Analyses of Patient-Reported Outcomes (PROs) With Mirvetuximab Soravtansine (MRV) Versus Standard Chemotherapy in the Forward III Ovarian Cancer (GOG 3011)

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BACKGROUND
Mirvetuximab soravtansine (MRV) is a first-in-class antibody-drug conjugate (ADC) comprising a Fc-recombinant chimeric CD38-targeting agent,linker, and maytansinoid DM1 payload, a potent tubulin targeting agent.1
- MRV has demonstrated clinically meaningful antitumor activity with a favorable safety profile in patients with FR-positive ovarian cancer as monotherapy and in combination.2–5
- During the phase 3 FORWARD trial, patient-reported outcomes (PROs) regarding chemotherapy side effects, cancer-specific symptoms, and quality of life (QoL) were collected.6
- Preplanned and exploratory analyses of PRO data were conducted to determine differences with IMR and to inform the collection of PRO data in subsequent trials with MRV (phase 3 FORWARD; NCT03634556).

METHODS
The phase 3, open-label, randomized trial FORWARD II (NCT03634556) enrolled patients with platinum-resistant FR-positive advanced epithelial ovarian cancer (OC) in the post-first-line chemotherapy (1L) setting. Patients who failed to achieve ≥PR with prior chemotherapy were randomized 1:1 to receive MRV or paclitaxel (250 mg/m² every 3 weeks) for 6 cycles. Spontaneous PRO assessments (90 days) were collected during screening, on day 1 of cycle 1, every 9 weeks thereafter, with disease progression, and at the end of the treatment visit. Differences between treatment groups were not calculated. Descriptive statistics, OLS-regressed analyses, Fisher’s exact test, stratified Kaplan-Meier curves, and unadjusted log rank p values, and α tables were calculated. A value based on stratified log-rank test using randomization stratification factors. "P"-value based on stratified log-rank test using randomization stratification factors.

RESULTS: OV28 Adenoviral/IG Score
The proportion of patients with an 15-point improvement on the OV28 Adenoviral/IG score at week 8 was significantly higher in the MRV ITT group vs IC chemotherapy (Figure 1a). Patients who responded to treatment with MRV demonstrated better improvement; however, these findings did not reach statistical significance compared with IC chemotherapy (Supplementary Table 1).

CONCLUSIONS
- Improved PROs were observed with MRV treatment compared with IC chemotherapy across multiple symptoms, including chemotherapy side effects, sexuality, hair loss, pain, weight gain, performance, and body image (Figure 3).

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