

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

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SUMMARY AND CONCLUSIONS

- There remains an unmet need for effective therapies in gynecologic cancers, including platinum-resistant and platinum-sensitive ovarian cancer, as well as endometrial cancer
- In the phase 3 ROSELLA trial, the addition of relacorilant to nab-paclitaxel significantly improved progression-free survival and demonstrated a meaningful overall survival benefit at the interim analysis, with minimal added toxicity, in patients with platinum-resistant ovarian cancer
- The currently 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

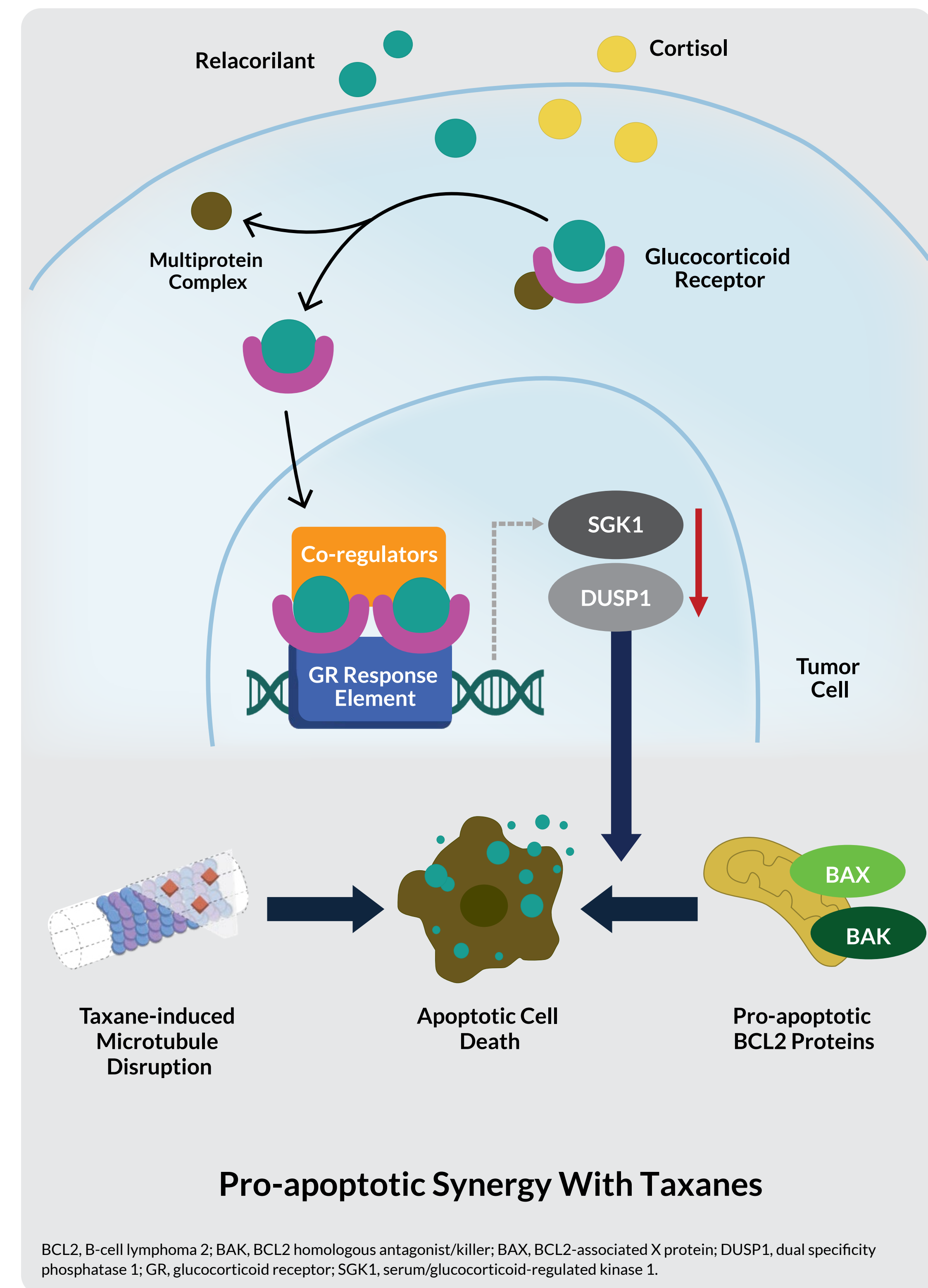
BACKGROUND AND OBJECTIVE

- Ovarian and endometrial cancers remain leading causes of gynecologic cancer morbidity and mortality worldwide^{1,2}
- Despite initial responses to standard therapies, relapse rates remain high in advanced-stage ovarian cancer (~80%)^{3,4} and endometrial cancer (up to 40%)⁵
- Treatment options for recurrent ovarian and endometrial cancers are limited, with single-agent therapies associated with poor survival outcomes⁶⁻¹¹
 - In patients with platinum-resistant ovarian cancer (PROC), single-agent chemotherapy ± anti-angiogenic agents have an overall survival (OS) of ~10–17 months^{6,7}
 - Patients with platinum-sensitive ovarian cancer (PSOC) who progress while receiving PARP inhibitor maintenance have a median progression-free survival (PFS) of ~7 months^{8,9}
 - In recurrent endometrial cancer, salvage chemotherapy (eg, doxorubicin or weekly paclitaxel) has limited survival benefit (median PFS ~4 months, OS ~12 months)^{10,11}
- Nab-paclitaxel has shown manageable safety and promising efficacy in recurrent ovarian and endometrial cancers, comparable to standard paclitaxel regimens,^{12,13} supporting its use as a combination partner in these settings

Role of the Glucocorticoid Receptor Pathway in Oncology

- Glucocorticoid receptor (GR) signaling suppresses chemotherapy-induced apoptosis of tumors and the antitumor immune response^{14,15}
- Ovarian and endometrial cancers express the GR, a marker of poor prognosis^{16,17}
- Relacorilant, a selective glucocorticoid receptor antagonist (SGRA), increases the sensitivity of cancers to cytotoxic chemotherapies, including nab-paclitaxel, by reducing cortisol signaling at the GR (Figure 1)^{14,18-20}

Figure 1. Relacorilant Mechanism of Action



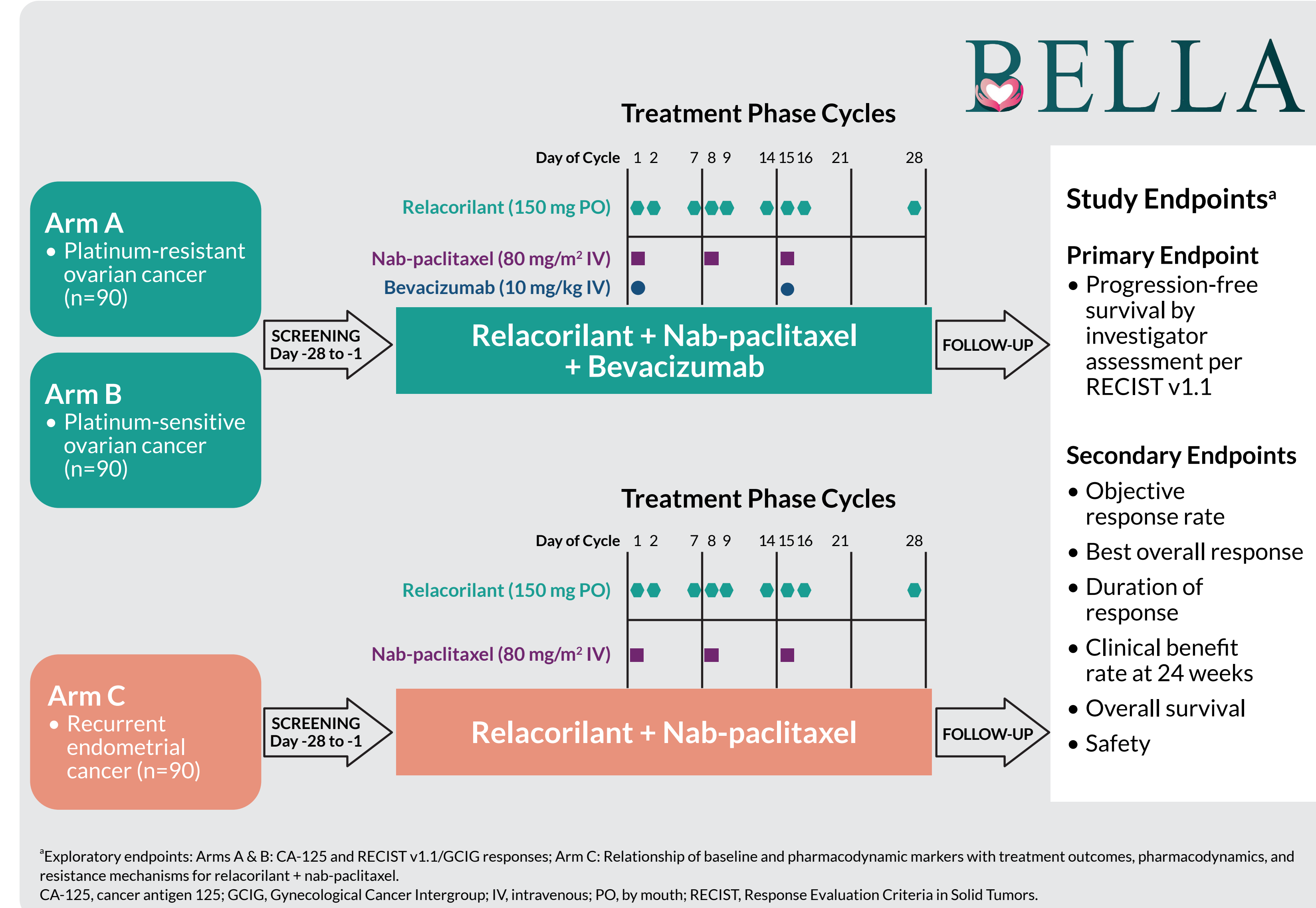
Relacorilant in Gynecologic Cancers

- 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; $P=0.066$)¹⁹
- In the phase 3 ROSELLA trial, the addition of relacorilant to nab-paclitaxel resulted in a 30% improvement in PFS compared with nab-paclitaxel alone (HR, 0.70; $P=0.0076$) and a clinically meaningful OS benefit at an interim analysis with minimal additional toxicity in patients with PROC who had received 1–3 prior lines of therapy, including bevacizumab²¹
- 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

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



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



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 (progression <183 days from last dose of platinum) Arm B: Platinum-sensitive disease (progression ≥183 days from last dose of platinum) and radiographic progression while on a PARP inhibitor (niraparib, olaparib, or rucaparib) 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 (unless unsuitable or unable to access) - Baseline urine protein <2+ by dipstick (If ≥2+, 24-hour urine must demonstrate <1 g of protein)	- 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/mm³ - Platelet count ≥100,000/mm³ - 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 approved anti-PD-1/PD-L1 inhibitors (pembrolizumab, dostarlimab, or durvalumab) - 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 - Anticoagulants or thrombolytics for therapeutic purpose ≤10 days of C1D1	- Major surgery within 4 weeks - Prior treatment-related toxicities not resolved to grade ≤1 - Requirement for chronic or frequent corticosteroids - Washout period within 5 half-lives of the corticosteroid^a or anticancer treatment prior to C1D1 - Incomplete washout period for radiotherapy or hormonal anticancer treatment - Concurrent use of mifepristone or other GR modulators - Uncontrolled conditions (eg, unstable angina, myocardial infarction ≤6 months of C1D1, congestive heart failure NYHA grade ≥2, arrhythmias requiring medication, cirrhosis, gastric-outlet obstruction, acute renal failure)
Arm C - Progression while on weekly paclitaxel or nab-paclitaxel - Thromboembolic events and/or bleeding disorders ≤28 days prior to C1D1	- 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

^aSystemic, inhaled, or prescription-strength topical. C1, cycle 1; CNS, central nervous system; D1, day 1; GI, gastrointestinal; GR, glucocorticoid receptor; NYHA, New York Heart Association.

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Presenter Disclosure

Jae-Weon Kim reports: no competing interests.

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References

- Bray F, et al. *CA Cancer J Clin*. 2024;74(3):229–263.
- Siegel RL, et al. *CA Cancer J Clin*. 2025;75(1):10–45.
- Caruso G, et al. *JAMA*. 2025 Jul 21. Epub ahead of print.
- Tavares V, et al. *Int J Mol Sci*. 2024;25(3):1845.
- Ruscilli M, et al. *J Pers Med*. 2023;13(5):723.
- Richardson DL, et al. *JAMA Oncol*. 2023;9(6):851–859.
- Martorana F, et al. *Int J Gynecol Cancer*. 2025;35(1):100009.
- Harter P, et al. *Ann Oncol*. 2025;36(2):185–196.
- Kulkarni S, et al. *Front Oncol*. 2024;14:1414112.
- McMeekin S, et al. *Gynecol Oncol*. 2015;138(1):18–23.
- Makker V, et al. *J Clin Oncol*. 2023;41(16):2904–2910.
- Coleman RL, et al. *Gynecol Oncol*. 2011;122(1):111–115.
- Pothuri B, et al. *Gynecol Oncol*. 2024;190:209–214.
- Greenstein AE, Hunt HJ. *Oncotarget*. 2021;12(13):1243–1255.
- Acharya N, et al. *Immunity*. 2020;53(3):658–671.e6.
- Veneris JT, et al. *Gynecol Oncol*. 2017;146(1):153–160.
- Tangen IL, et al. *Gynecol Oncol*. 2017;147(3):672–677.
- Stringer-Reaser EM, et al. *Gynecol Oncol*. 2015;138(3):656–662.
- Colombo N, et al. *J Clin Oncol*. 2023;41(30):4779–4789.
- Munster PN, et al. *Clin Cancer Res*. 2022;28(15):3214–24.
- Olawaiye AB, et al. *Lancet*. 2025;405(10496):2205–2216.