynecologic cancers worldwide.
- Mirvetuximab soravtansine (MirV), an antibody-drug conjugate (ADC), received accelerated FDA approval in November 2022 for the treatment of adult patients with folate receptor alpha (FRα)-positive, platinum-resistant epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens.
- FRα, also known as folate receptor 1 (FOLR1), has limited expression on normal tissues but is elevated in most ovarian cancers, which makes it an attractive target for the development of novel therapies.

**Clinical Trial Information**
- MIRV has demonstrated clinically meaningful antitumor activity in patients with platinum-resistant ovarian cancer (PROC) regardless of the number of prior lines of therapy or PARPi use.
- The GLORIOSA phase 2 (single-arm trial): Investigator-assessed objective response rate (ORR) was 32.4% (95% CI, 23.6%–42.2%), including 5 complete responses (CRs), and median duration of response (DOR) was 6.9 months.
- MirV was tested for safety, tolerability, and efficacy in patients with platinum-sensitive ovarian cancer based on the results of the GLORIOSA phase 2 trial.

**Objectives**
- Investigator-assessed ORR and DOR were the primary endpoints of the main study.
- Key secondary endpoints included EOC progression-free survival (PFS), overall survival (OS), and quality-of-life outcomes.

**Methods**
- Patients were randomized 1:1 to receive either MirV or placebo in an adaptive, minimization-based design, with adaptive accrual of patients to ensure a power of 90% for the primary endpoint at a 0.05 significance level.

**Results**
- ORR, which includes best response for CR or PR
- DOR, defined as patients who achieved best overall response of CR or PR upon completion of triplet therapy
- OS, defined as the time from randomization to death or disease progression
- PFS, progression-free survival
- PFS2, progression-free survival 2
- PR, partial response
- CR, complete response
- SD, stable disease
- PD, progressive disease
- RECIST v1.1 criteria, after platinum-based chemotherapy (doublet) plus bevacizumab and randomized to MirV vs bevacizumab

**Conclusion**
- MirV (6 mg/kg AIBW) + bevacizumab (15 mg/kg AIBW) conferred an ORR of 48% (95% CI, 30%–67%), including 3 CRs and a median DOR of 12.7 months.
- MirV was generally well tolerated, with a manageable safety profile.
- These results suggest that MirV may offer potential benefit for patients with platinum-sensitive ovarian cancer as maintenance therapy.

**Acknowledgements**
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