

Pooled Safety Analysis of Relacorilant Plus Nab-paclitaxel in Patients With Platinum-resistant Ovarian Cancer Enrolled to ROSELLA and Study 552

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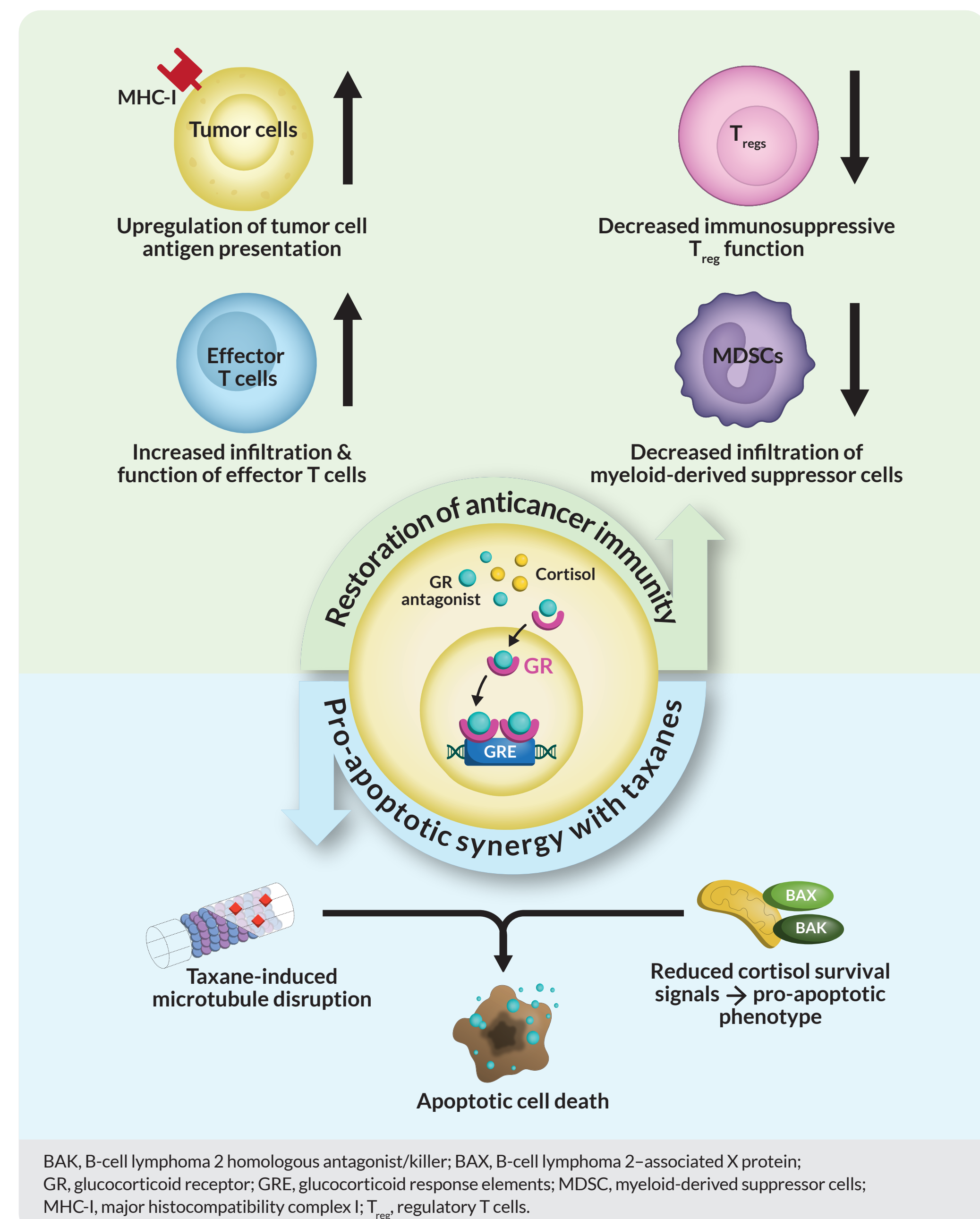
SUMMARY AND CONCLUSIONS

- This pooled analysis of 2 randomized, controlled studies provides further evidence of the manageable safety profile of relacorilant + nab-paclitaxel, supporting this combination as a new treatment option for patients with platinum-resistant ovarian cancer
- The most common treatment-emergent adverse events (AEs) experienced by patients were similar between studies
- Neutropenia risk should be managed according to established supportive care measures, including primary prophylaxis with granulocyte colony-stimulating factor, for patients at high risk, consistent with the American Society for Clinical Oncology 2026 guidelines
- Grade ≥ 3 and serious AEs generally were consistent with the expected complications from underlying ovarian cancer or the known safety profile of nab-paclitaxel
- The higher proportion of patients with grade ≥ 3 and serious AEs with relacorilant + nab-paclitaxel vs nab-paclitaxel monotherapy in the pooled analysis was consistent with the longer duration of nab-paclitaxel exposure in the combination group
- No new safety signals were identified in the pooled analysis when compared with the known safety profile of nab-paclitaxel

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 phase 2 Study 552⁹⁻¹¹
- To further characterize the safety profile of relacorilant in combination with nab-paclitaxel in patients with PROC, we conducted a pooled analysis of safety data from these trials

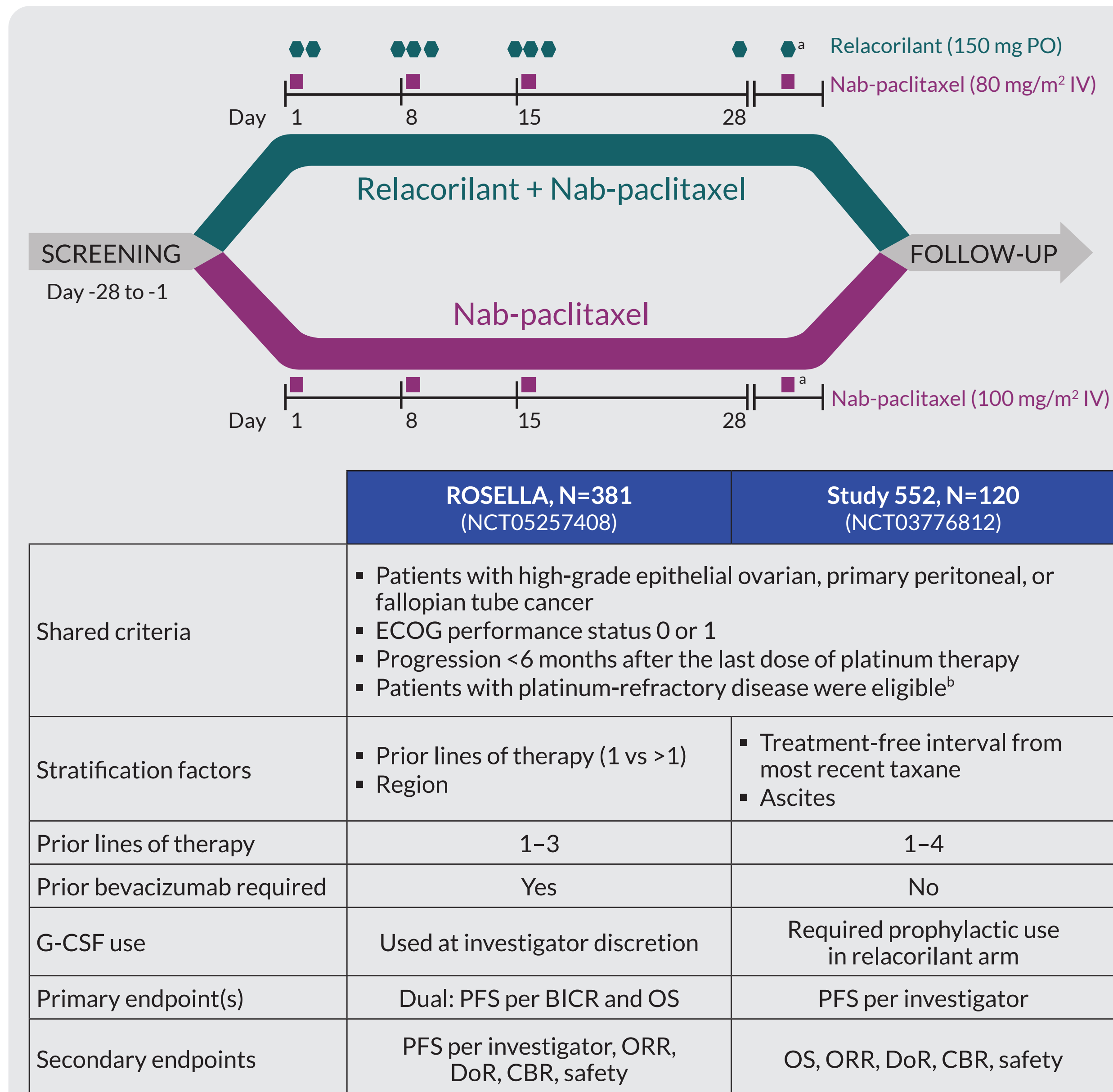
Figure 1. Mechanisms of Action of GR Antagonism⁵⁻⁷



METHODS

- ROSELLA and Study 552 were randomized, controlled studies of similar design in patients with PROC (Figure 2)
- Adverse event (AE) management guidance was similar, except primary prophylaxis with granulocyte colony-stimulating factor (G-CSF) was required with relacorilant + nab-paclitaxel in Study 552 but used at investigator discretion in ROSELLA
- For this safety analysis, data from the corresponding intermittent relacorilant + nab-paclitaxel arms and nab-paclitaxel monotherapy arms of both studies were combined
- The regimen is identical to the one approved by the US Food and Drug Administration¹²
- The population included all randomized patients in the intent-to-treat population who received ≥ 1 dose of study treatment
- Safety outcomes in the pooled analysis included treatment-emergent AEs; serious AEs (SAEs); grade ≥ 3 AEs; and AEs leading to treatment interruption, discontinuation, or death
- AEs were coded using the Medical Dictionary for Regulatory Activities version 27.0
- Results for a meta-analysis of efficacy outcomes from ROSELLA and Study 552 are presented separately (Olawaiye et al. ESMO 2026 Poster #1263P)

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 cycles: *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.

RESULTS

Summary of AEs

- The pooled analysis included 498 patients (relacorilant + nab-paclitaxel, n=248; nab-paclitaxel, n=250)
- Grade ≥ 3 and SAE frequencies were higher for relacorilant + nab-paclitaxel vs nab-paclitaxel monotherapy (Table 1)
- Higher grade ≥ 3 and SAE frequencies for relacorilant + nab-paclitaxel are partly explained by the 38% longer median treatment duration vs nab-paclitaxel alone, as measured in the pooled analysis

Table 1. Summary of Safety Outcomes in Study ROSELLA, Study 552, and the Pooled Analysis

	ROSELLA		Study 552		Pooled	
	Relacorilant + nab-paclitaxel (n=188)	Nab-paclitaxel monotherapy (n=190)	Relacorilant + nab-paclitaxel (n=60)	Nab-paclitaxel monotherapy (n=60)	Relacorilant + nab-paclitaxel (n=248)	Nab-paclitaxel monotherapy (n=250)
Median duration of study drug treatment, months	4.7	3.5	5.1	3.5	4.9	3.5
Any AEs, n (%)	188 (100)	189 (99.5)	60 (100)	60 (100)	248 (100)	249 (99.6)
Grade ≥ 3 AEs, n (%)	141 (75.0)	113 (59.5)	33 (55.0)	28 (46.7)	174 (70.2)	141 (56.4)
SAEs, n (%)	66 (35.1)	45 (23.7)	15 (25.0)	18 (30.0)	81 (32.7)	63 (25.2)
Dose reductions of relacorilant due to AEs, n (%)	14 (7.4)	NA	6 (10.0)	NA	20 (8.1)	NA
Dose reductions of nab-paclitaxel due to AEs, n (%)	91 (48.4)	60 (31.6)	20 (33.3)	20 (33.3)	111 (44.8)	80 (32.0)
Interruptions of relacorilant (+ nab-paclitaxel) due to AEs, n (%) ^a	138 (73.4)	NA	26 (43.3)	NA	164 (66.1)	NA
Interruptions of nab-paclitaxel due to AEs, n (%)	137 (72.9)	105 (55.3)	25 (41.7)	23 (38.3)	162 (65.3)	128 (51.2)
Discontinuations of relacorilant (+ nab-paclitaxel) due to AEs, n (%) ^a	19 (10.1)	NA	10 (16.7)	NA	29 (11.7)	NA
Discontinuations of nab-paclitaxel due to AEs, n (%)	18 (9.6)	15 (7.9)	11 (18.3)	3 (5.0)	29 (11.7)	18 (7.2)
AEs leading to death, n (%)	4 (2.1)	0	1 (1.7)	0	5 (2.0)	0

^aIn both studies, patients in the relacorilant + nab-paclitaxel arms who interrupted or discontinued nab-paclitaxel were also required to interrupt or discontinue relacorilant. AE, treatment-emergent adverse event; NA, not applicable; SAE, treatment-emergent serious adverse event.

Most Common AEs

- The most common AEs were similar between groups and consistent with the established safety profile of nab-paclitaxel with and without relacorilant (Figure 3A and B)

Figure 3A. Pooled Analysis of the Most Common AEs of Any Grade ($\geq 10\%$) and Grade ≥ 3 by Preferred Term

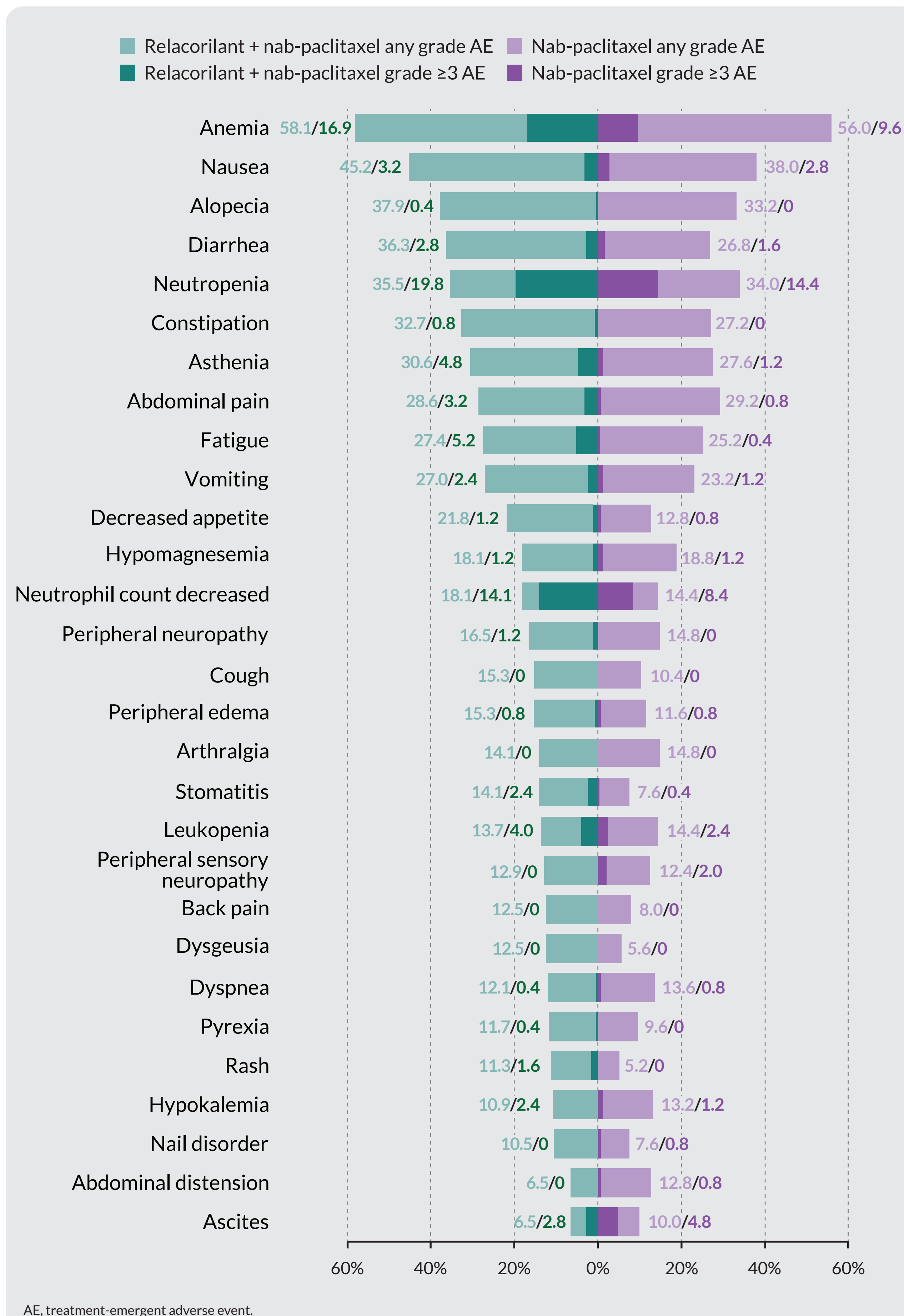
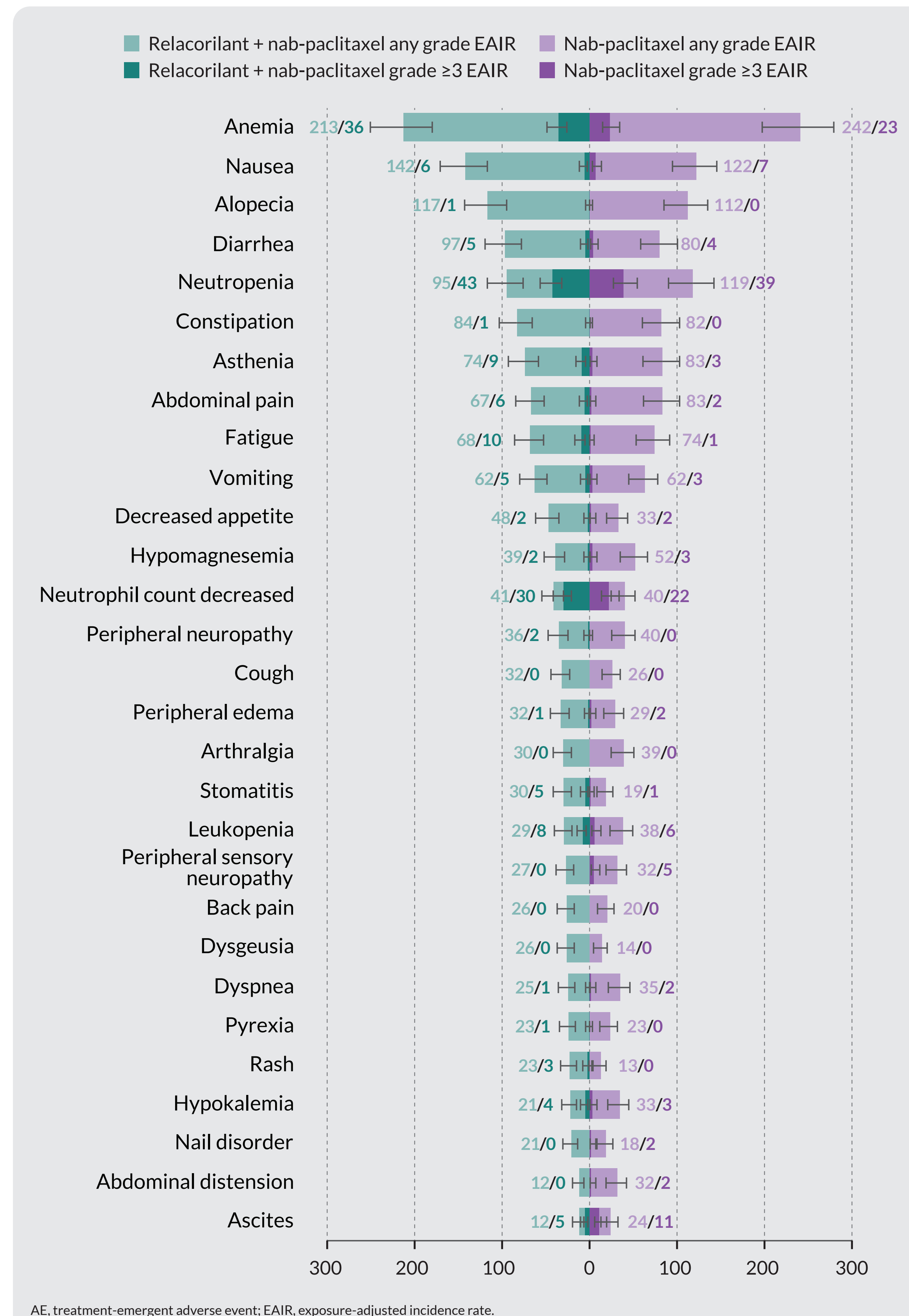


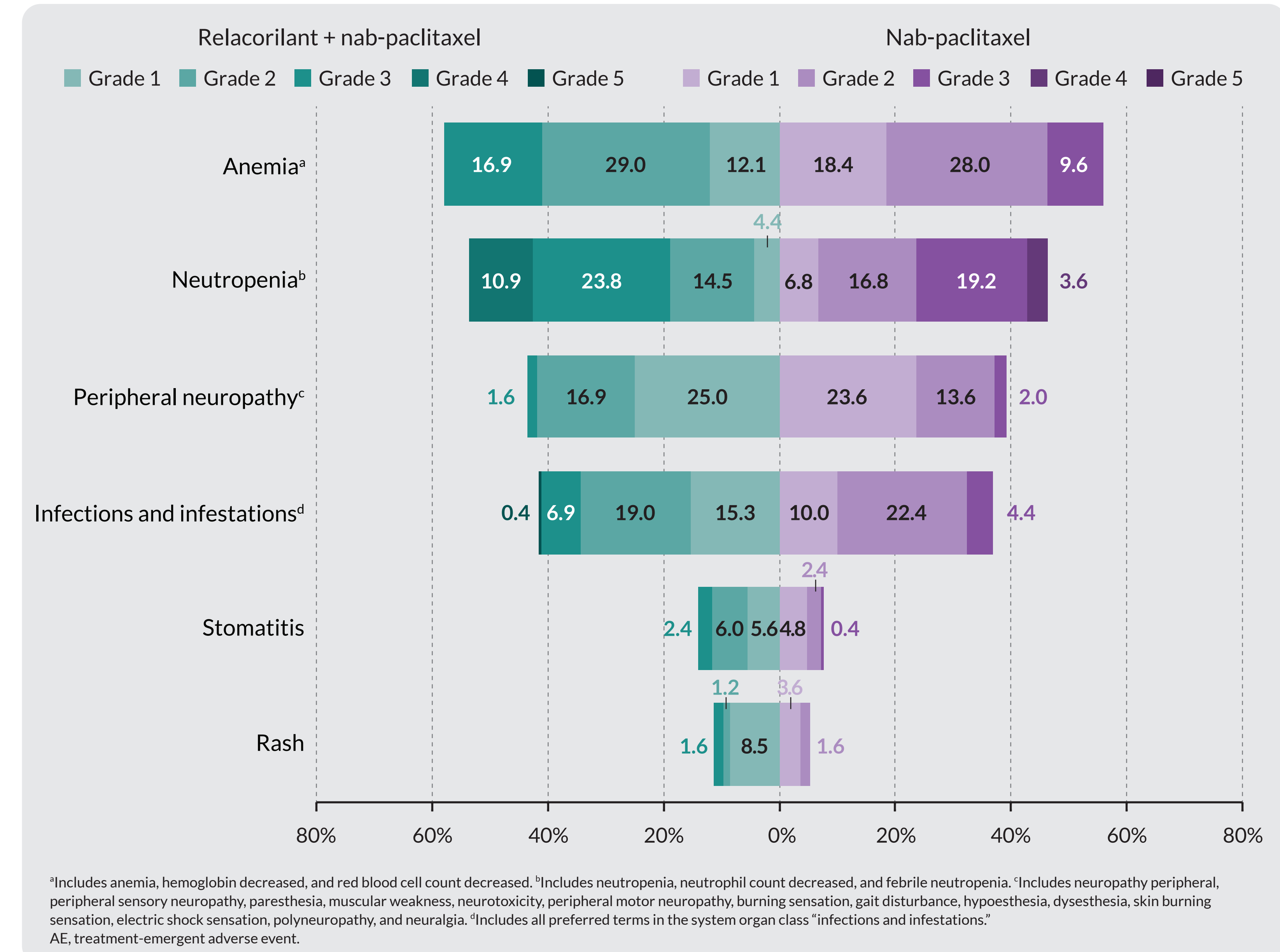
Figure 3B. Pooled Analysis of the Exposure-adjusted Incidence Rate of the Most Common AEs



Selected Safety Topics of Interest

- Selected AEs of interest are shown in Figure 4
- There were no cases of excessive GR antagonism or adrenal insufficiency

Figure 4. Analysis of Selected Safety Topics



- Higher rates of any grade and grade ≥ 3 neutropenia were observed with relacorilant + nab-paclitaxel in ROSELLA (64.4% and 43.6%, respectively) vs Study 552 (20.0% and 6.7%, respectively)
- Most patients (55.3%) treated with relacorilant + nab-paclitaxel in ROSELLA did not require or receive G-CSF
- In Study 552, prophylactic use of G-CSF was required in patients who received relacorilant
- The frequency of liver function test abnormalities was low in both treatment arms (Table 2)

Table 2. Summary of Liver Function Test Abnormalities in the Pooled Analysis.^a

	Relacorilant + nab-paclitaxel (n=248)	Nab-paclitaxel monotherapy (n=250)
ALT or AST increase, n (%)		
>3 × ULN	3 (1.2)	17 (6.8)
>5 × ULN	5 (2.0)	3 (1.2)
>8 × ULN	2 (0.8)	1 (0.4)
>10 × ULN	1 (0.4)	2 (0.8)
Total bilirubin increase, n (%)		
>2 × ULN	3 (1.2)	4 (1.6)
ALP increase, n (%)		
>2 × ULN	19 (7.7)	30 (12.0)

^aPatients are counted once based on the most severe post-baseline value. ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ULN, upper limit of normal.

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Presenter Disclosure

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

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