**Final overall survival data from a randomized, open-label, phase II study of relacorilant, a selective glucocorticoid receptor modulator, in combination with nab-paclitaxel among patients with recurrent platinum-resistant ovarian cancer**

**Objectives**

Effective treatment options remain limited for patients with advanced, platinum-resistant ovarian cancer. Even physiologic cortisol levels can reduce chemotherapy efficacy and promote tumor progression in pre-clinical models by suppressing apoptosis. In pre-clinical and early-phase clinical trials, the selective glucocorticoid receptor modulator, relacorilant, has shown potential in restoring chemosensitivity and enhancing chemotherapy efficacy. Results of a phase II study among patients with ovarian cancer showed that intermittently dosed relacorilant + nab-paclitaxel (NP) improved progression-free survival (PFS), duration of response, and overall survival (OS) compared with NP alone (Colombo et al. J Clin Oncol 2023). Following the study closure of this trial, we report the final OS results for the intermittent relacorilant + NP versus NP monotherapy arms.

**Methods**

A total of 178 women with recurrent, platinum-resistant/refractory, high-grade serous or endometrioid epithelial ovarian, primary peritoneal, or fallopian tube cancer or ovarian carcinosarcoma and up to 4 prior chemotherapeutic regimens were enrolled in this open-label, phase II study (NCT03776812). Patients were randomized 1:1:1 to (1) NP (80 mg/m2) + intermittent relacorilant (150 mg on the day before, of, and after NP); (2) NP (80 mg/m2) + continuous relacorilant (100 mg QD); or (3) NP monotherapy (100 mg/m2). NP was administered on days 1, 8, and 15 of each 28-day cycle. PFS was the primary endpoint, with OS as a key secondary endpoint. This abstract focused on the intermittent relacorilant versus NP monotherapy arms, which are the treatment regimens being evaluated in the confirmatory phase III ROSELLA trial (NCT05257408).

**Results**

After a median follow-up of 38 months, the median OS was 13.9 months (95% CI: 11.1-18.4) for intermittent relacorilant + NP and 12.2 months (7.7-15.3) for NP monotherapy (hazard ratio [HR]: 0.69; 95% CI: 0.46-1.02). Kaplan-Meier estimates of OS were 29.4% (95% CI: 17.7-42.1) and 14.1% (6.6-24.3) at 24 months, and 9.8% (3.6-19.7) and 5.3% (1.4-13.2) at 36 months in the intermittent relacorilant + NP and NP monotherapy arms, respectively. In the subgroup population similar to that being enrolled in the ROSELLA study (patients with 1-3 prior therapies, including prior bevacizumab, without primary platinum-refractory disease), median OS was 17.9 months (95% CI: 11.9-23.1) for intermittent relacorilant + NP (n=26) and 12.6 months (6.4-15.3) for NP monotherapy (n=31) (HR: 0.49; 95% CI: 0.25-0.92). The safety profile, in the final analysis, remained consistent with the primary analysis, with few event differences between the 2 arms.

**Conclusions**

With an additional ~16 months of follow-up, the findings from the primary OS analysis were confirmed. The chance of survival at 24 months was doubled for patients receiving relacorilant + NP versus NP alone, with no added safety burden. These promising results have paved the way for the currently accruing phase III ROSELLA trial.

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