

Relacorilant Plus Nab-Paclitaxel Demonstrates a Progression-Free Survival Benefit in Ovarian Cancer Independent of Tumor Glucocorticoid Receptor (GR) Expression Levels

Poster #247

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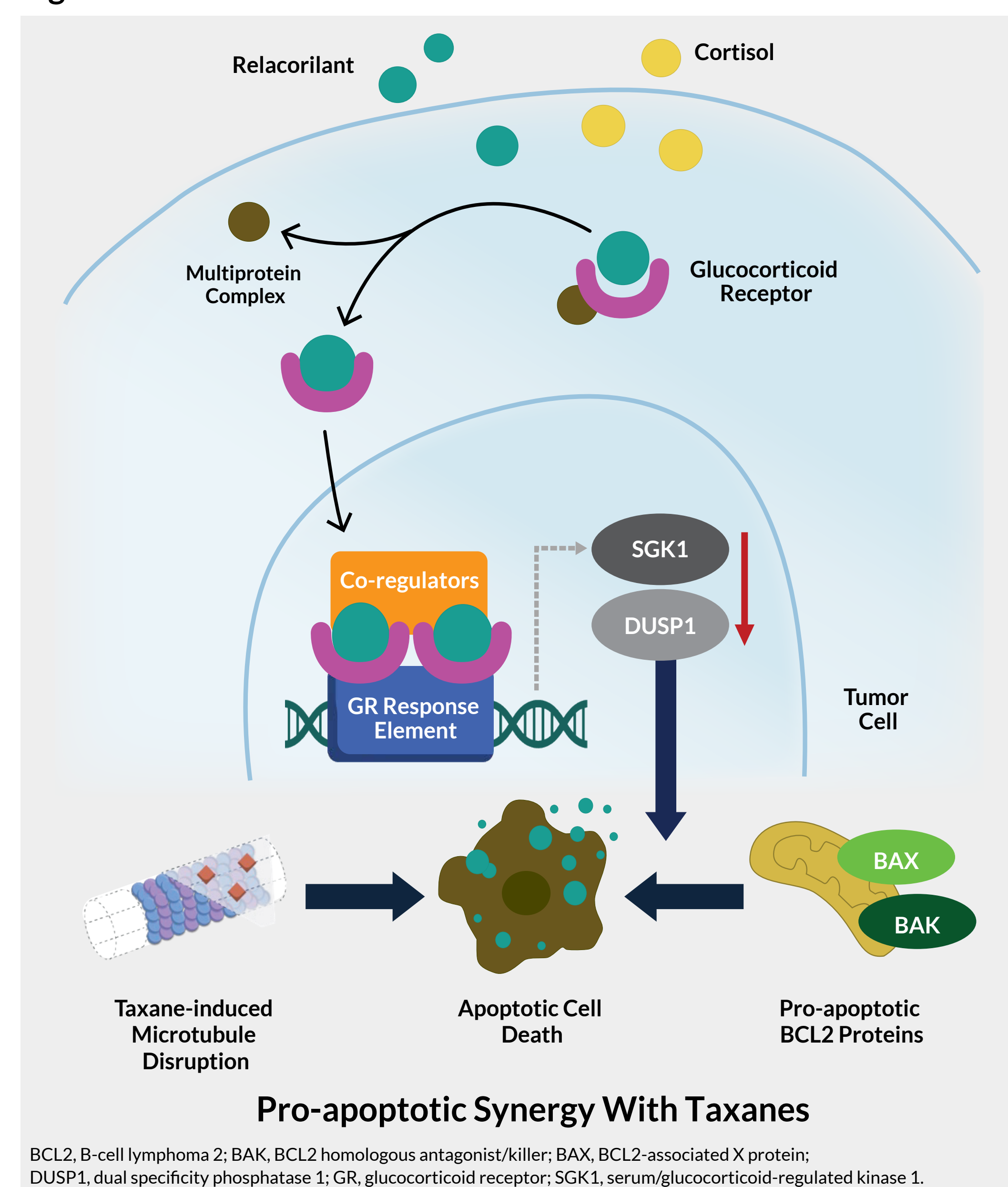
SUMMARY AND CONCLUSIONS

- GR protein was expressed in the tumor cell nuclei of >95% of ovarian cancers, and GR mRNA was expressed in all ovarian cancers from Study-552
- Progression-free survival (PFS) with the selective GR antagonist relacorilant + nab-paclitaxel was not associated with GR expression level, and relacorilant + nab-paclitaxel improved PFS vs nab-paclitaxel monotherapy regardless of GR expression level
- These data support positive final overall survival data from the ROSELLA phase 3 study that relacorilant + nab-paclitaxel is a new potential standard for patients with platinum-resistant ovarian cancer without the need for biomarker selection

BACKGROUND AND OBJECTIVE

- Patients with platinum-resistant ovarian cancer (PROC) have an overall survival (OS) of ~1 year and need new treatments¹
- The GR is abundantly expressed in ovarian tumors^{2,3}
- GR signaling reduces tumor sensitivity to chemotherapy by increasing the expression of anti-apoptotic proteins^{4,7}
- Relacorilant is a novel, selective GR antagonist that restores the sensitivity of cancers to cytotoxic chemotherapy (Figure 1)^{5,7,8}
- In the phase 3 ROSELLA study (NCT05257408) in patients with PROC, adding relacorilant to nab-paclitaxel significantly prolonged progression-free survival (PFS) and OS and was well tolerated, with a manageable safety profile^{9,10}
- A previous phase 2 study in PROC (Study-552) also demonstrated a PFS benefit and a trend toward improved OS with intermittent relacorilant + nab-paclitaxel vs nab-paclitaxel monotherapy³
- Using samples from this phase 2 study, we sought to determine if the clinical benefit observed with relacorilant + nab-paclitaxel was associated with tumor GR expression levels

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.

METHODS

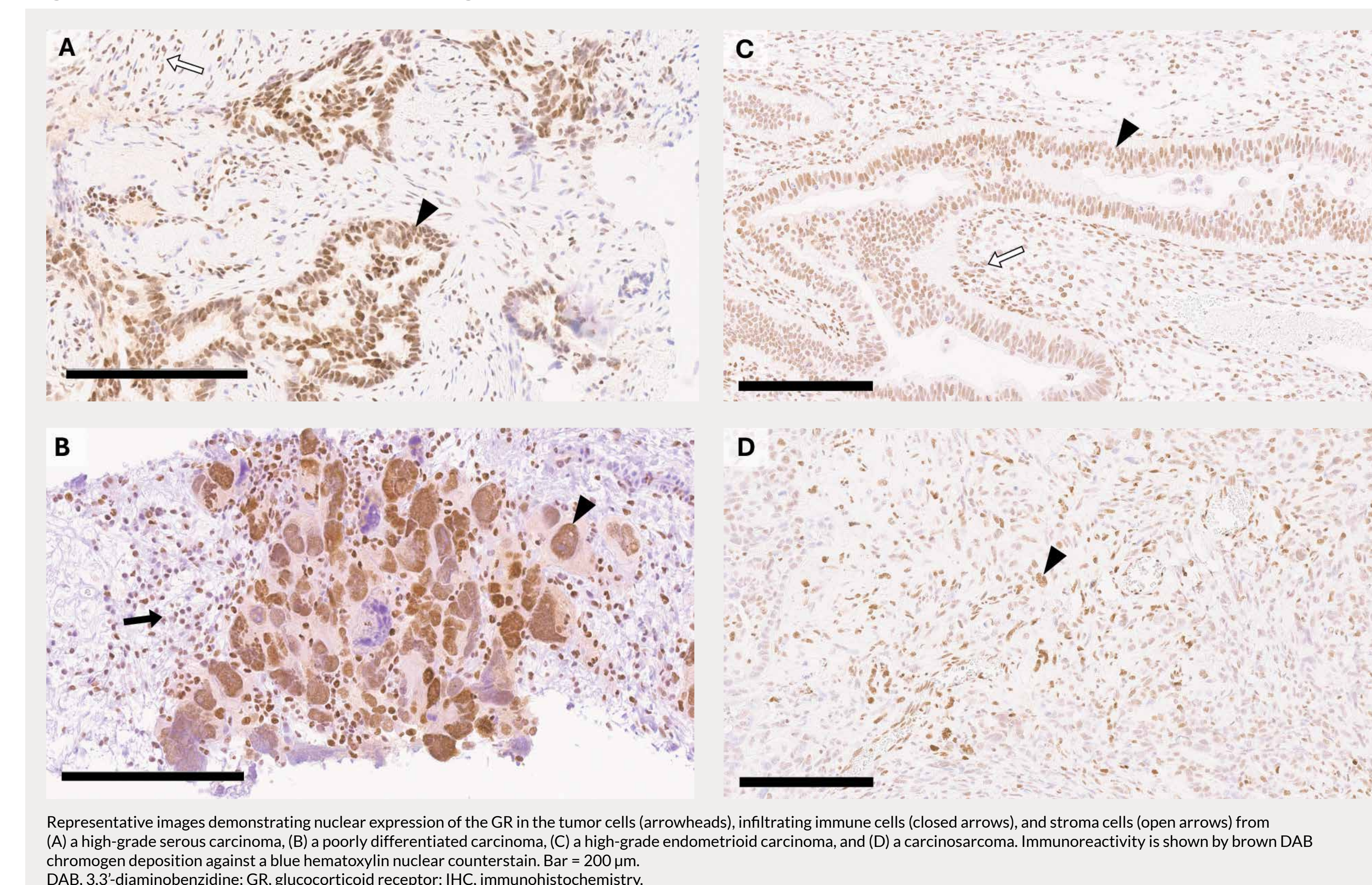
- Data were derived from Study-552 (NCT03776812), a phase 2 study in women with recurrent PROC (Figure 2)³
- GR expression was analyzed using archival formalin-fixed paraffin-embedded tumor tissue
- GR protein levels were assessed using a CLIA-validated immunohistochemistry (IHC) assay with the D8H2 rabbit monoclonal anti-GR antibody. Tumor nuclear staining intensity was quantified by a pathologist using the H-score method (0 [negative], 1+ [weak], 2+ [moderate], or 3+ [strong]), resulting in a score range of 0-300, with higher values indicating higher GR expression
- GR mRNA levels were quantified using the NR3C1 probe on the NanoString nCounter[®] FLEX system and normalized with standard nSolver[™] normalization
- GR protein level (H-score) and mRNA expression were stratified into tertiles, with tertile cutoffs derived using data from all 3 study treatment arms
- Associations with PFS were evaluated using Cox proportional hazards regression model with treatment as a covariate stratified by randomization factors for the intermittent relacorilant + nab-paclitaxel arm (the dosing regimen evaluated in the phase 3 ROSELLA study). Comparisons in this analysis were limited to the intermittent relacorilant + nab-paclitaxel vs nab-paclitaxel monotherapy arms

CLIA, Clinical Laboratory Improvement Amendments.

RESULTS

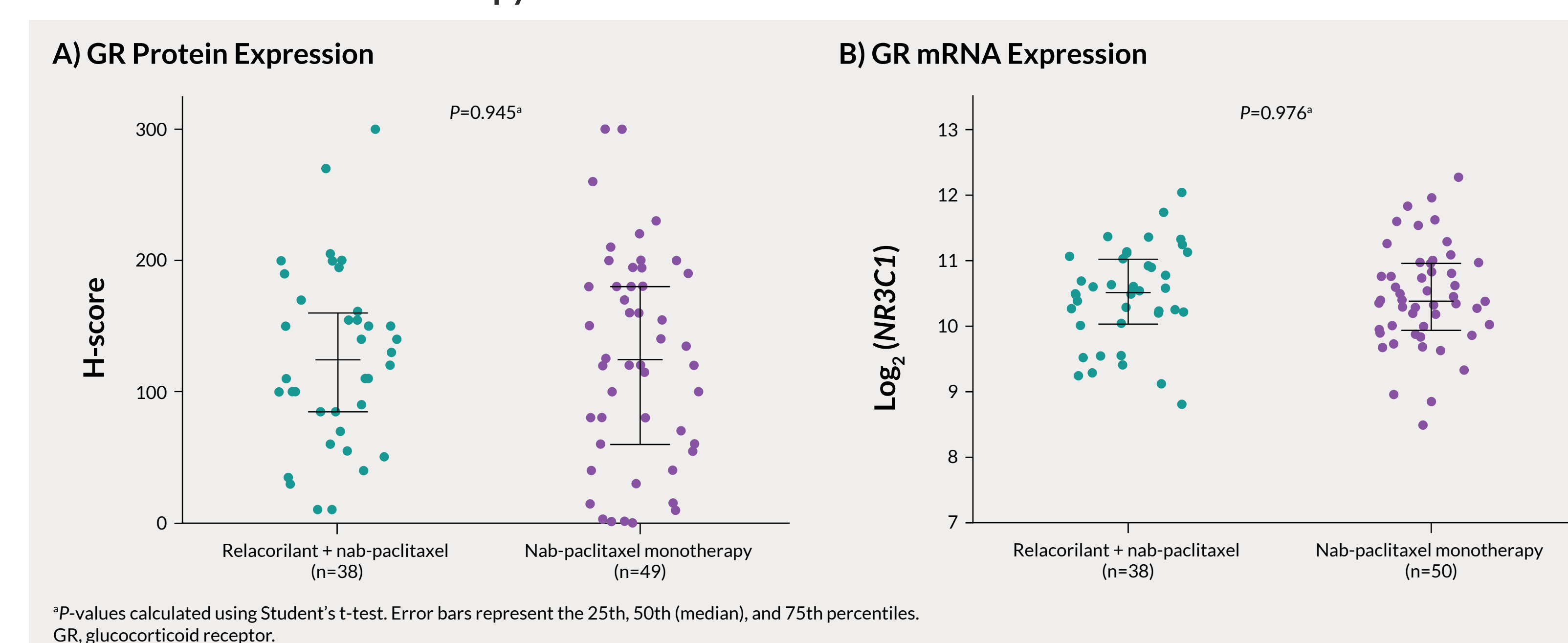
- Approximately 73% of enrolled patients in the intermittent relacorilant + nab-paclitaxel and nab-paclitaxel monotherapy arms had GR protein (87/120) and mRNA (88/120) data
 - >95% (83/87) of ovarian cancers from the intermittent relacorilant + nab-paclitaxel and nab-paclitaxel monotherapy arms expressed GR protein (H-score ≥ 10) in tumor cell nuclei (Figure 3)
 - All 88 tumors expressed high levels of GR mRNA
- Tumor GR protein (Figure 4A) and mRNA expression levels (Figure 4B) were similar between treatment arms

Figure 3. Representative IHC Images of GR Protein Expression in Tumor Cell Nuclei From Study-552



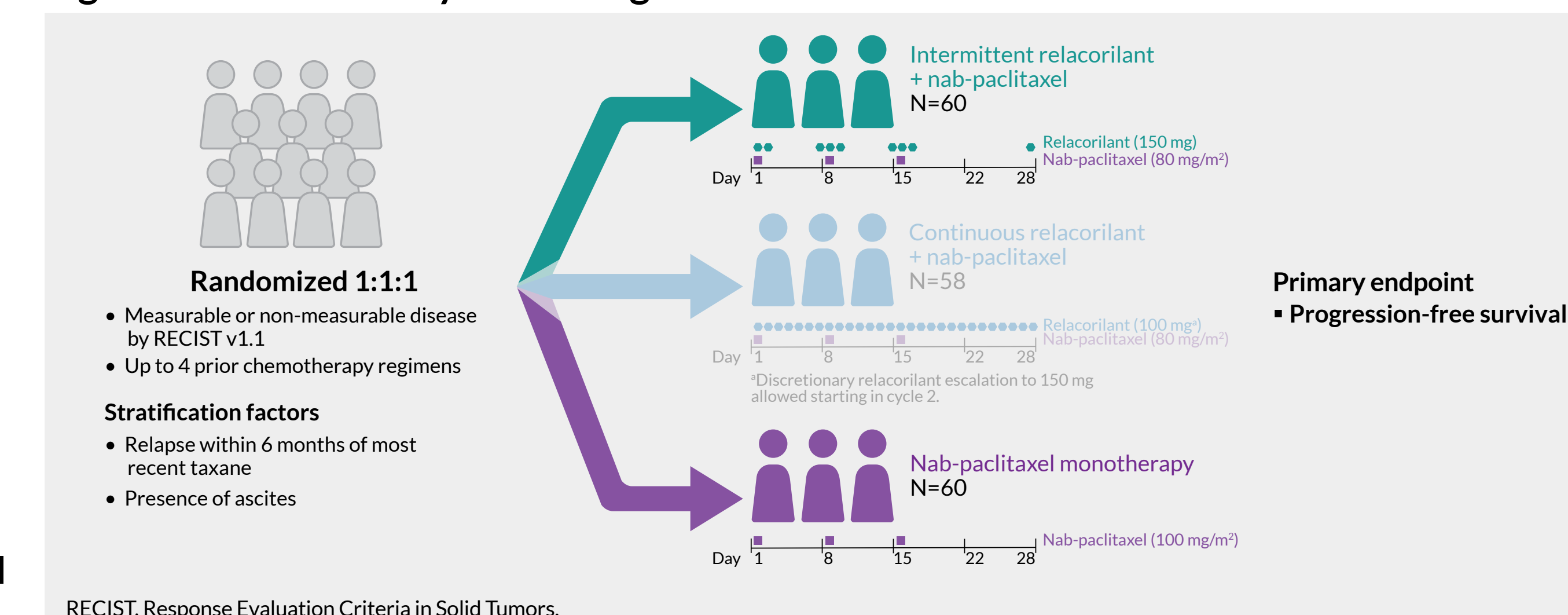
Representative images demonstrating nuclear expression of the GR in the tumor cells (arrowheads), infiltrating immune cells (closed arrows), and stroma cells (open arrows) from (A) a high-grade serous carcinoma, (B) a poorly differentiated carcinoma, (C) a high-grade endometrioid carcinoma, and (D) a carcinosarcoma. Immunoreactivity is shown by brown DAB chromogen deposition against a blue hematoxylin nuclear counterstain. Bar = 200 μ m. DAB, 3,3'-diaminobenzidine; GR, glucocorticoid receptor; IHC, immunohistochemistry.

Figure 4. Tumor GR A) Protein and B) mRNA Expression in the Intermittent Relacorilant + Nab-Paclitaxel and Nab-Paclitaxel Monotherapy Arms



*P-values calculated using Student's t-test. Error bars represent the 25th, 50th (median), and 75th percentiles. GR, glucocorticoid receptor.

Figure 2. Phase 2 Study-552 Design³



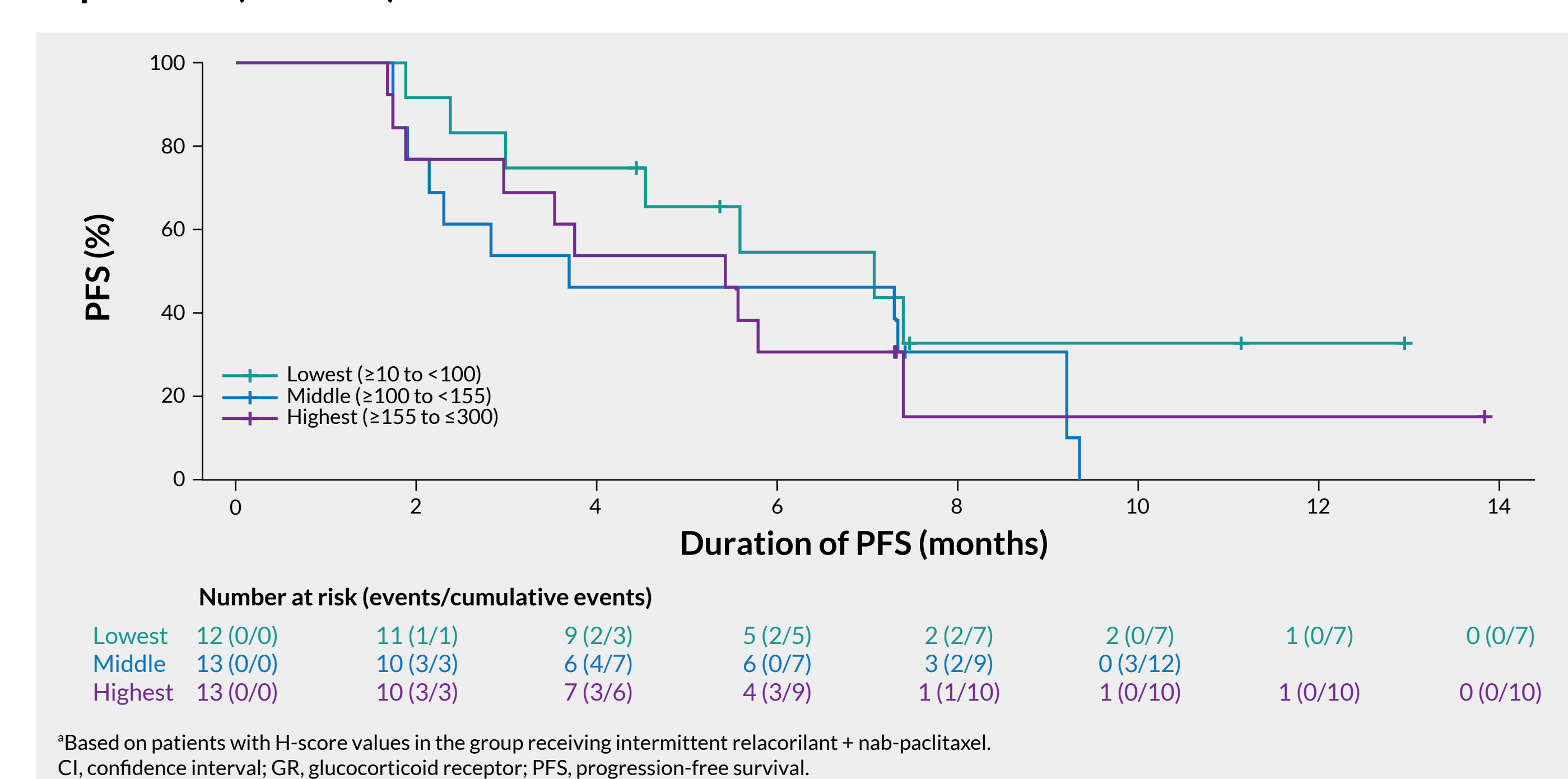
- PFS benefit from the addition of relacorilant to nab-paclitaxel was positive and consistent across the range of GR protein and mRNA expression, with favorable hazard ratios vs nab-paclitaxel monotherapy (Table 1)
- Kaplan-Meier analysis showed no statistically significant difference in PFS across the range of GR protein expression (P=0.562) (Figure 5)

Table 1. PFS HRs for Intermittent Relacorilant + Nab-Paclitaxel Versus Nab-Paclitaxel Monotherapy by GR Protein (H-Score) and mRNA Tertile^a

	Expression Tertile	Patients (n)	HR ^b	95% CI
All patients	N/A	120	0.66	0.44, 0.98
GR protein	Lowest (≥ 0 to <100)	29	0.64	0.25, 1.64
	Middle (≥ 100 to <180)	33	0.67	0.30, 1.50
	Highest (≥ 180 to ≤ 300)	25	0.80	0.31, 2.12
GR mRNA	Lowest (≥ 8.5 to <10.22)	29	0.54	0.22, 1.32
	Middle (≥ 10.22 to <10.83)	33	0.70	0.29, 1.71
	Highest (≥ 10.83 to ≤ 12.28)	26	0.64	0.25, 1.67

^aBased on all patients with H-score or NR3C1 mRNA values from both treatment groups included in the analysis. ^bFor each tertile group, the HR was based on a stratified Cox proportional hazards regression model with treatment as a covariate, stratified by randomization factors. The nab-paclitaxel monotherapy arm was used as the reference group. CI, confidence interval; GR, glucocorticoid receptor; HR, hazard ratio; N/A, not applicable; PFS, progression-free survival.

Figure 5. PFS in the Intermittent Relacorilant + Nab-Paclitaxel Arm by GR Protein Expression (H-Score) Tertile^a



^aBased on patients with H-score values in the group receiving intermittent relacorilant + nab-paclitaxel. CI, confidence interval; GR, glucocorticoid receptor; PFS, progression-free survival.

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Presenter Disclosure

Alexander Olawaye reports: No competing interests.

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