ANNUAL MEETING ON WOMEN'S CANCER

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SAN JUAN, PR | APRIL 10-13, 2026 | WWW.SGO.ORG

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APRIL 10-13, 2026

Financial Disclosure for:
Dr. Alexander B. Olawaiye

I have the following financial relationships with ACCME defined ineligible companies to report over the past 24 months:

AstraZeneca, Foundation Medicine, GSK, Merck, Daiichi Sankyo, Eisai, Corcept, and Eli Lilly

Unlabeled/Investigational Uses

Relacorilant in combination with nab-paclitaxel is FDA-approved as a treatment option for patients with platinum-resistant ovarian cancer, who have received 1–3 prior lines of therapy, including bevacizumab.

This presentation may include data that are not included in the approved Prescribing Information for relacorilant. These data are provided for scientific exchange purposes only.

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Final Overall Survival Results From the Phase 3 ROSELLA Trial: Relacorilant Plus Nab-Paclitaxel vs Nab-Paclitaxel Monotherapy in Patients With Platinum-Resistant Ovarian Cancer

(GOG-3073, ENGOT-ov72, APGOT-Ov10, LACOG-0223, and ANZGOG-2221/2023)

Alexander B Olawaiye,[1] Stanislas Quesada, Lucy Gilbert, Jae-Weon Kim, Mariana Scaranti, Elena Giudice, Elizabeth Hopp, Linda Mileshkin, Toon Van Gorp, Michael E McCollum, Ana Oaknin, Aliza L Leiser, Philippe Follana, Chiara Cassani, Boglárka Balázs, Andrew Clamp, Hristina I. Pashova, Sachin G Pai, Nicoletta Colombo and Domenica Lorusso

[1]University of Pittsburgh School of Medicine and UPMC Magee-Women's Hospital, Gynecologic Oncology Group, Pittsburgh, PA, USA.

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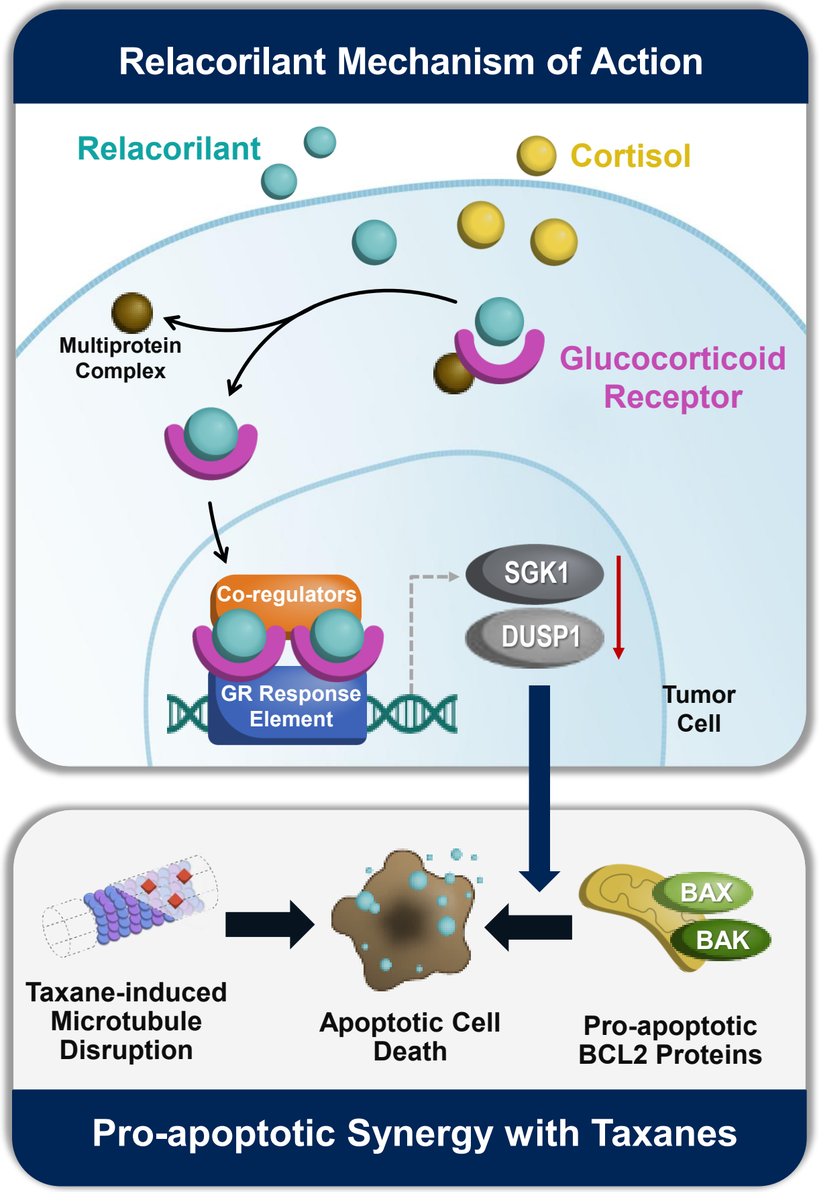
In collaboration with:

GOG FOUNDATION Transforming the standard of care
ENGOT European Network of Gynaecological Oncological Trial groups
APGOT Asia-Pacific Gynecologic Oncology Trials Group
LACOG LATIN AMERICAN COOPERATIVE ONCOLOGY GROUP
ANZGOG

Background

- Patients with platinum-resistant ovarian cancer have an overall survival of ~1 year and need new treatments[1]
- Ovarian cancers express the glucocorticoid receptor (GR), a marker of 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]



1. Martorana, et al. *Int J Gynecol Cancer*. 2025;35(1):100009. 2. Veneris, et al. *Gynecol Oncol*. 2017;146(1):153-60.
3. Greenstein, et al. *Oncotarget*. 2021;12(13):1243-55. 4. Melhelm, et al. *Clin Cancer Res*. 2009;15(9):3196-3204.
5. Stringer-Reasor, et al. *Gynecol Oncol*. 2015;138(3):656-62.6. Munster, et al. *Clin Cancer Res*. 2022;28(15):3214-24.

Relacorilant Oncology Development Timeline

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Nab-paclitaxel is one of the most efficacious therapies in patients with platinum-resistant ovarian cancer;[1-3] as it does not require steroid pretreatment, it is a rational partner for relacorilant

May 2020

Phase 1/2 Dose Finding[4]

A study of relacorilant in combination with nab-paclitaxel in advanced solid tumors

Mar 2021

Phase 2 Platinum-resistant Ovarian Cancer[2]

A randomized controlled trial of two dose regimens of relacorilant & nab-paclitaxel

The addition of intermittently dosed relacorilant to nab-paclitaxel extended progression-free survival (HR 0.66, P=0.038) and showed a trend to improved overall survival (HR 0.67, P=0.066)

Feb 2025
Primary Analysis

Jan 2026
Final OS

ROSELLA Phase 3[5]

A positive trial of relacorilant plus nab-paclitaxel in patients with platinum-resistant ovarian cancer that met both dual primary endpoints of progression-free and overall survival

Mar 2026
FDA approval*

Here we present the final overall survival results from ROSELLA

*Relacorilant (Lifyorli) in combination with nab-paclitaxel was approved in the USA on Mar 25, 2026 as a treatment option for patients with platinum-resistant ovarian cancer, who have received 1–3 prior lines of therapy, including bevacizumab.

1. Martorana F, et al. *Int J Gynecol Cancer.* 2025;35:100009. 2. Colombo, et al. *J Clin Oncol.* 2023;41(30):4779-89. 3. Coleman RL, et al. *Gynecol Oncol.* 2011;122:111-15. 4. Munster, et al. *Clin Cancer Res.* 2022;28(15):3214-24. 5. Olawaiye, et al. *Lancet.* 2025; 405(10496):2205-2216.

HR, hazard ratio; OS, overall survival.

ROSELLA | Study Schema

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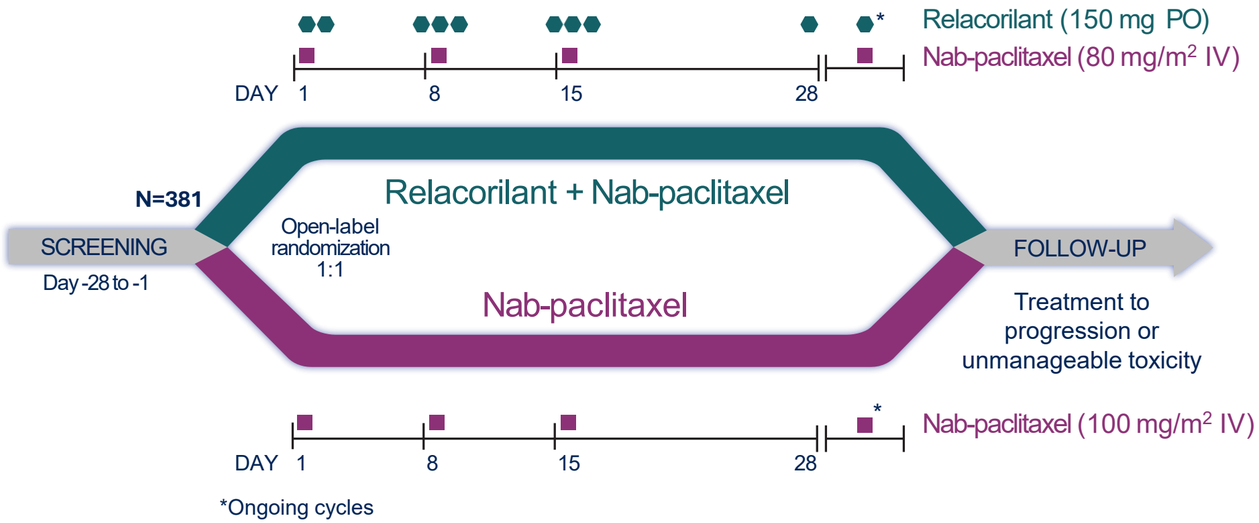
Population

- Epithelial ovarian, primary peritoneal, or fallopian tube cancer
- ECOG performance status 0 or 1
- Progression <6 months after the last dose of platinum therapy (excluding no response to, or progression in <1 month of primary platinum)
- 1–3 prior lines of therapy
- Prior bevacizumab required

NCT05257408



Stratification Factors

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

Dual Primary Endpoints

- Progression-free survival (PFS) by RECIST v1.1 per blinded independent central review
- Overall survival (OS)

Secondary Endpoints

- PFS by RECIST v1.1 per Investigator
- ORR, DoR, CBR (RECIST v1.1)
- Response by CA-125 GCIG criteria
- Combined response (RECIST v1.1 and CA-125 GCIG criteria)
- Safety

First patient enrolled: Jan 5, 2023
Last patient enrolled: Apr 8, 2024
Primary results data cutoff: Feb 24, 2025
Final OS data cutoff: Jan 8, 2026
Conducted at 117 sites in 14 countries.

CA, cancer antigen; CBR, clinical benefit rate; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; GCIG, Gynecologic Cancer Intergroup; IV, intravenous; ORR, objective response rate; PO, by mouth; RECIST, Response Evaluation Criteria in Solid Tumors.

ROSELLA | Baseline Characteristics Were Well Balanced

		Relacorilant + Nab-paclitaxel (N=188)	Nab-paclitaxel (N=193)
Age, median (range), years		**61** (26–85)	**62** (33–86)
Race, n (%)	White Black or African-American Asian (92% Korean) Other / Not Reported	136 **(72.3)** 3 **(1.6)** 22 **(11.7)** 27 **(14.4)**	135 **(69.9)** 2 **(1.0)** 26 **(13.5)** 30 **(15.5)**
Ethnicity, n (%)	Hispanic	16 **(8.5)**	17 **(8.8)**
Region	North America Europe Korea, Australia, and Latin America	45 **(23.9)** 107 **(56.9)** 36 **(19.1)**	45 **(23.3)** 109 **(56.5)** 39 **(20.2)**
ECOG Performance Status, n (%)*	1 or 2	53 **(28.2)**	63 **(32.6)**
BRCA1/2 Mutation, n (%)	Yes	23 **(12.2)**	24 **(12.4)**
Prior Lines of Therapy, n (%)	1 2 3	15 **(8.0)** 92 **(48.9)** 81 **(43.1)**	18 **(9.3)** 89 **(46.1)** 86 **(44.6)**
Primary Platinum Refractory, n (%)†	Yes	13 **(6.9)**	13 **(6.7)**
Prior Lines of Therapy in the Platinum-resistant Setting, n (%)	≥1	67 **(35.6)**	82 **(42.5)**
Prior Taxane in the Platinum-resistant Setting, n (%)	Yes	8 **(4.3)**	7 **(3.6)**
Prior Therapies, n (%)	Bevacizumab Taxanes Pegylated Liposomal Doxorubicin PARP Inhibitor	188 **(100)** 187 **(99.5)** 121 **(64.4)** 114 **(60.6)**	193 **(100)** 192 **(99.5)** 125 **(64.8)** 120 **(62.2)**

*In the nab-paclitaxel monotherapy arm, 1 patient had an ECOG performance status of 2. †Progressed within 3 months of the last dose of platinum from their first line platinum regimen. 97% of patients had high-grade serous carcinoma; 8 patients had high-grade endometrioid carcinoma and 2 patients had carcinosarcoma. BRCA, Breast Cancer Gene; ECOG, Eastern Cooperative Oncology Group; PARP, poly(ADP-ribose) polymerase.

Data cutoff: Feb 24, 2025

ROSELLA | Relacorilant Significantly Improved Progression-Free Survival Assessed by Blinded Review at the Primary Analysis

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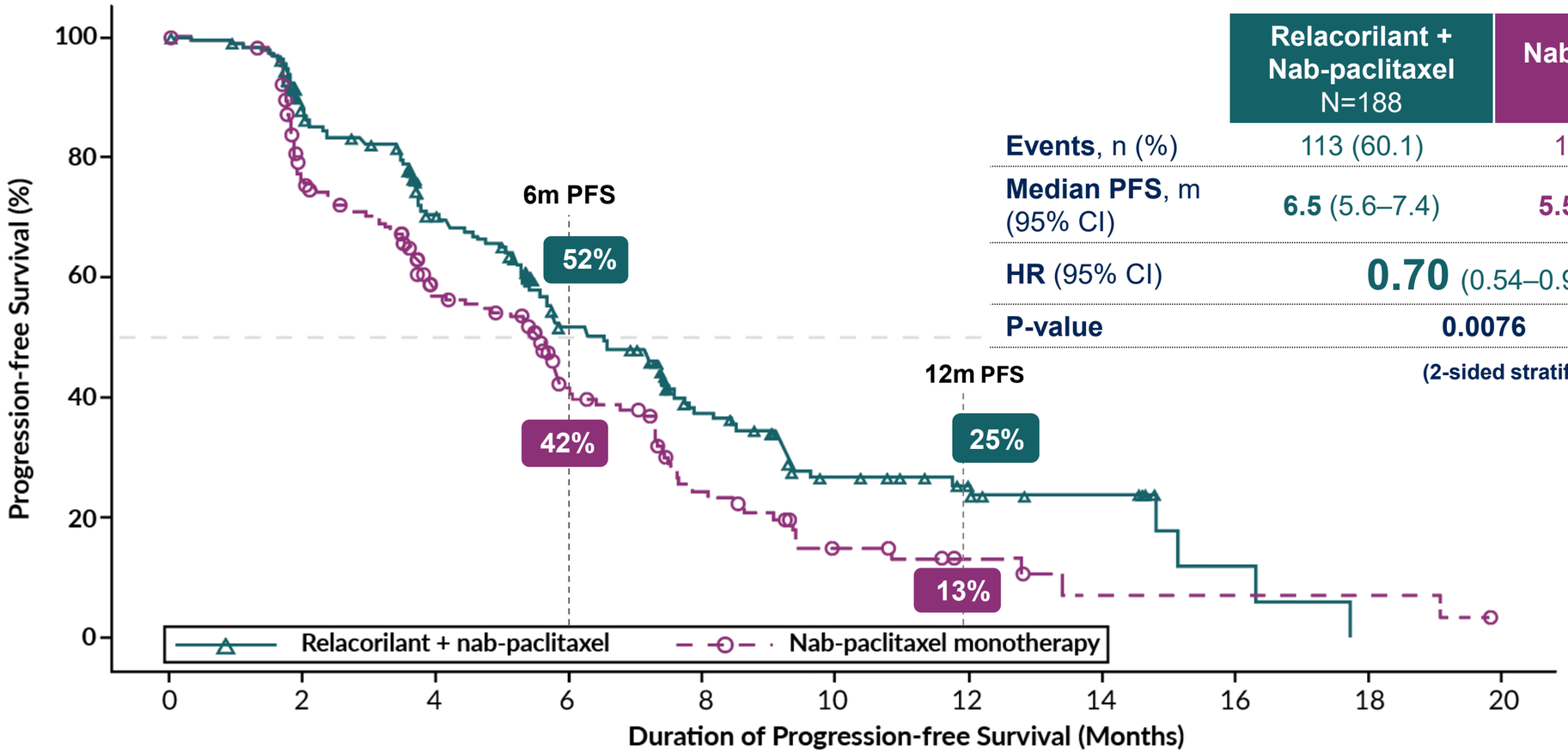


	Relacorilant + Nab-paclitaxel N=188	Nab-paclitaxel N=193
Events, n (%)	113 (60.1)	121 (62.7)
Median PFS, m (95% CI)	**6.5** (5.6–7.4)	**5.5** (3.9–5.9)
HR (95% CI)	**0.70** (0.54–0.91)	
P-value	**0.0076**	

(2-sided stratified log-rank test)

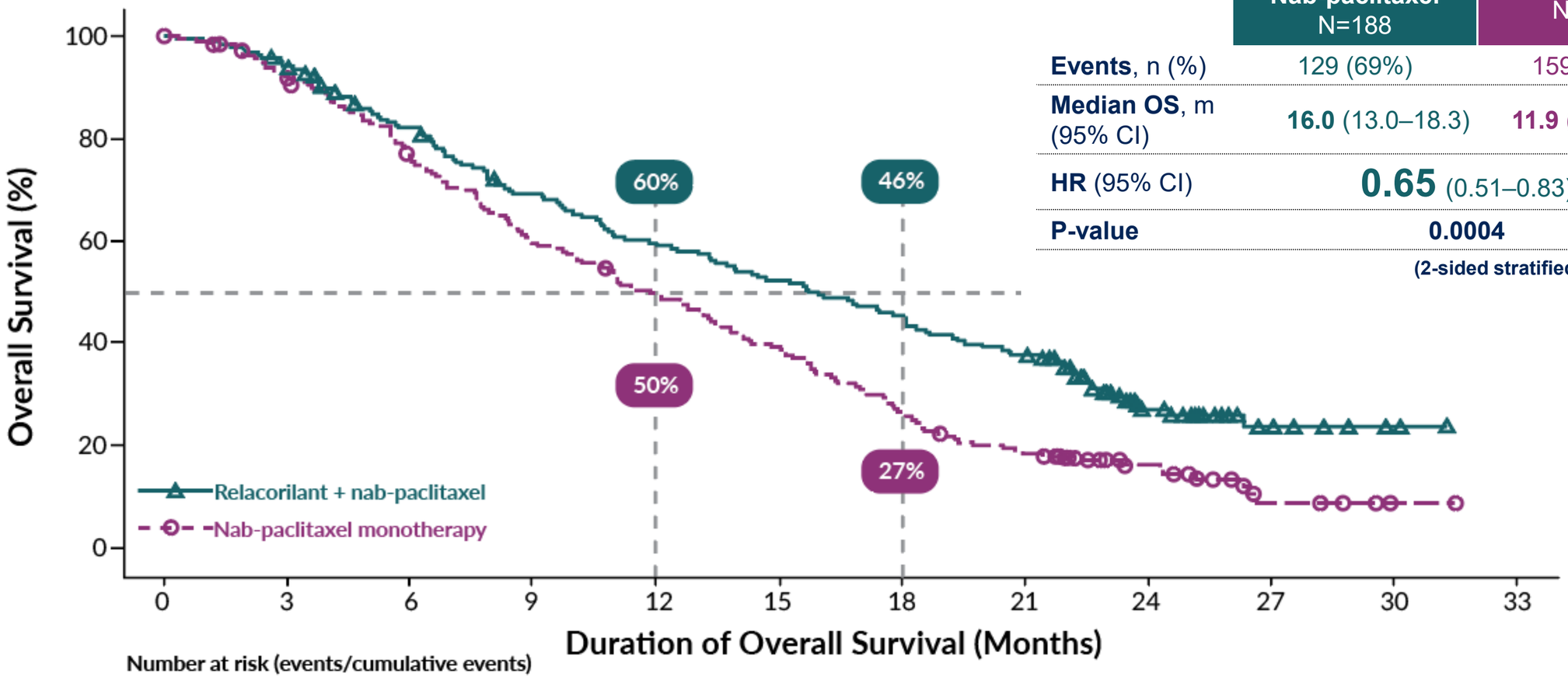
No. at risk (events/cumulative events)

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)

Median follow-up time: 9.0 months; statistical significance threshold: P≤0.04. The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% CIs for progression-free survival in each treatment arm. The HR and the associated 95% CI were estimated using a Cox regression model with treatment group as the main effect and stratification factors at randomization as covariates.
CI, confidence interval; HR, hazard ratio; m, months; PFS, progression-free survival.

Data cutoff: Feb 24, 2025

ROSELLA | Relacorilant Significantly Improved Overall Survival at the Final Analysis



	Relacorilant + Nab-paclitaxel N=188	Nab-paclitaxel N=193
Events, n (%)	129 (69%)	159 (82%)
Median OS, m (95% CI)	**16.0** (13.0–18.3)	**11.9** (10.0–13.8)
HR (95% CI)	**0.65** (0.51–0.83)	
P-value	**0.0004**	

(2-sided stratified log-rank test)

76% maturity

Number at risk (events/cumulative events)

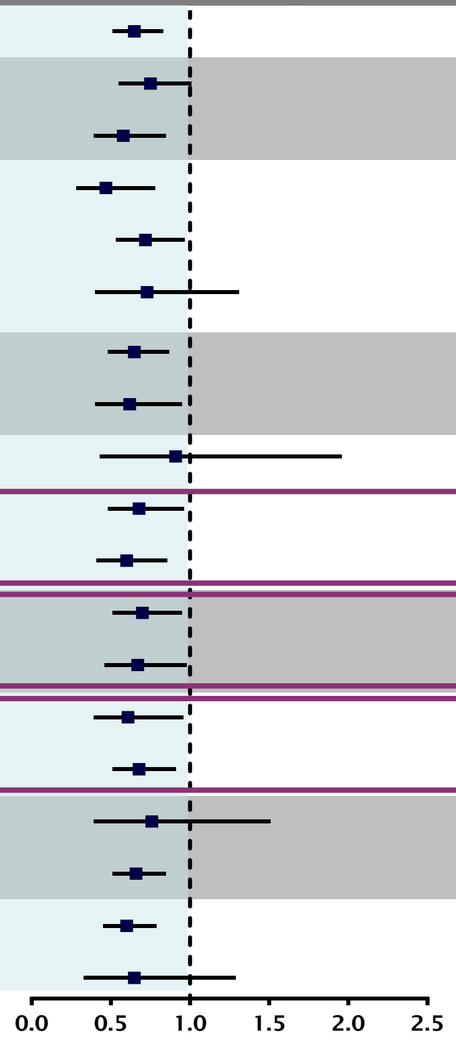
Relacorilant + nab-paclitaxel	188 (0/0)	176 (11/11)	148 (22/33)	123 (23/56)	106 (17/73)	93 (13/86)	81 (12/98)	67 (14/112)	28 (15/127)	10 (2/129)	3 (0/129)	0 (0/129)
Nab-paclitaxel monotherapy	193 (0/0)	173 (15/15)	142 (28/43)	110 (32/75)	91 (18/93)	72 (19/112)	49 (23/135)	33 (15/150)	18 (3/153)	5 (6/159)	1 (0/159)	0 (0/159)

Median follow-up time: 24.8 months; statistical significance threshold at the final analysis: P≤0.0499. The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% CIs for OS in each treatment arm. The HR and the associated 95% CI were estimated using a Cox regression model with treatment group as the main effect and stratification factors at randomization as covariates.
CI, confidence interval; HR, hazard ratio; m, months; OS, overall survival.

Data cutoff: Jan 8, 2026

ROSELLA | Relacorilant Improved Overall Survival Across Key Subgroups

Subgroup		Patients, n	Events, n	Hazard Ratio (95% CI)
All Patients		381	288	0.65 (0.51–0.83)
Age	<65 years	229	172	0.75 (0.55–1.01)
	≥65 years	152	116	0.58 (0.39–0.85)
Region	North America	90	71	0.47 (0.28–0.78)
	Europe	216	169	0.72 (0.53–0.97)
	Korea, Australia, Latin America	75	48	0.73 (0.40–1.31)
ECOG Performance Status	0	262	189	0.65 (0.48–0.87)
	1	115	97	0.62 (0.40–0.95)
Prior Lines of Therapy	1	33	30	0.91 (0.43–1.96)
	2	181	136	0.68 (0.48–0.96)
	3	167	122	0.60 (0.41–0.86)
Prior PARP Inhibitor	Yes	234	173	0.70 (0.51–0.95)
	No	147	115	0.67 (0.46–0.98)
Primary Platinum-free Interval	≤6 months	112	88	0.61 (0.39–0.96)
	>6 months	269	200	0.68 (0.51–0.91)
BRCA1/2 Mutation	Positive	47	40	0.76 (0.39–1.51)
	Negative / Unknown	334	248	0.66 (0.51–0.85)
Largest Target Lesion	<5 cm	299	221	0.60 (0.45–0.79)
	≥5 cm	45	37	0.65 (0.33–1.29)



BICR, blinded independent central review; BRCA, Breast Cancer Gene; CI, confidence interval; ECOG, Eastern Cooperative Oncology Group; OS, overall survival; PARP, poly(ADP-ribose) polymerase.

Data cutoff: Jan 8, 2026

ROSELLA | First and All Subsequent Therapies Were Well Balanced

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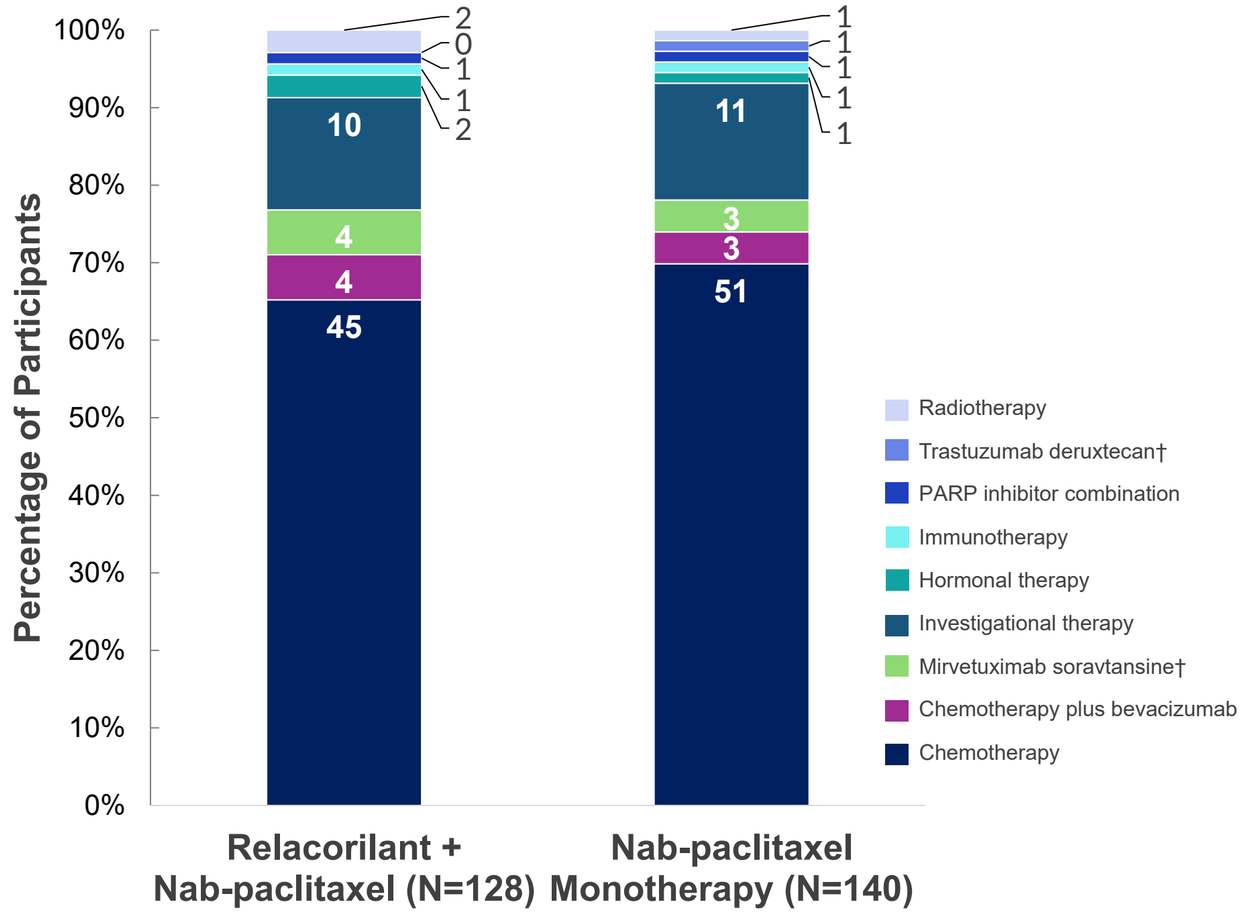
First Subsequent Anticancer Therapies*



All Subsequent Systemic Anticancer Therapies

	Relacorilant + Nab-paclitaxel (N=188)	Nab-paclitaxel Monotherapy (N=193)
Patients Receiving Subsequent Systemic Anticancer Therapies, n (%)	127 **(67.6)**	139 **(72.0)**
Gemcitabine	66 **(35.1)**	62 **(32.1)**
Pegylated Liposomal Doxorubicin	44 **(23.4)**	40 **(20.7)**
Investigational Antineoplastic Drugs	27 **(14.4)**	29 **(15.0)**
Carboplatin	28 **(14.9)**	25 **(13.0)**
Cyclophosphamide	26 **(13.8)**	23 **(11.9)**
Topotecan	18 **(9.6)**	25 **(13.0)**
Paclitaxel	18 **(9.6)**	21 **(10.9)**
Bevacizumab	17 **(9.0)**	12 **(6.2)**
Cisplatin	15 **(8.0)**	8 **(4.1)**
Mirvetuximab Soravtansine	12 **(6.4)**	11 **(5.7)**

*Shown is the first subsequent therapy received by patients who discontinued their assigned trial treatment and received subsequent therapy. Chemotherapy in the first subsequent regimen included both monotherapy and combination regimens. †Monotherapy or combination therapy.
PARP, poly(ADP-ribose) polymerase.

Data cutoff: Jan 8, 2026

ROSELLA | Safety Summary

Relacorilant + Nab-paclitaxel was Well-Tolerated, with a Favorable and Consistent Safety Profile

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Safety Population Who Received at Least One Dose of Study Drug (N=378)	Relacorilant + Nab-paclitaxel (N=188)	Nab-paclitaxel (N=190)
Weeks of nab-paclitaxel therapy, mean (range)	**24.5** (0.1–102.4)	**19.3** (0.1–109.6)
Any AEs, n (%)	188 **(100)**	189 **(99.5)**
Grade ≥3 AEs, n (%)	141 **(74.5)**	113 **(59.5)**
Serious AEs, n (%)	66 **(35.1)**	45 **(23.7)**
All deaths on treatment or within 30 days of the last dose, n (%)*	10 **(5.3)**	8 **(4.2)**
Any AEs leading to relacorilant discontinuation, n (%)	19 **(10.1)**	—
Any AEs leading to nab-paclitaxel discontinuation, n (%)	18 **(9.6)**	15 **(7.9)**

There were no relacorilant-related fatal AEs and no cases of adrenal insufficiency.
At the final OS analysis, the safety profile was consistent with that at the time of the primary analysis.
No new safety signals were identified with longer follow-up.

*There were 4 deaths on study treatment in the combination arm due to adverse events (1 each due to cardiac arrest, intestinal perforation, ischemic stroke, and septic shock).1 death was considered related to nab-paclitaxel by the investigator.
AEs, adverse events; OS, overall survival.

Data cutoff: Jan 8, 2026

ROSELLA | Treatment Discontinuations Due to Adverse Events Were Infrequent

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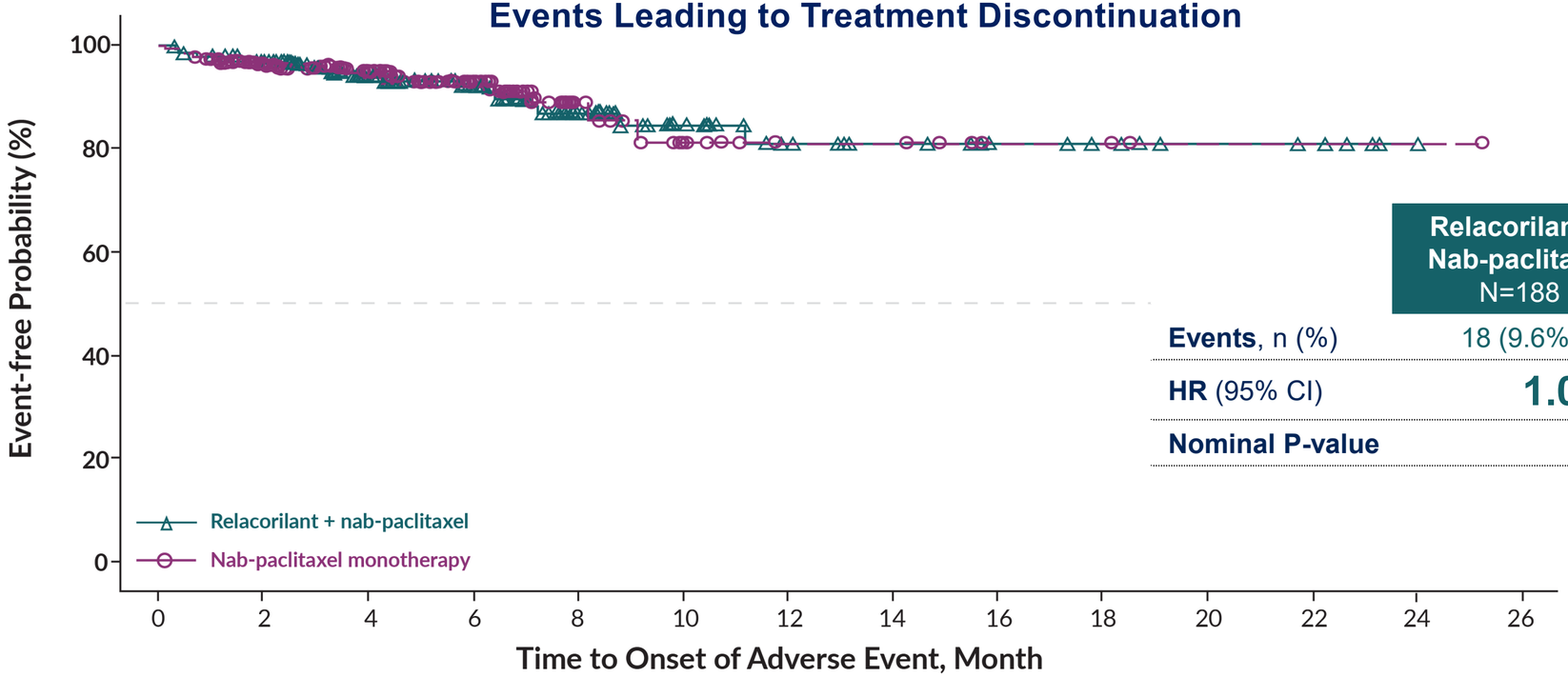
Kaplan-Meier Curve Showing Time to First Onset of Adverse Events Leading to Treatment Discontinuation



	Relacorilant + Nab-paclitaxel N=188	Nab-paclitaxel N=190
Events, n (%)	18 (9.6%)	15 (7.9%)
HR (95% CI)	**1.00** (0.50–2.00)	
Nominal P-value	**0.998**	

(2-sided log-rank test)

Number at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	188 (0/0)	170 (6/6)	123 (4/10)	83 (2/12)	51 (4/16)	30 (1/17)	21 (1/18)	17 (0/18)	11 (0/18)	9 (0/18)	6 (0/18)	5 (0/18)	0 (0/18)	
Nab-paclitaxel monotherapy	190 (0/0)	163 (7/7)	115 (2/9)	69 (2/11)	27 (2/13)	15 (2/15)	8 (0/15)	8 (0/15)	4 (0/15)	4 (0/15)	1 (0/15)	1 (0/15)	1 (0/15)	0 (0/15)

Discontinuations due to AEs were infrequent, well balanced across arms, and occurred in a similar timeframe in both arms

AEs, adverse events.

Data cutoff: Jan 8, 2026

ROSELLA | Common (>20%) Adverse Events

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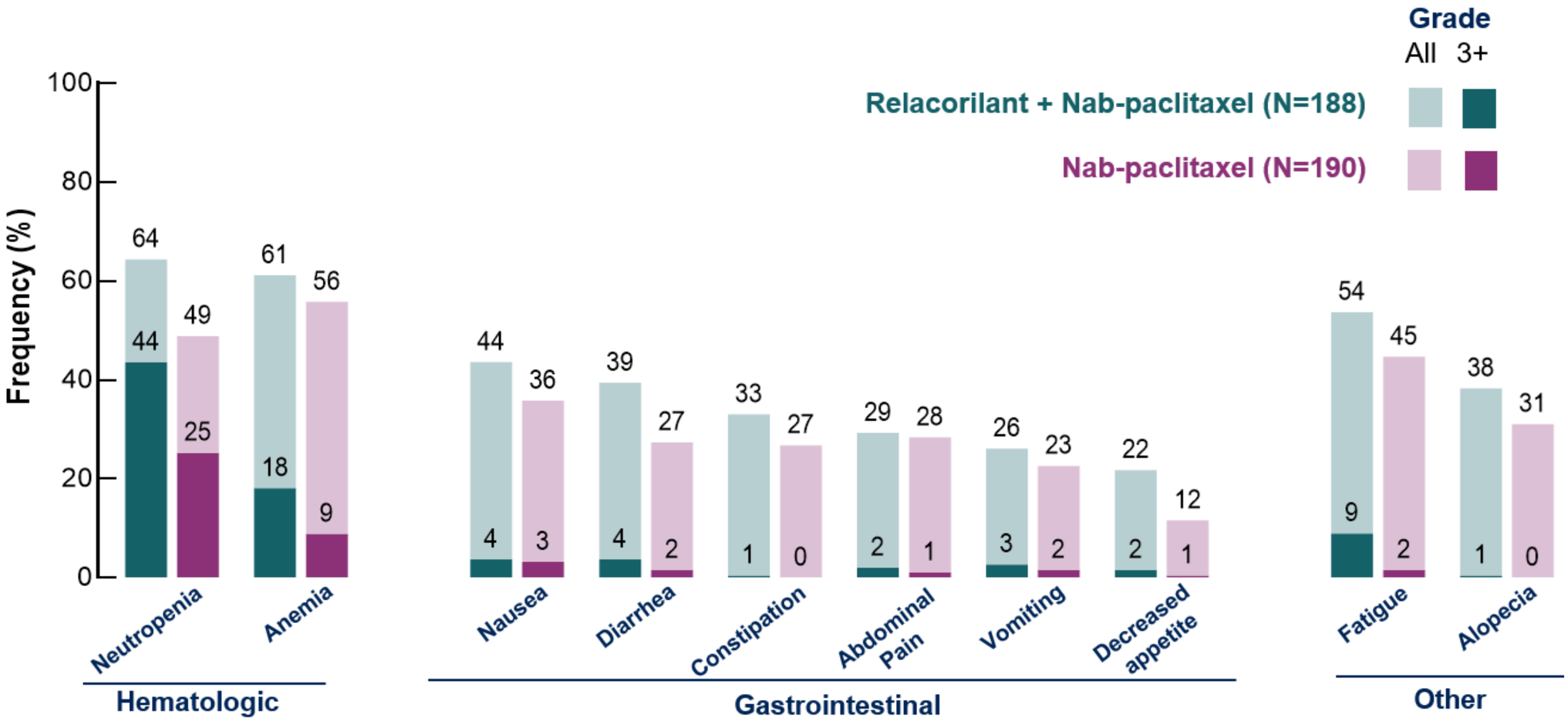

When adjusted for duration of exposure, the incidence rates of neutropenia and anemia were similar between study arms.
Peripheral neuropathy occurred with similar frequency in both arms (19.1% and 17.4%).
5 SAEs of febrile neutropenia: 4 (2.1%) vs 1 (0.5%).* 5 SAEs of sepsis: 3 (1.6%) vs 2 (1.1%).*

Treatment-emergent adverse events that occurred in >20% of patients. Assessed in the safety population of patients who received at least one dose of study drug, N=378. Combined terms are presented for neutropenia (neutropenia, reduced neutrophil count, and febrile neutropenia), anemia (anemia, reduced hemoglobin, and reduced red blood cell count) and fatigue (fatigue and asthenia). SAEs, serious adverse events. *Comparing the relacorilant combination arm to the nab-paclitaxel monotherapy arm, respectively.

Data cutoff: Jan 8, 2026

ROSELLA | Conclusions

1	**ROSELLA met both dual primary endpoints of PFS and OS**	At the primary analysis, the addition of relacorilant (**a first-in-class SGRA**) to nab-paclitaxel resulted in a statistically and clinically significant improvement in PFS by BICR (HR 0.70, P=0.0076). At the final analysis, the addition of relacorilant to nab-paclitaxel resulted in a statistically and clinically significant **35% reduction in the risk of death from any cause** (OS HR 0.65, P=0.0004); **median overall survival was extended by 4.1 months**.
2	**Consistent benefit across subgroups**	Overall survival results favored the relacorilant combination arm across all prespecified subgroups, including those with high unmet need.
3	**Well-tolerated, favorable safety profile**	Relacorilant plus nab-paclitaxel was well-tolerated, with a favorable and consistent safety profile. No new safety signals were observed with additional follow-up.
4	**A new standard for PROC without biomarker selection**	A clinically significant median overall survival improvement of 4.1 months positions relacorilant plus nab-paclitaxel as a new treatment option for patients **without the need for biomarker selection**.

BICR, blinded independent central review; HR, hazard ratio; OS, overall survival; PFS, progression-free survival; PROC, platinum-resistant ovarian cancer; SGRA, selective glucocorticoid receptor antagonist.

ROSELLA | Acknowledgements

Thank you to all the patients, caregivers, family members, investigators, and site staff who supported this global trial.

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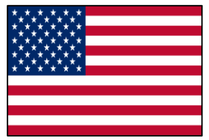

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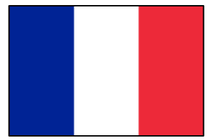

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The Sponsor Team: Adrian Jubb, Celeste Love, Darin Dobler, Doro Alatorre, Heidi Cossentine, Ian Evans, Jake Strzelecki, Joseph Custodio, Stephen Smith, Amanda Kesner-Hays, Cristina Tudor, Deepa Venkataraman, David Upchurch, Samir Shambharkar, Anna Lam, Sachin Pai, Nina Pashova, William Guyer, Abhijit Ramachandran, Don Pham, Alan Arroyo, Priya Choudhry, Honkai Chang, Kavitha Seenivasan, Amy Plodek, Tara Foley, Patience Park, Yuan Xu, Morgan Heinrich, Diana Pak, Prachi Khanna, Kavya Rathi, Deval Modi, Alison Wendt, Tarjani Ranade, Anna Borowiecka, Jill Magadia, Phoebe Rogers, and Nikoletta Toth. **Publications Support:** Farida Khan and Tina Schlafly.

THE LANCET

Overall survival with relacorilant and nab-paclitaxel in patients with platinum-resistant ovarian cancer (ROSELLA): a phase 3 randomised controlled trial

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