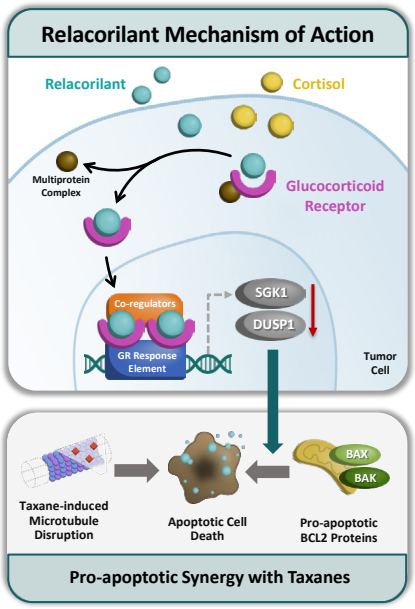
ROSELLA
Relacorilant with Nab-paclitaxel in Ovarian Cancer

Relacorilant and nab-paclitaxel in patients with platinum-resistant ovarian cancer: a phase 3, randomized, controlled, open-label trial

The Phase 3 ROSELLA Study | Background

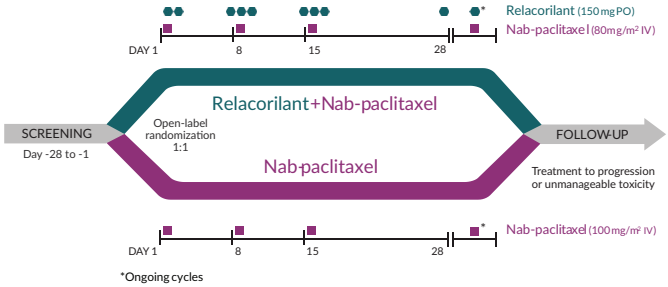
- Patients with platinum-resistant ovarian cancer have a median overall survival of approximately one year and need new treatments[1]
- Ovarian cancers express the glucocorticoid receptor (GR)[2]
- Expression of GR is associated with poor prognosis[2]
- GR signaling reduces sensitivity to chemotherapy[3,4]
- **Relacorilant** is a novel, selective GR antagonist (SGRA) that restores the sensitivity of cancers to cytotoxic chemotherapy[3,5,6]
- In a phase 2 trial, the addition of relacorilant to nab-paclitaxel in patients with platinum-resistant ovarian cancer extended progression-free and showed a trend to improved overall survival[7]



Study Design

Population

- Epithelial ovarian, primary peritoneal or fallopian tube cancer
- ECOG 0 or 1
- Progression <6 m after last dose of platinum therapy
- 1–3 prior lines of therapy
- Must have received prior bevacizumab



Stratification Factors
- Prior lines of therapy (1 vs >1)
- Region (North America vs Europe vs Korea, Australia, & Latin America)

Dual 1° endpoints

- Progression-free survival per BICR
- Overall survival

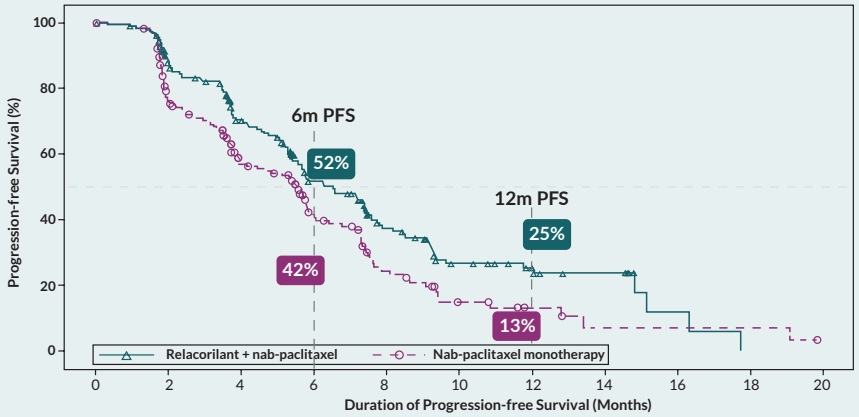
Key 2° endpoints

- Progression-free survival per Investigator
- Objective response rate, duration of response, and clinical benefit rate

ROSELLA Met the Primary Efficacy Endpoint (Progression-free Surival by BICR)

	Relacorilant + nab-paclitaxel N=188	Nab-paclitaxel N=193
Events, n (%)	113 (60.1)	121 (62.7)
Median PFS, m (95% CI)	6.54 (5.55–7.43)	5.52 (3.94–5.88)
HR (95% CI)	0.70 (0.54–0.91)	
	P=0.0076 (Log-rank Test)	

- Progression-free survival by blinded independent central review and by Investigator were consistent
- Consistent progression-free survival improvements were observed across key subgroups, including those with poor prognosis



No. at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	188 (0/0)	151 (22/22)	109 (29/51)	70 (27/78)	43 (18/96)	24 (11/107)	16 (1/108)	11 (1/109)	2 (2/111)	0 (2/113)
Nab-paclitaxel monotherapy	193 (0/0)	129 (42/42)	85 (31/73)	47 (20/93)	21 (17/110)	9 (7/117)	5 (1/118)	2 (2/120)	2 (0/120)	2 (0/120)	0 (1/121)

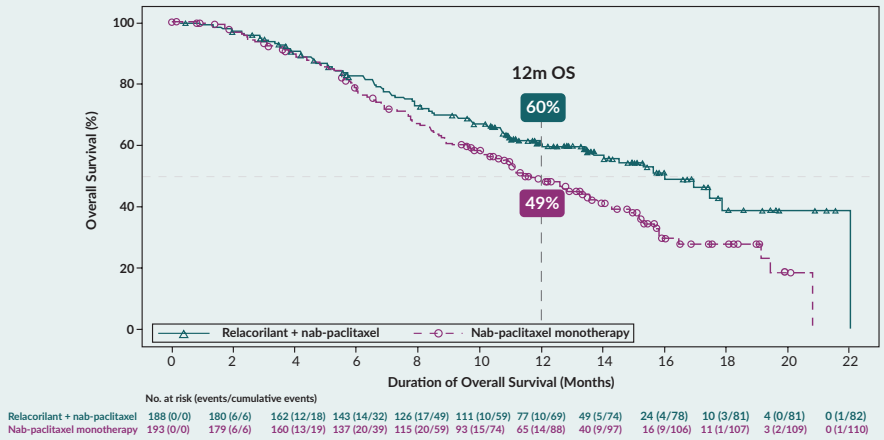
Abbreviations: BICR, blinded independent central review; CI, confidence interval; ECOG, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; IV, intravenous; PFS, progression-free survival; PO, oral; OS, overall survival.

Improvement in Overall Survival Observed at this Interim Analysis (Dual Primary Endpoint)

	Relacorilant + nab-paclitaxel N=188	Nab-paclitaxel N=193
Events, n (%)	82 (43.6)	110 (57.0)
Median OS, m (95% CI)	**15.97** (13.47–NR)	**11.50** (10.02–13.57)
HR (95% CI)	**0.69** (0.52–0.92)	

Nominal P=0.0121 (Log-rank Test)

- Consistent overall survival improvements were observed across key subgroups, including those with poor prognosis

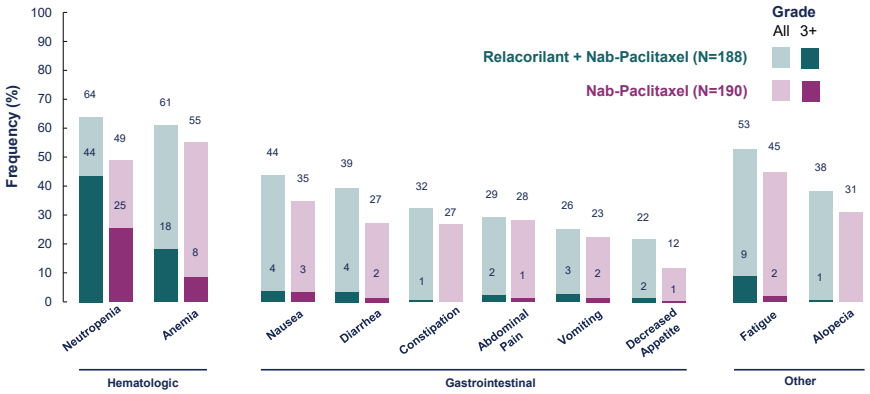


No. at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	188 (0/0)	180 (6/6)	162 (12/18)	143 (14/32)	126 (17/49)	111 (10/59)	77 (10/69)	49 (5/74)	24 (4/78)	10 (3/81)	4 (0/81)	0 (1/82)
Nab-paclitaxel monotherapy	193 (0/0)	179 (6/6)	160 (13/19)	137 (20/39)	115 (20/59)	93 (15/74)	65 (14/88)	40 (9/97)	16 (9/106)	11 (1/107)	3 (2/109)	0 (1/110)

The Safety Profile of Relacorilant + Nab-paclitaxel Was Manageable

- Relacorilant dosing compliance was high (median relative dose intensity [% of planned], 92%)
- The combination arm had a 30% longer median treatment duration with nab-paclitaxel compared to the monotherapy arm
- When adjusted for duration of exposure, the incidence rates of neutropenia and anemia were comparable between study arms
- Ascites was less frequent in the combination arm when adjusted for duration of exposure
- Discontinuations due to adverse events were infrequent in the combination (9.0%) and monotherapy (7.9%) arms



ROSELLA | Conclusions

- Relacorilant is an oral, selective glucocorticoid receptor antagonist (SGRA) in development for the treatment of patients with cancer
- ROSELLA met its primary endpoint: The addition of relacorilant to nab-paclitaxel extended progression-free survival assessed by BICR (log-rank P=0.0076; HR 0.70), in patients with platinum-resistant ovarian cancer, in a population including patients who progressed within 1–3 months after their primary platinum regimen
- At this interim overall survival analysis, the addition of relacorilant to nab-paclitaxel showed a clinically meaningful improvement in overall survival (nominal log-rank P=0.0121, HR 0.69, median 16.0 vs 11.5 months)
- Relacorilant plus nab-paclitaxel was well-tolerated, with a favorable safety profile that was comparable between treatment arms when adjusted for duration of exposure. The safety profile was consistent with previously reported data; no new safety signals were identified

Abbreviations: BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; OS, overall survival; SGRA, selective glucocorticoid receptor antagonist

Further information

- This plain-language summary covers the presentation by A. Olawaiye et al. presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, IL, May 30–June 3, 2025; Abstract number: LBA5507.
- The first and senior authors have reviewed and approved this content.
- This study was registered at www.clinicaltrials.gov under trial ID NCT05257408.

References

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