THE RELATIONSHIP BETWEEN MISMATCH REPAIR SAFETY OF DOSTARLIMAB IN COMBINATION WITH CHEMOTHERAPY IN PATIENTS WITH PRIMARY ADVANCED OR RECURRENT ENDOMETRIAL CANCER IN A PHASE 3, RANDOMIZED, PLACEBO-CONTROLLED TRIAL (ENGOT-EN6-NSGO/GOG-3031/RUBY)

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Introduction/Background In the phase 3 RUBY trial (NCT03981796) in patients with primary advanced or recurrent endometrial cancer (pA/rEC) dostarlimab+carboplatin/paclitaxel significantly improved PFS versus carboplatin/paclitaxel alone in the mismatch repair deficient/microsatellite instability-high (HR 0.28) and overall populations (HR 0.64) with a favourable OS trend (HR 0.64). Here, we report on safety for the RUBY trial.

Methodology Patients with pA/rEC were randomised 1:1 to dostarlimab 500 mg, or placebo, plus carboplatin AUC 5 and paclitaxel 175 mg/m2 Q3W for 6 cycles, followed by dostarlimab 1000 mg, or placebo, Q6W for up to 3 years. Adverse events (AEs) were assessed according to CTCAE v4.03. Results The safety population included 487 patients who received ≥1 dose of treatment (241 dostarlimab+carboplatin/paclitaxel; 246 placebo+carboplatin/paclitaxel). Treatment-emergent adverse events (TEAEs) were experienced by 100% of patients; 70.5% of the dostarlimab arm and 59.8% of the placebo arm experienced grade ≥3 TEAEs (table 1). Median time to TEAE was 2.0 days in the dostarlimab+carboplatin/paclitaxel arm and 2.5 days in the placebo+carboplatin/paclitaxel arm. TEAEs led to discontinuation in 23.7% of the dostarlimab+carboplatin/paclitaxel arm and 16.7% of the placebo +carboplatin/paclitaxel arm. Higher rates of discontinuation were reported during the chemotherapy phase (cycles 1–6) versus the monotherapy phase (cycles ≥7). TEAEs led to discontinuation of dostarlimab or placebo in 17.4% and 9.3% of...