

Meta-analysis of Relacorilant Plus Nab-paclitaxel Efficacy in Patients With Platinum-resistant Ovarian Cancer (PROC) Enrolled to ROSELLA and Study 552

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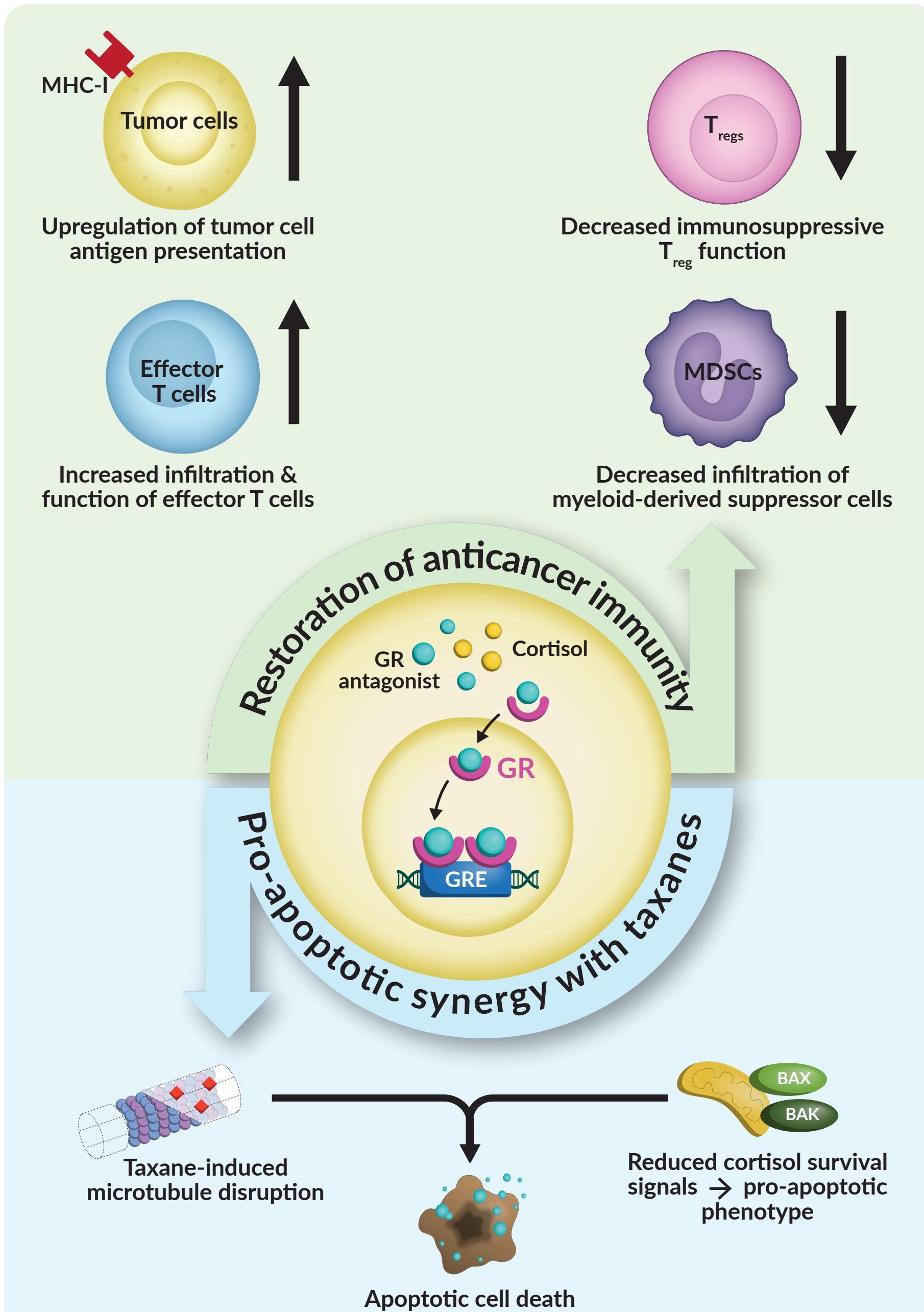
SUMMARY AND CONCLUSIONS

- Relacorilant is a novel, selective glucocorticoid receptor antagonist that activates the anticancer immune response and restores the sensitivity of cancers to cytotoxic chemotherapy
- Consistent with results from the pivotal phase 3 ROSELLA study, this meta-analysis showed that adding relacorilant to nab-paclitaxel led to significant and clinically meaningful improvements in progression-free survival and overall survival in patients with platinum-resistant ovarian cancer (PROC)
- Relacorilant + nab-paclitaxel was well tolerated, with a manageable safety profile
- The results of this meta-analysis reinforce the efficacy benefit of relacorilant + nab-paclitaxel across 2 positive randomized controlled trials in PROC. The analysis confirms the consistency and reproducibility of the observed benefit across independent study populations, providing a stronger and more robust evidence base than is available for many therapies in this setting

BACKGROUND AND OBJECTIVES

- Patients with platinum-resistant ovarian cancer (PROC) have an overall survival (OS) of ~1 year and need new treatments¹
- Cortisol, acting through the glucocorticoid receptor (GR), provides survival signals that reduce the sensitivity of tumor cells to chemotherapy and also suppresses the anticancer immune response²⁻⁵
- Inhibition of GR signaling promotes anticancer immunity, upregulating antigen presentation, increasing effector T-cell infiltration and function, and reducing the immunosuppressive cancer microenvironment⁵⁻⁷
- Relacorilant is a novel, selective GR antagonist (SGRA) that promotes anticancer immune control and restores the sensitivity of cancers to cytotoxic chemotherapy^{2,5-8}
- Adding relacorilant to nab-paclitaxel resulted in statistically and clinically significant improvements in progression-free survival (PFS) and OS in patients with PROC, with a manageable safety profile in the phase 3 ROSELLA trial, confirming the results of the phase 2 Study 552⁹⁻¹¹
- To further elucidate the efficacy and safety of relacorilant in combination with nab-paclitaxel in patients with PROC, we conducted a meta-analysis of efficacy data and a pooled analysis of safety data from these trials

Figure 1. Mechanisms of Action of GR Antagonism⁵⁻⁷

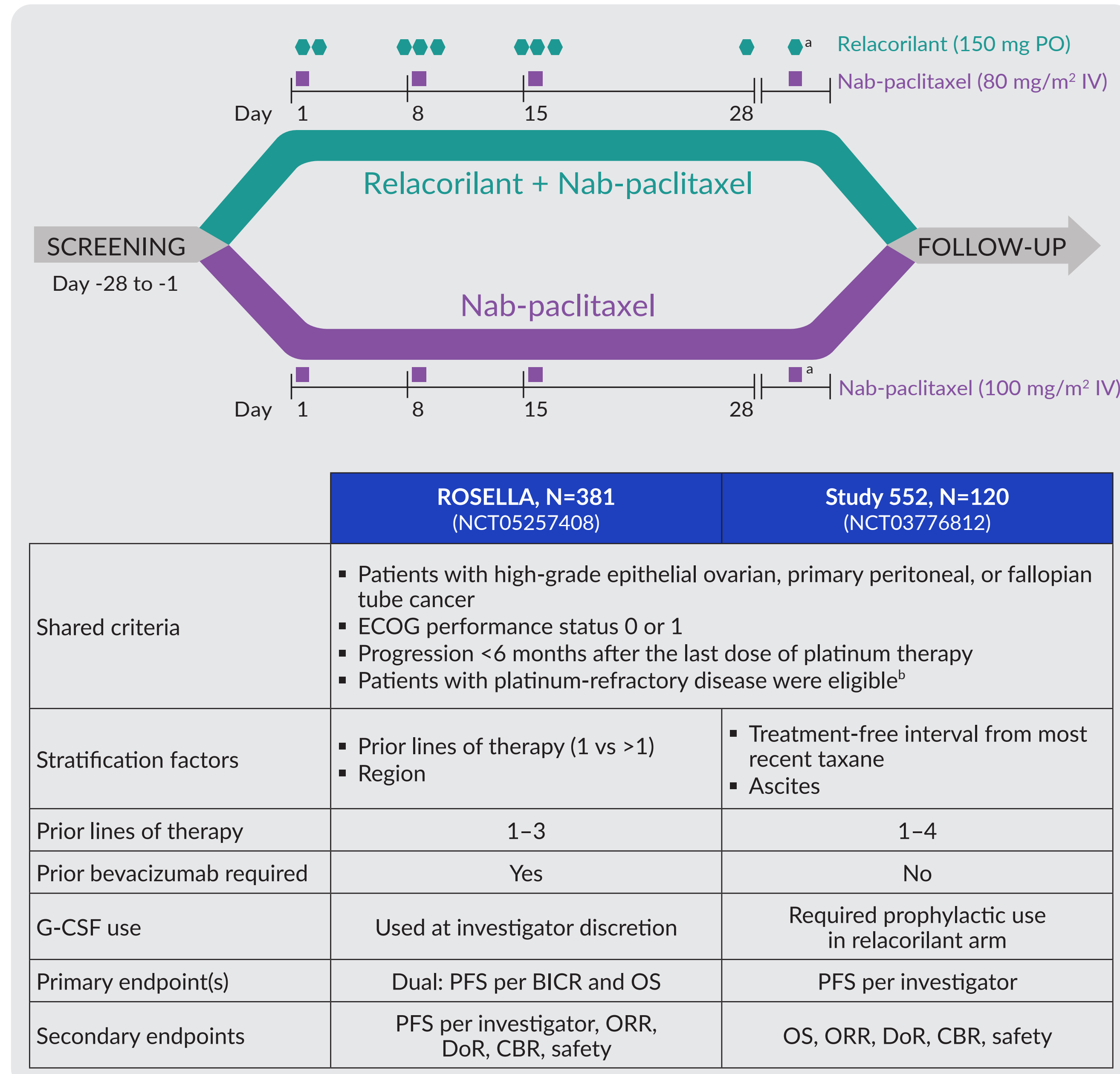


BAK, B-cell lymphoma 2 homologous antagonist/killer; BAX, B-cell lymphoma 2-associated X protein; GR, glucocorticoid receptor; GRE, glucocorticoid response elements; MDSC, myeloid-derived suppressor cell; MHC-I, major histocompatibility complex I; T_{reg}, regulatory T cells.

METHODS

- ROSELLA and Study 552 were randomized, controlled studies in similar populations of patients with PROC (Figure 2)
- Prior treatment with bevacizumab was required in ROSELLA but optional in Study 552
- For the current analyses, data from the corresponding intermittent relacorilant + nab-paclitaxel arms and nab-paclitaxel monotherapy arms of both studies were combined
- The intermittent relacorilant + nab-paclitaxel regimen used in these studies is the US Food and Drug Administration–approved regimen for PROC treatment¹²
- The intent-to-treat (ITT) population in the meta-analysis included all patients randomized in ROSELLA and in Study 552 who received intermittent relacorilant + nab-paclitaxel or nab-paclitaxel monotherapy
- The safety population in the pooled safety analysis included all randomized patients in the ITT population who received ≥1 dose of study treatment
- Efficacy outcomes assessed in the meta-analysis included investigator-assessed PFS and OS
- A stratified log-rank test was used to obtain the overall P-value, utilizing the study as the stratification factor
- The overall hazard ratio (HR) was estimated using a mixed-effect Cox proportional hazards model, incorporating the study as a random effect
- Safety outcomes in the pooled analysis included treatment-emergent adverse events (AEs); serious AEs; grade ≥3 AEs; and AEs leading to treatment interruption, discontinuation, or death; full results of the pooled safety analysis are presented separately (Olawaiye et al. ESMO 2026 Poster #1264P)

Figure 2. Study Designs for Study 552 and ROSELLA



NOTE: Study 552 also included a third treatment arm of continuous relacorilant (100 mg PO) + nab-paclitaxel (80 mg/m² IV), which was not included in the current analyses. *Ongoing cycle. *ROSELLA excluded patients with no response to or progression in <1 month of primary platinum therapy. BICR, blinded independent central review; CBR, clinical benefit rate; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; G-CSF, granulocyte colony-stimulating factor; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PO, by mouth.

Patients

- The meta-analysis included 501 patients (relacorilant + nab-paclitaxel, n=248; nab-paclitaxel, n=253; Table 1)
- The baseline characteristics were well balanced across the relacorilant + nab-paclitaxel vs nab-paclitaxel monotherapy arms

Table 1. Baseline Characteristics in ROSELLA and Study 552

Characteristics		ROSELLA ^a		Study 552 ^c	
		Relacorilant + nab-paclitaxel (n=188)	Nab-paclitaxel (n=193)	Relacorilant + nab-paclitaxel (n=60)	Nab-paclitaxel (n=60)
Age, mean (SD), years		61.5 (9.8)	62.0 (9.6)	60.3 (9.7)	61.8 (8.8)
Race, n (%)	White	136 (72.3)	135 (69.9)	52 (86.7)	50 (83.3)
	Black or African American	3 (1.6)	2 (1.0)	1 (1.7)	1 (1.7)
	Asian	22 (11.7)	26 (13.5)	3 (5.0)	3 (5.0)
	Other/not reported/missing	27 (14.4)	30 (15.5)	4 (6.7)	5 (8.3)
Region, n (%)	North America	45 (23.9)	45 (23.3)	24 (40.0)	22 (36.7)
	Europe	107 (56.9)	109 (56.5)	36 (60.0)	38 (63.3)
	Latin America and Asia-Pacific	36 (19.1)	39 (20.2)	0	0
ECOG performance status of 1 or 2, n (%)		53 (28.2)	63 (32.6) ^b	18 (30.0)	22 (36.7)
BRCA1 or BRCA2 mutation, n (%)		23 (12.2)	24 (12.4)	6 (10.0) ^d	10 (16.7) ^d
Prior lines of therapy, n (%)	1	15 (8.0)	18 (9.3)	10 (16.7)	7 (11.7)
	2	92 (48.9)	89 (46.1)	19 (31.7)	22 (36.7)
	3	81 (43.1)	86 (44.6)	23 (38.3)	22 (36.7)
	4	0	0	8 (13.3)	9 (15.0)
	≥1 prior lines of therapy in the platinum-resistant setting, n (%)	67 (35.6)	82 (42.5)	31 (51.7) ^d	38 (63.3) ^d
Prior therapies, n (%)	Bevacizumab	188 (100)	193 (100)	31 (51.7)	37 (61.7)
	Taxanes	187 (99.5)	192 (99.5)	58 (96.7) ^d	60 (100) ^d
	Pegylated liposomal doxorubicin	121 (64.4)	125 (64.8)	39 (65.0) ^d	36 (60.0) ^d
	PARP inhibitor	114 (60.6)	120 (62.2)	18 (30.0)	20 (33.3)

^aData cutoff date: 24 February 2025.

^bIn the nab-paclitaxel monotherapy arm of ROSELLA, 1 patient had an ECOG performance status of 2.

^cData cutoff date (unless otherwise specified): 22 March 2021.

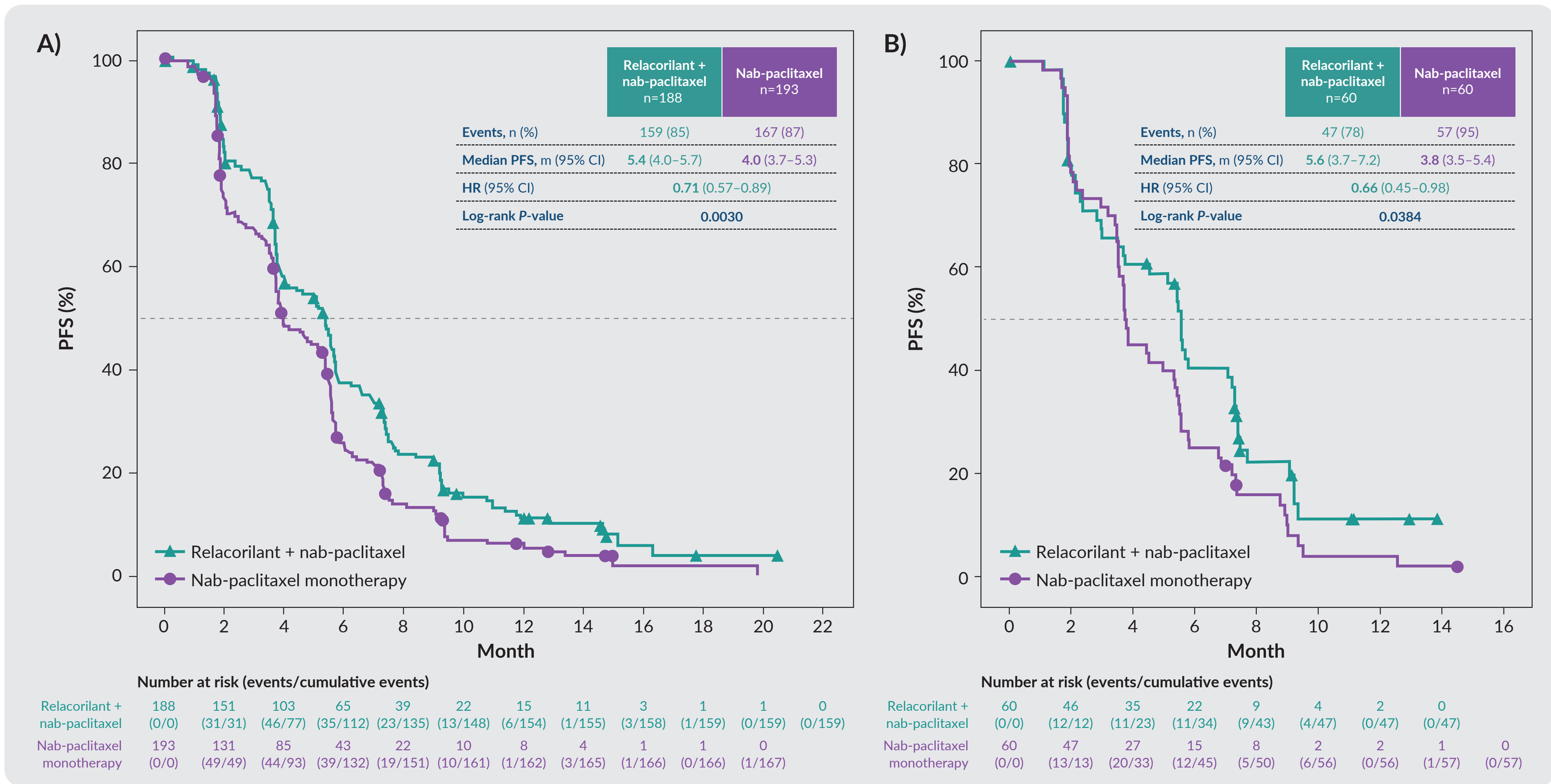
^dData cutoff date: 25 August 2023.

BRCA, breast cancer gene; ECOG, Eastern Cooperative Oncology Group; PARP, poly(ADP-ribose) polymerase; SD, standard deviation.

Efficacy Meta-analysis (continued)

- Relacorilant + nab-paclitaxel resulted in a significant improvement in PFS over nab-paclitaxel monotherapy in the meta-analysis (log-rank P=0.0006), consistent with the results from the individual studies (Figure 4)
- There was no significant heterogeneity between the 2 studies (Cochran's Q test: P=0.74)
- In ROSELLA, PFS by blinded independent central review (not assessed in Study 552) was also significantly prolonged in the relacorilant combination arm vs the nab-paclitaxel monotherapy arm (HR, 0.70; log-rank P=0.0076)

Figure 4. PFS per Investigator in ROSELLA^a (A) and Study 552^b (B)



^aFigure adapted from Olawaiye AB, et al. *Lancet*. 2025. ^bFigure adapted from Colombo N, et al. *J Clin Oncol*. 2023.

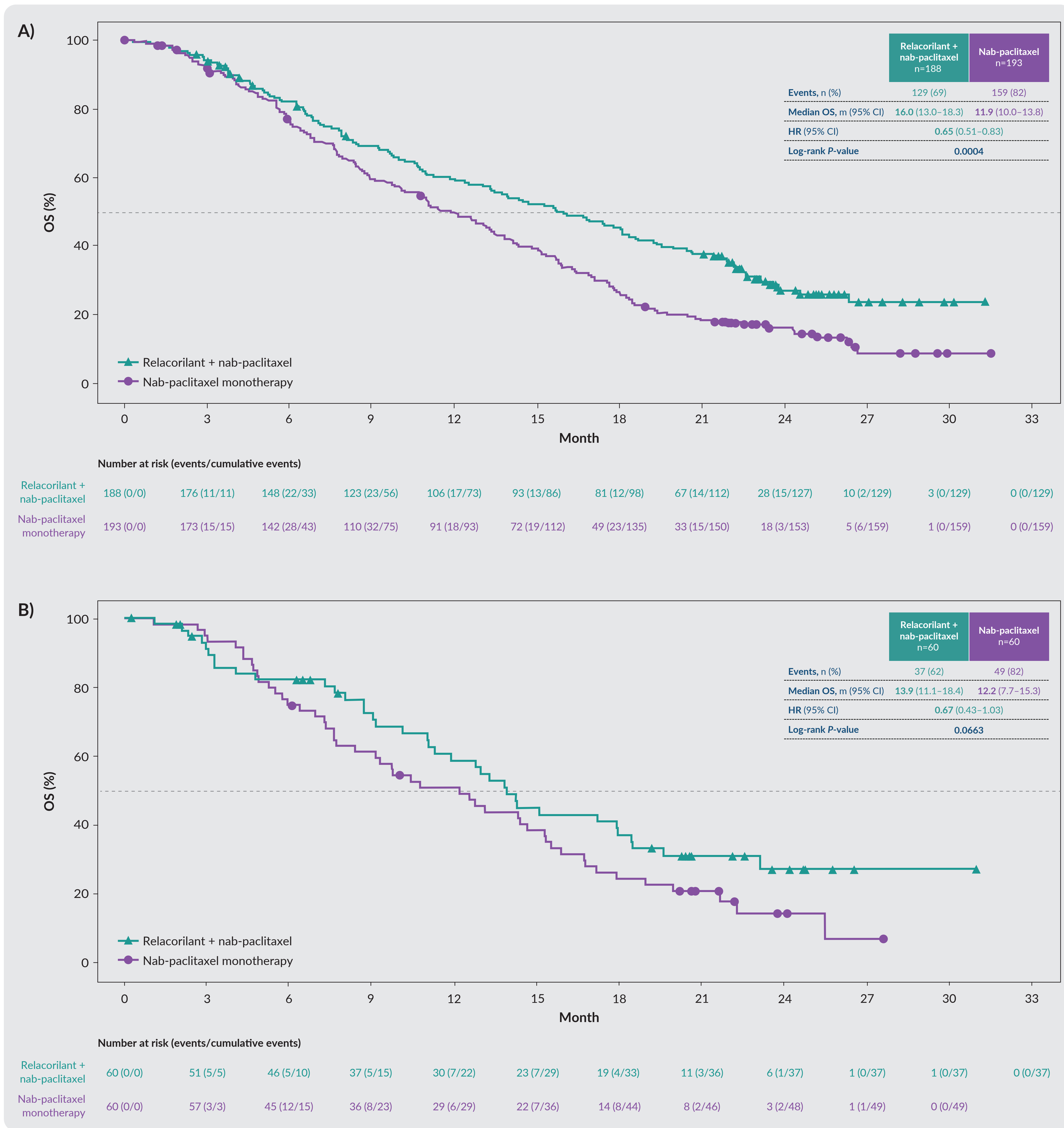
CI, confidence interval; HR, hazard ratio; m, months; PFS, progression-free survival.

RESULTS

Efficacy Meta-analysis

- Concordant with results from the individual studies (Figure 3), the efficacy meta-analysis showed that adding relacorilant to nab-paclitaxel led to significant improvement in OS (log-rank P=0.0001)
- There was no significant heterogeneity between the 2 studies (Cochran's Q test: P=0.93)

Figure 3. OS in ROSELLA^a (A) and Study 552^b (B)



^aFigure adapted from Lorusso D, et al. *Lancet*. 2026. ^bFigure adapted from Colombo N, et al. *J Clin Oncol*. 2023.

CI, confidence interval; HR, hazard ratio; m, months; OS, overall survival.

Safety Pooled Analysis

- In the pooled analysis for safety, the most common AEs were similar between groups and consistent with the known safety profile of nab-paclitaxel ± relacorilant
- Higher AE frequency in the pooled analysis for relacorilant + nab-paclitaxel is partly explained by the 38% longer median nab-paclitaxel treatment duration vs nab-paclitaxel alone, as measured in the pooled analysis
- Full results of the pooled safety analysis from ROSELLA and Study 552 are presented separately (Olawaiye et al. ESMO 2026 Poster #1264P)

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Presenter Disclosure

Alexander Olawaiye reports financial relationships with AstraZeneca, Corcept, Daiichi Sankyo, Eisai, Eli Lilly, Foundation Medicine, GSK, and Merck.

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