ESGO2026 Congress

27th European Congress on Gynaecological Oncology
FEBRUARY 26–28 | 2026
COPENHAGEN | DENMARK

ROSELLA: A Phase 3 Study of Relacorilant + Nab-Paclitaxel in Patients with Platinum-Resistant Ovarian Cancer

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

Domenica Lorusso[1], Stanislas Quesada, John K. Chan, Jung-Yun Lee, Mariana Scaranti, Vanda Salutari, Carolyn Y. Muller, Linda Mileshkin, Toon Van Gorp, Lyndsay Willmott, Ana Santaballa Bertrán, Elizabeth Munro, Saira Khalique, Nicoletta Colombo, Philippe Follana, Giuseppa Scandurra, Robert Poka, Hristina I. Pashova, Bhagyashree Yadav, Alexander B. Olawaiye

[1]Department of Biomedical Science, Humanitas University, Pieve Emanuele, Milan and Humanitas San Pio X Hospital, Milan, Italy

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

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Presented at the 27th European Congress of Gynaecological Oncology | February 26 – 28, 2026

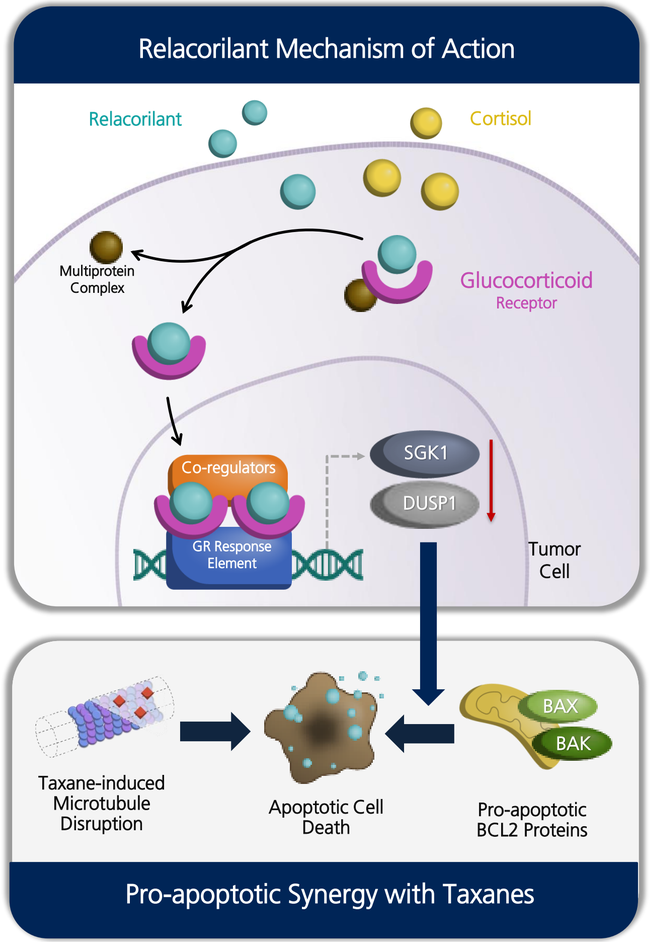
Disclosures

	No, nothing to disclose
X	Yes, please specify:

Company Name	*Receipt of grants/ research supports*	*Receipt of honoraria or consulting fees*	*Participation in Company sponsored speaker's bureau*	*Stock shareholder*	*Spouse/ partner*	*Other support (please specify)*
Abbvie	X	X	X			
AstraZeneca	X	X	X			Travel
Corcept	X		X			
Genmab		X	X			
GSK	X	X	X			Travel
Incyte	X					
MSD	X	X	X			Travel
Pharma &		X				
Regeneron			X			

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. 7. Colombo, et al. *J Clin Oncol*. 2023;41(30):4779-89.

Presented by: Domenica Lorusso

ROSELLA | Study Schema

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

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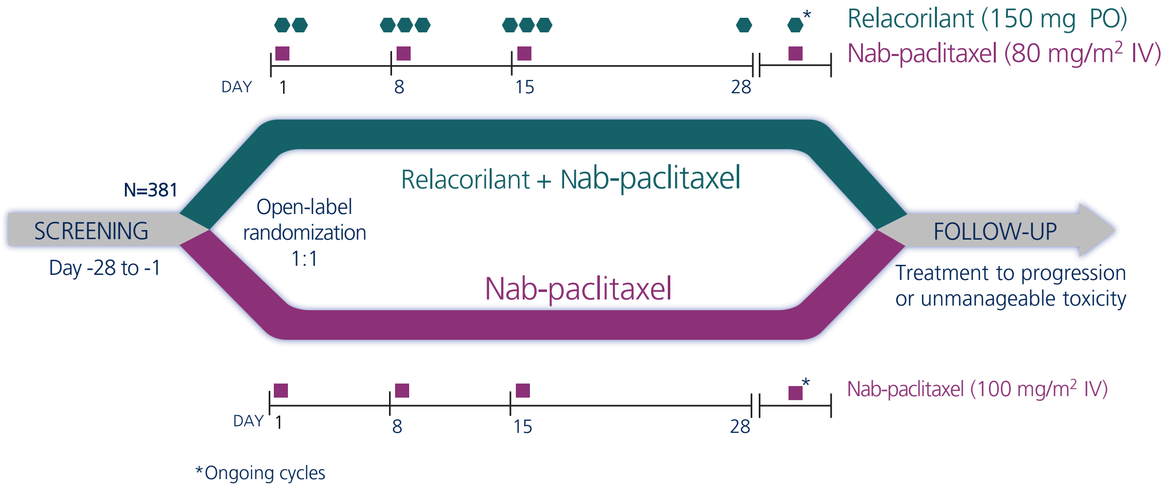

Stratification Factors

- ▸ 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

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: 5th January 2023
Last patient enrolled: 8th April 2024
Data cutoff: 24th February 2025
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; PFS, progression-free survival; PO, by mouth; RECIST, Response Evaluation Criteria in Solid Tumors.

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ROSELLA | Baseline Characteristics Were Well Balanced

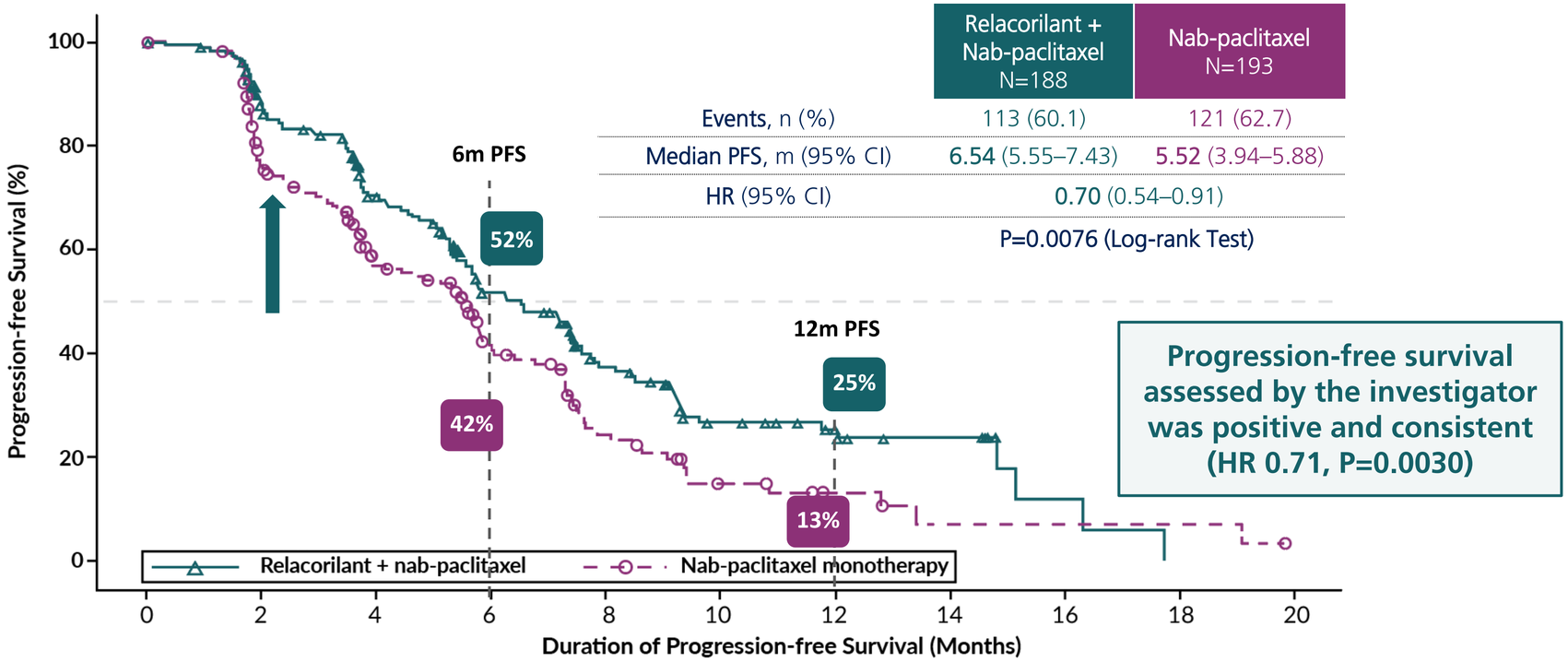
		Relacorilant + Nab-paclitaxel (N=188)	Nab-paclitaxel (N=193)
Age, median (range), years		61 (26–85)	62 (33–86)
Race, n (%)	White Black or African-American Asian (92% Korean) Other / Not Reported	136 (72.3) 3 (1.6) 22 (11.7) 27 (14.4)	135 (69.9) 2 (1.0) 26 (13.5) 30 (15.5)
Ethnicity, n (%)	Hispanic	16 (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.

Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA | Relacorilant Significantly Improved Progression-Free Survival Assessed by Blinded Review



	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 assessed by the investigator was positive and consistent (HR 0.71, P=0.0030)

No. at risk (events/cumulative events)

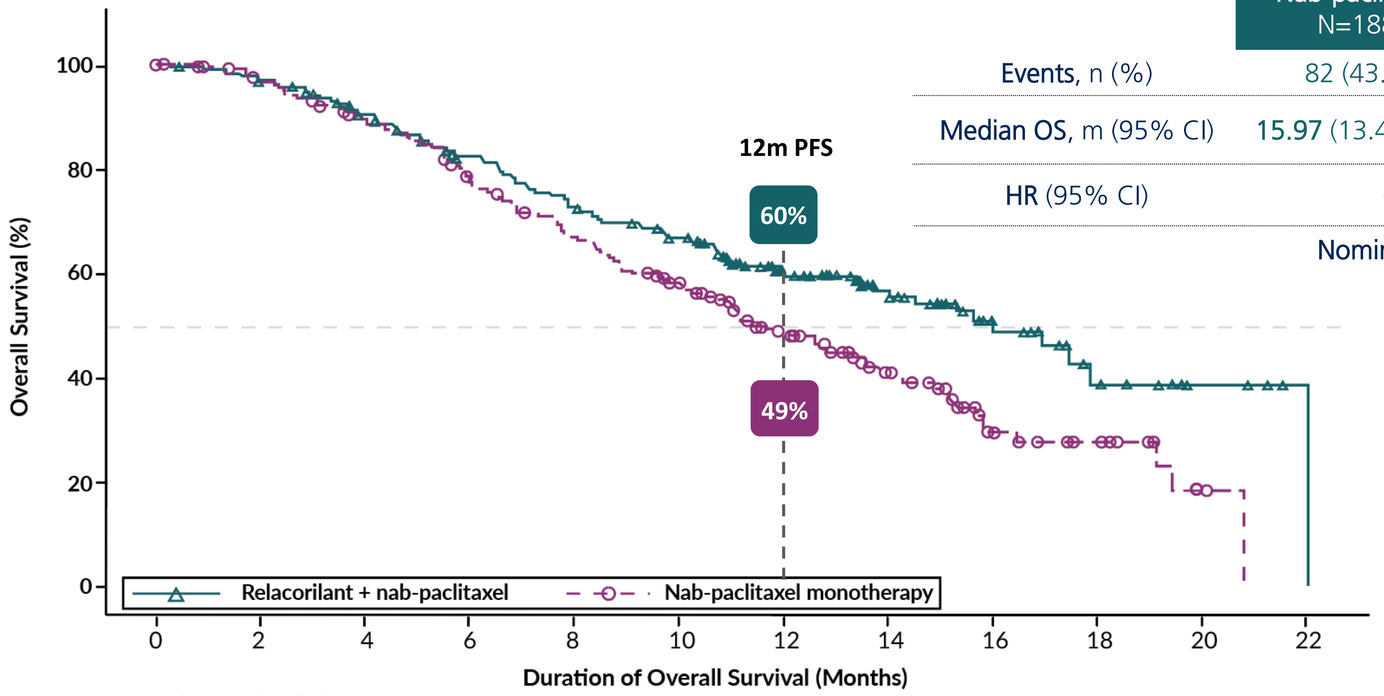
Relacorilant + nab-paclitaxel	188 (0/0)	151 (22/22)	109 (29/51)	70 (27/78)	43 (18/96)	24 (11/107)	16 (1/108)	11 (1/109)	2 (2/111)	0 (2/113)	
Nab-paclitaxel monotherapy	193 (0/0)	129 (42/42)	85 (31/73)	47 (20/93)	21 (17/110)	9 (7/117)	5 (1/118)	2 (2/120)	2 (0/120)	2 (0/120)	0 (1/121)

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.
BICR, blinded-independent central review; CI, confidence interval; HR, hazard ratio; m, months; PFS, progression-free survival.

Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA | Relacorilant Improved Overall Survival at this Interim Analysis



	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)

Maturity: 50%

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)

Median follow-up time: 13.9 months; statistical significance threshold at the interim analysis: P≤0.0001; 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 overall 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; NR, not reached; OS, overall survival.

Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA
Relacorilant with nab-paclitaxel in Ovarian Cancer

Overall Survival (OS) Primary Endpoint Met in Corcept's Pivotal Phase 3 ROSELLA Trial of Relacorilant in Patients with Platinum- Resistant Ovarian Cancer

OS Hazard Ratio 0.65, P=0.0004
Median OS 16.0 vs 11.9 months

January 22, 2026 at 8:00 AM EST

- Data demonstrate a 35 percent reduction in the risk of death
- Both dual primary endpoints (progression-free and overall survival) were met, without the need for biomarker selection and without increased safety burden
- Relacorilant's New Drug Application (NDA) is under review by the U.S. Food and Drug Administration (FDA) as a treatment for patients with platinum-resistant ovarian cancer with a Prescription Drug User Fee Act (PDUFA) target action date of July 11, 2026
- Relacorilant's Marketing Authorization Application (MAA) for patients with platinum-resistant ovarian cancer is also under review by the European Medicines Agency (EMA)

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jan. 22, 2026-- Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of medications to treat severe endocrinologic, oncologic, metabolic and neurologic disorders by modulating the effects of the hormone cortisol, today announced that ROSELLA, the company's pivotal Phase 3 trial of relacorilant plus nab-paclitaxel to treat patients with platinum-resistant ovarian cancer, met its overall survival (OS) primary endpoint.

In ROSELLA, patients treated with relacorilant in addition to nab-paclitaxel chemotherapy experienced a 35 percent reduction in the risk of death compared to patients treated with nab-paclitaxel alone (hazard ratio: 0.65; p-value: 0.0004). The median OS for patients receiving relacorilant was 16.0 months, compared to 11.9 months for patients receiving nab-paclitaxel alone, a difference of 4.1 months. Relacorilant in combination with nab-paclitaxel was well-tolerated, consistent with its known safety profile. Importantly, the type, frequency and severity of adverse events in the combination arm were comparable to those in the nab-paclitaxel monotherapy arm. Relacorilant conferred its benefit without increasing the safety burden of the patients who received it.

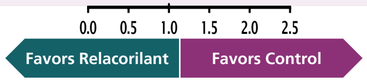
Corcept previously announced that ROSELLA also met its primary endpoint of improved progression-free survival, as assessed by blinded independent central review (PFS-BICR). Patients who received relacorilant in addition to nab-paclitaxel experienced a 30 percent reduction in the risk of disease progression (hazard ratio: 0.70; p-value: 0.008). Findings were first presented at ASCO 2025 (American Society of Clinical Oncology) with simultaneous publication in The Lancet. Complete results from ROSELLA will be presented at an upcoming medical conference.

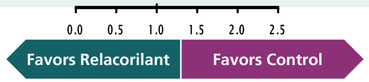
Corcept Therapeutics Incorporated press release 22 January 2026.

Presented by: Domenica Lorusso

ROSELLA | Relacorilant Improved PFS & OS Across Key Subgroups

Subgroup		Patients, n	Events, n	Hazard Ratio for PFS (BICR), (95% CI)	Events, n	Hazard Ratio for OS, (95% CI)
All Patients		381	234	0.70 (0.54–0.91)	192	0.69 (0.52–0.92)
Age	<65 years	229	140	0.76 (0.54–1.08)	119	0.83 (0.57–1.20)
	≥65 years	152	94	0.61 (0.40–0.94)	73	0.55 (0.34–0.89)
Region	North America	90	56	0.62 (0.36–1.07)	45	0.69 (0.38–1.27)
	Europe	216	130	0.73 (0.52–1.04)	111	0.67 (0.46–0.98)
	Korea, Australia, Latin America	75	48	0.70 (0.39–1.26)	36	0.76 (0.39–1.48)
ECOG Performance Status	0	262	154	0.72 (0.52–1.00)	118	0.72 (0.50–1.05)
	1	115	80	0.62 (0.39–0.98)	74	0.59 (0.36–0.97)
Prior Lines of Therapy	1	33	21	0.88 (0.35–2.22)	21	0.80 (0.32–1.97)
	2	181	119	0.63 (0.43–0.91)	91	0.74 (0.49–1.12)
	3	167	94	0.71 (0.47–1.08)	80	0.66 (0.42–1.04)
Prior PARP Inhibitor	Yes	234	138	0.60 (0.42–0.85)	116	0.77 (0.53–1.13)
	No	147	96	0.84 (0.55–1.28)	76	0.66 (0.42–1.05)
Primary Platinum-free Interval	≤6 months	112	73	0.50 (0.30–0.84)	62	0.52 (0.31–0.89)
	>6 months	269	161	0.78 (0.57–1.06)	130	0.82 (0.58–1.16)
BRCA1/2 Mutation	Positive	47	32	1.08 (0.49–2.37)	23	0.82 (0.33–2.07)
	Negative / Unknown	334	202	0.65 (0.49–0.87)	169	0.70 (0.52–0.96)
Largest Target Lesion	<5 cm	299	181	0.68 (0.51–0.92)	141	0.65 (0.46–0.91)
	≥5 cm	45	30	0.50 (0.23–1.09)	25	0.58 (0.25–1.34)





BICR, blinded independent central review; BRCA, Breast Cancer Gene; CI, confidence interval; ECOG, Eastern Cooperative Oncology Group; OS, overall survival; PFS, progression-free survival.

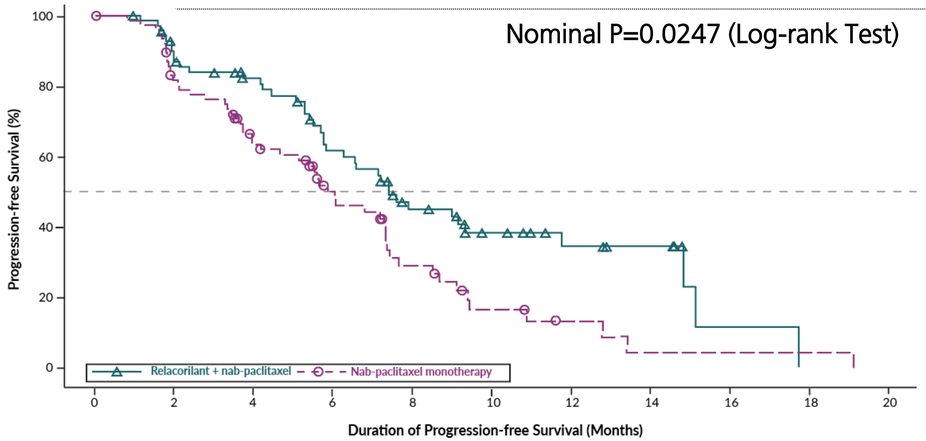
Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA | Relacorilant Improved PFS Assessed by BICR in Patients Aged ≥65 Years

	Relacorilant + Nab-paclitaxel N=72	Nab-paclitaxel N=80
Events, n (%)	40 (55.6)	54 (67.5)
Median PFS, m (95% CI)	**7.39** (5.82–11.76)	**5.85** (4.17–7.29)
HR (95% CI)	**0.61** (0.40–0.94)	

Nominal P=0.0247 (Log-rank Test)



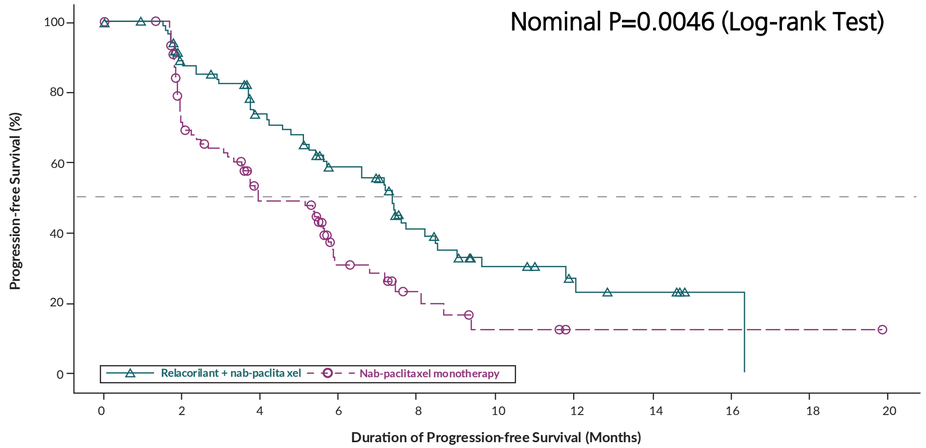
No. at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	72 (0/0)	59 (9/9)	49 (3/12)	35 (12/24)	22 (9/33)	14 (3/36)	9 (1/37)	7 (0/37)	1 (2/39)	0 (1/40)	
Nab-paclitaxel monotherapy	80 (0/0)	60 (14/14)	43 (13/27)	26 (8/35)	13 (10/45)	6 (5/50)	3 (1/51)	1 (2/53)	1 (0/53)	1 (0/53)	0 (1/54)

ROSELLA | Relacorilant Improved PFS Assessed by BICR in the Subgroup of Patients Who had Progressed on a PARP Inhibitor

	Relacorilant + Nab-paclitaxel N=86	Nab-paclitaxel N=97
Events, n (%)	48 (55.8)	57 (58.8)
Median PFS, m (95% CI)	**7.36** (5.39–8.44)	**3.94** (3.32–5.72)
HR (95% CI)	**0.56** (0.37–0.84)	

Nominal P=0.0046 (Log-rank Test)



No. at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	86 (0/0)	67 (9/9)	50 (11/20)	36 (10/30)	21 (10/40)	12 (5/45)	7 (1/46)	5 (1/47)	6 (0/47)	0 (1/48)	
Nab-paclitaxel monotherapy	97 (0/0)	58 (24/24)	34 (17/41)	14 (10/51)	7 (3/54)	3 (3/57)	1 (0/57)	1 (0/57)	1 (0/57)	1 (0/57)	0 (0/57)

ORR (Investigator): 34.9% (30/86) vs **26.8%** (26/97)

The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% confidence intervals (CI) 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. ORR was assessed among patients with baseline measurable disease.

BICR, blinded-independent central review; CI, confidence interval; HR, hazard ratio; m, months; ORR, objective response rate; PFS, progression-free survival

Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA | Safety Summary

Relacorilant + Nab-Paclitaxel was Well-Tolerated, with a Favorable Safety Profile

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)	**23.2** (0.1–90.3)	**18.6** (0.1–68.1)
Any TEAEs, n (%)	188 **(100)**	189 **(99.5)**
Grade ≥3 TEAEs, n (%)	140 **(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)**
Dose Reductions of Relacorilant Due to TEAEs, n (%)	13 **(6.9)**	—
Dose Reductions of Nab-paclitaxel Due to TEAEs, n (%)	91 **(48.4)**	60 **(31.6)**
Interruptions of Nab-paclitaxel (+ Relacorilant) Due to TEAEs, n (%)*	137 **(72.9)**	104 **(54.7)**
Discontinuations of Nab-paclitaxel (+ Relacorilant) Due to TEAEs, n (%)*	17 **(9.0)**	15 **(7.9)**

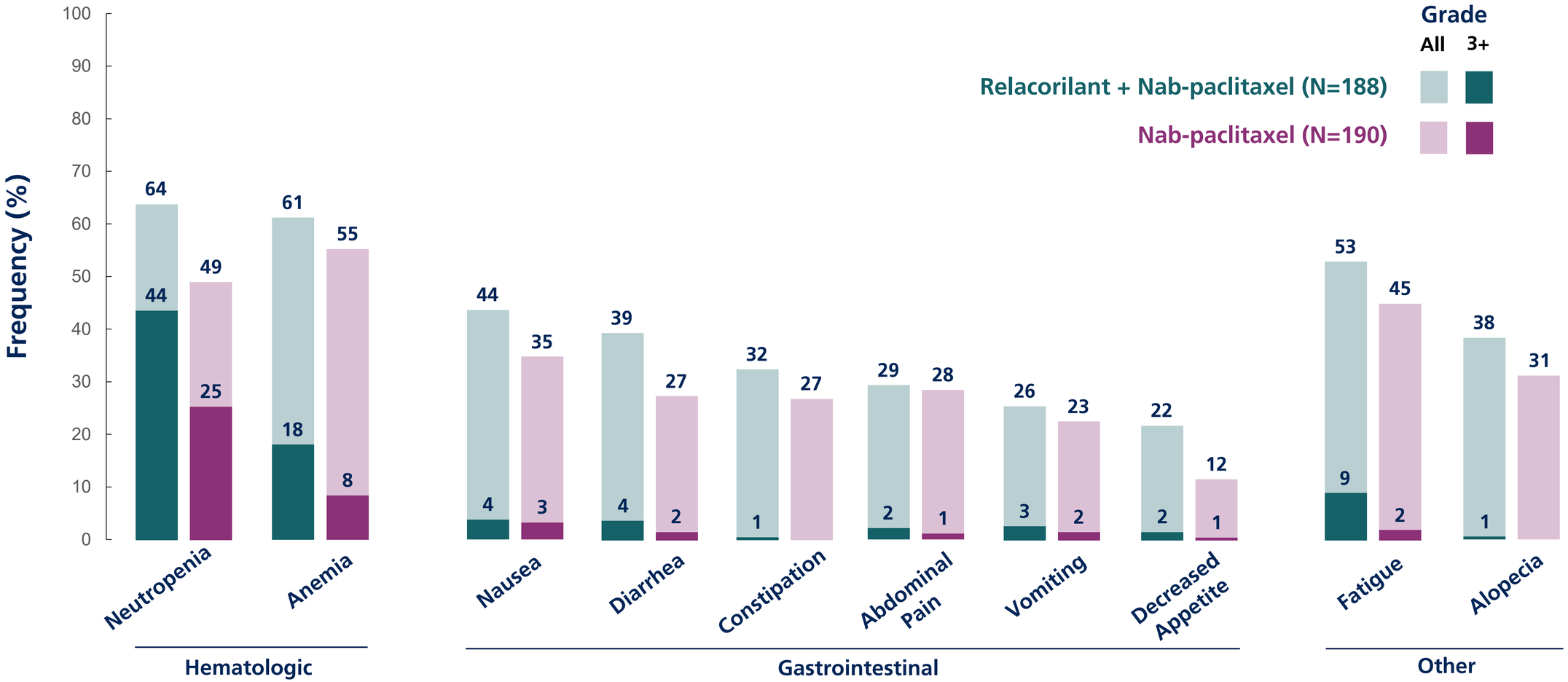
*Relacorilant was always interrupted or discontinued when nab-paclitaxel was interrupted or discontinued. AEs, adverse events; TEAEs, treatment-emergent adverse events.

AEs leading to treatment discontinuation in >2 patients included intestinal obstruction and paresthesia. There were no relacorilant-related fatal AEs.

Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA | Common (>20%) Adverse Events



When adjusted for duration of exposure, the incidence rates of neutropenia and anemia were comparable between study arms.
5 SAEs of febrile neutropenia were reported, 4 (2.1%) with relacorilant + nab-paclitaxel and 1 (0.5%) with nab-paclitaxel monotherapy.
5 SAEs of sepsis were reported, 3 (1.6%) with relacorilant + nab-paclitaxel and 2 (1.1%) with nab-paclitaxel monotherapy.

TEAEs 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; TEAEs, treatment-emergent adverse events.

Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA | Liver Function Test Abnormalities

ALT/AST Increases Were Numerically Lower in the Combination Arm (5% vs 9%)

Safety Population Who Received at Least One Dose of Study Drug (N=378)	Relacorilant + Nab-paclitaxel (N=188)	Nab-paclitaxel (N=190)
ALT or AST increase, n (%)		
>3-5× ULN	3 (1.6%)	13 (6.8%)
>5-8× ULN	5 (2.7%)	3 (1.6%)
>8-10× ULN	1 (0.5%)	0
>10× ULN	1 (0.5%)	2 (1.1%)
Total bilirubin increase, n (%)		
>2× ULN	3 (1.6%)	4 (2.1%)
ALP increase, n (%)		
>2× ULN	16 (8.5%)	23 (12.1%)
Hy's law criteria met, n (%)	0	0

ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; LFT, liver function tests; ULN, upper limit of normal.

Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA | Conclusions

1	**ROSELLA met both dual primary endpoints of OS and PFS**	Relacorilant, **a first-in-class, oral, SGRA, extended progression-free survival** by BICR (log-rank test P=0.0076, HR 0.70) compared to nab-paclitaxel monotherapy in patients with platinum-resistant ovarian cancer.
2	**Median survival prolonged by 4.1 months**	**At the final overall survival analysis, the addition of relacorilant to nab-paclitaxel showed a clinically and statistically significant improvement in overall survival** (log-rank test P=0.0004, HR 0.65, median 16.0 vs 11.9 months).
3	**Consistent benefit in PARPi-progressor & older patients**	Relacorilant + nab-paclitaxel showed a PFS benefit in patients who progressed while on a PARP inhibitor (HR 0.56, nominal P=0.0046), with a median PFS of 7.36 months, and patients ≥65 years (PFS HR 0.61, nominal P=0.0247), with a median PFS of 7.39 months.
4	**Well-tolerated, favorable safety profile**	Relacorilant plus nab-paclitaxel was well-tolerated, with a favorable safety profile that was comparable between treatment arms when adjusted for duration of exposure.
5	**A new standard for PROC**	Relacorilant plus nab-paclitaxel offers an efficacious treatment regimen for women with platinum-resistant ovarian cancer, without the need for a biomarker.

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

Presented by: Domenica Lorusso

Data cutoff: Feb 24, 2025

ROSELLA | Acknowledgements

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

Alvarez
Azzouquoa
Bank
Callahan
Chambers
Chan
Chandler
Cloven
Cohen
Corr
Croft
de la Garza
Eskander
Fehniger
Fishman
Frederickson
Gill
Gordinier
Green
Grosse-Perdekamp
Gubbi
Guy
Hopp
Jenkins-Vogel
Jewell
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Lee
Leiser
LyBarger
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McCollum
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Ulm
Wilmott
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Barlow
Clamp
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Nicum

Lorusso
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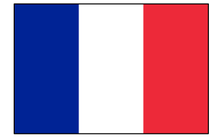

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