BELLA: A Phase 2 Study of Relacorilant + Nab-Paclitaxel ± Bevacizumab in Patients With Gynecologic Cancers

Poster #267

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SGO ANNUAL MEETING ON WOMEN'S CANCER

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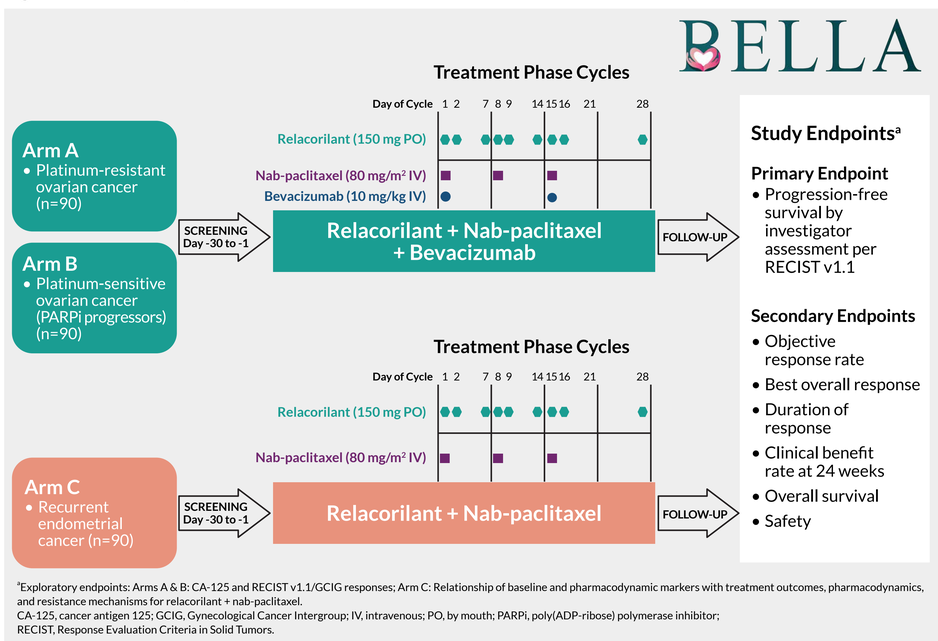
SUMMARY AND CONCLUSIONS

- There is an unmet need for effective therapies in platinum-resistant and platinum-sensitive ovarian cancer, and endometrial cancer
- The phase 3 ROSELLA trial met both dual primary endpoints with statistically and clinically significant improvements in progression-free survival and overall survival in patients with platinum-resistant ovarian cancer
- The enrolling BELLA phase 2 study is designed to evaluate the potential benefit of combining relacorilant + nab-paclitaxel with bevacizumab in ovarian cancer and relacorilant + nab-paclitaxel in endometrial cancer
- Findings from the BELLA study will expand our understanding of relacorilant-based combinations and inform future treatment strategies for patients with gynecologic cancers

STUDY DESIGN

- **BELLA** is an open-label, global, multi-arm study evaluating relacorilant + nab-paclitaxel, with or without bevacizumab, in patients with gynecologic cancers (**Figure 2**)

Figure 2. BELLA Study Schema

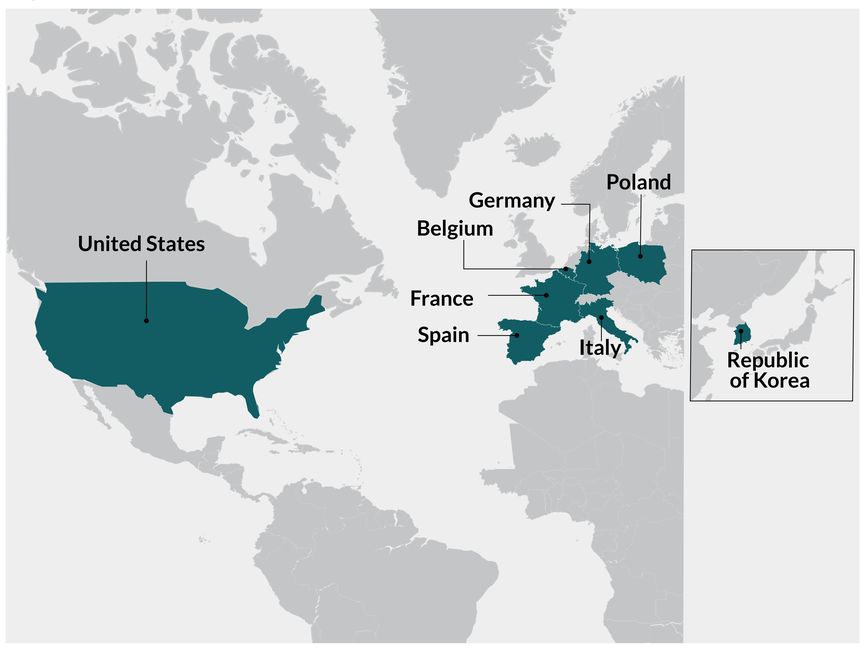


[a]Exploratory endpoints: Arms A & B: CA-125 and RECIST v1.1/GCIG responses; Arm C: Relationship of baseline and pharmacodynamic markers with treatment outcomes, pharmacodynamics, and resistance mechanisms for relacorilant + nab-paclitaxel.
CA-125, cancer antigen 125; GCIG, Gynecological Cancer Intergroup; IV, intravenous; PO, by mouth; PARPi, poly(ADP-ribose) polymerase inhibitor; RECIST, Response Evaluation Criteria in Solid Tumors.

STUDY SITES

- The study is being conducted worldwide at ~50 locations in the United States, Europe, and the Republic of Korea (**Figure 3**)

Figure 3. BELLA Study Sites



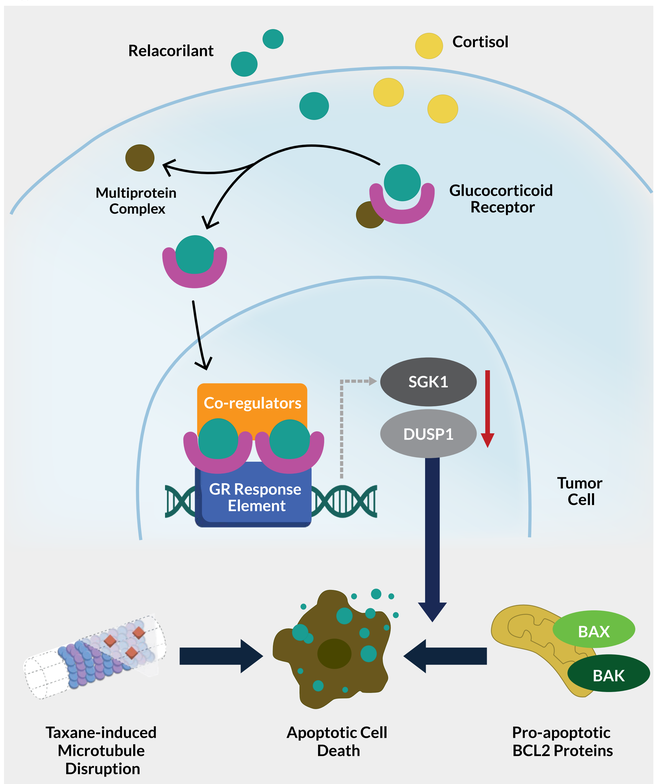
BACKGROUND AND OBJECTIVE

- Despite initial responses to standard therapies, relapse rates remain high in advanced-stage ovarian cancer (~80%)[1,2] and endometrial cancer (up to 40%)[3]
- Treatment options for recurrent ovarian and endometrial cancers are limited, with single-agent therapies associated with poor survival outcomes[4–9]
  - In patients with platinum-resistant ovarian cancer (PROC), single-agent chemotherapy ± anti-angiogenic agents have an overall survival (OS) of ~10–17 months[4,5]
  - Patients with platinum-sensitive ovarian cancer (PSOC) who progress while receiving PARP inhibitor maintenance have a median progression-free survival (PFS) of ~7 months[6,7]
  - In recurrent endometrial cancer, salvage chemotherapy (eg, doxorubicin or weekly paclitaxel) has limited survival benefit (median PFS ~4 months, OS ~12 months)[8,9]
- Nab-paclitaxel has shown manageable safety and promising efficacy in recurrent ovarian and endometrial cancers, comparable to standard paclitaxel regimens,[10,11] supporting its use as a combination partner in these settings

Role of the Glucocorticoid Receptor Pathway in Oncology

- Relacorilant, a selective glucocorticoid receptor antagonist (SGRA), increases the sensitivity of cancers to cytotoxic chemotherapies, including nab-paclitaxel, by reducing cortisol signaling at the glucocorticoid receptor (**Figure 1**)[12–15]

Figure 1. Relacorilant Mechanism of Action



BCL2, B-cell lymphoma 2; BAK, BCL2 homologous antagonist/killer; BAX, BCL2-associated X protein; DUSP1, dual specificity phosphatase 1; GR, glucocorticoid receptor; SGK1, serum/glucocorticoid-regulated kinase 1.

Relacorilant in Gynecologic Cancers

- In a phase 2 trial, the addition of intermittent relacorilant to nab-paclitaxel in patients with PROC extended PFS (hazard ratio [HR], 0.66; *P*=0.038) with a trend toward improved OS (HR, 0.67; *P*=0.066)[14]
- In the phase 3 ROSELLA trial, the addition of relacorilant to nab-paclitaxel demonstrated statistically and clinically significant improvements in PFS (HR, 0.70; *P*=0.0076) and OS (HR, 0.65; *P*=0.0004) in patients with PROC who had received 1–3 prior lines of therapy, including bevacizumab. Relacorilant in combination with nab-paclitaxel was well tolerated, consistent with its known safety profile[16,17]
- **Objective:** The phase 2 BELLA study (NCT06906341) builds on findings from ROSELLA to evaluate the efficacy and safety of relacorilant + nab-paclitaxel with bevacizumab in ovarian cancer and relacorilant + nab-paclitaxel in endometrial cancer

KEY ELIGIBILITY CRITERIA

Table 1. Key Inclusion Criteria

	Arm-specific Criteria	Common Criteria for All Arms
Arms A/B	▪ High-grade serous/endometrioid, epithelial ovarian, primary peritoneal, or fallopian-tube carcinoma ○ **Arm A:** Platinum-resistant disease ○ **Arm B:** Platinum-sensitive disease and radiographic progression while on a PARP inhibitor ▪ 1–3 prior lines of anticancer treatment; at least 1 prior line of platinum-containing therapy ▪ Prior treatment with bevacizumab permitted but not required ▪ If *BRCA1/2* mutated, must have received a PARP inhibitor ▪ No proteinuria	▪ Aged ≥18 years ▪ ECOG performance status 0–1 ▪ Life expectancy ≥3 months ▪ At least 1 measurable target lesion per RECIST v1.1 criteria ▪ Can swallow and retain oral medications and no uncontrolled emesis ▪ Baseline laboratory parameters: ○ Absolute neutrophil count ≥1,500 cells/mm^3 ○ Platelet count ≥100,000/mm^3 ○ Hemoglobin ≥9 g/dL ○ AST or ALT ≤2.5 ULN ○ Albumin ≥2.5 g/dL ○ Creatinine clearance ≥35 mL/min
Arm C	▪ Stage III or IV, recurrent or metastatic, histologically or cytologically confirmed endometrial cancer ▪ Endometrioid, clear cell, or serous histology, or mixed histology including these subtypes ▪ 1–2 prior lines of anticancer treatment; at least 1 prior line of platinum-containing therapy ▪ Prior treatment with approved anti–PD-1/PD-L1 inhibitors ▪ Consent to provide available tumor tissue	

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BRCA, breast cancer gene; ECOG, Eastern Cooperative Oncology Group; PARP, poly(ADP-ribose) polymerase; PD-1, programmed death-1; PD-L1, programmed cell death ligand 1; RECIST, Response Evaluation Criteria in Solid Tumors; ULN, upper limit of normal.

Table 2. Key Exclusion Criteria

	Arm-specific Criteria	Common Criteria for All Arms
Arms A/B	▪ **Arm A Only:** Progression while on weekly paclitaxel or nab-paclitaxel for platinum-resistant disease ▪ Hypertension: Blood pressure ≥150 mmHg systolic or ≥100 mmHg diastolic ▪ Rectosigmoid/bowel involvement by ovarian cancer	▪ Major surgery within 4 weeks ▪ Prior treatment-related toxicities not resolved to grade ≤1 ▪ Requirement for chronic or frequent corticosteroids ▪ Concurrent use of mifepristone or other GR modulators ▪ Uncontrolled conditions ▪ Partial or complete bowel obstruction ≤12 weeks of C1D1, paracentesis for ascites/effusions ≤30 days of C1D1 ▪ History of abdominal fistula, GI perforation, or intra-abdominal abscess ≤6 months prior to C1D1 ▪ Symptomatic or untreated CNS metastases ▪ Recent thrombotic/thromboembolic events
Arm C	▪ Progression while on weekly paclitaxel or nab-paclitaxel	

C1, cycle 1; CNS, central nervous system; D1, day 1; GI, gastrointestinal; GR, glucocorticoid receptor.

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Presenter Disclosure

Jae-Weon Kim reports: No competing interests.

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