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

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

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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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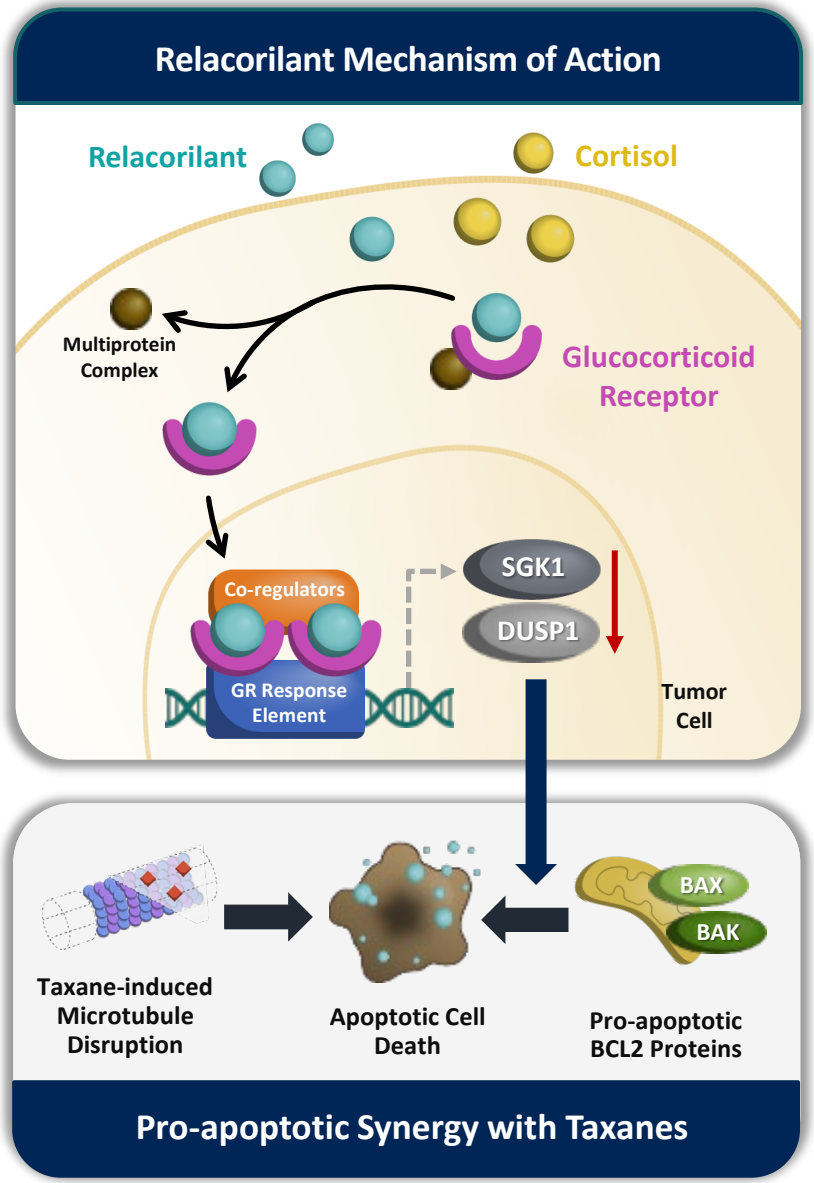
Background

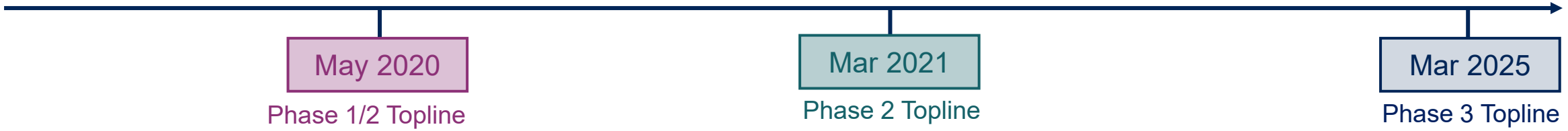
- Patients with platinum-resistant ovarian cancer have an overall survival of ~1 year and need new treatments[1]
- Ovarian cancers express the glucocorticoid receptor (GR), a marker of poor prognosis[2]
- GR signaling reduces sensitivity to chemotherapy[3,4]
- Relacorilant is a novel, selective GR antagonist (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.

Relacorilant Oncology Development Timeline

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



Phase 1/2 | Dose Finding[4]

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

38% durable (≥16 weeks) disease control in patients with ovarian cancer

28% with longer duration of benefit than on prior taxane

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)

ROSELLA Phase 3

A positive trial of relacorilant plus nab-paclitaxel, showing improvements in the dual primary endpoints of progression-free and overall survival in patients with platinum-resistant ovarian cancer

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.
HR, hazard ratio.

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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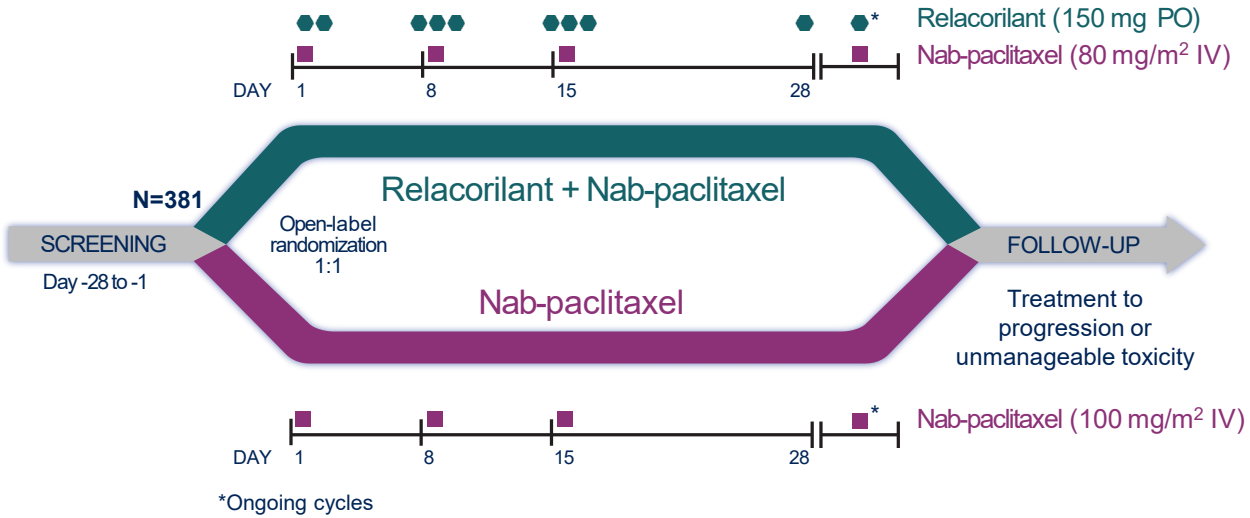


Stratification Factors

- 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

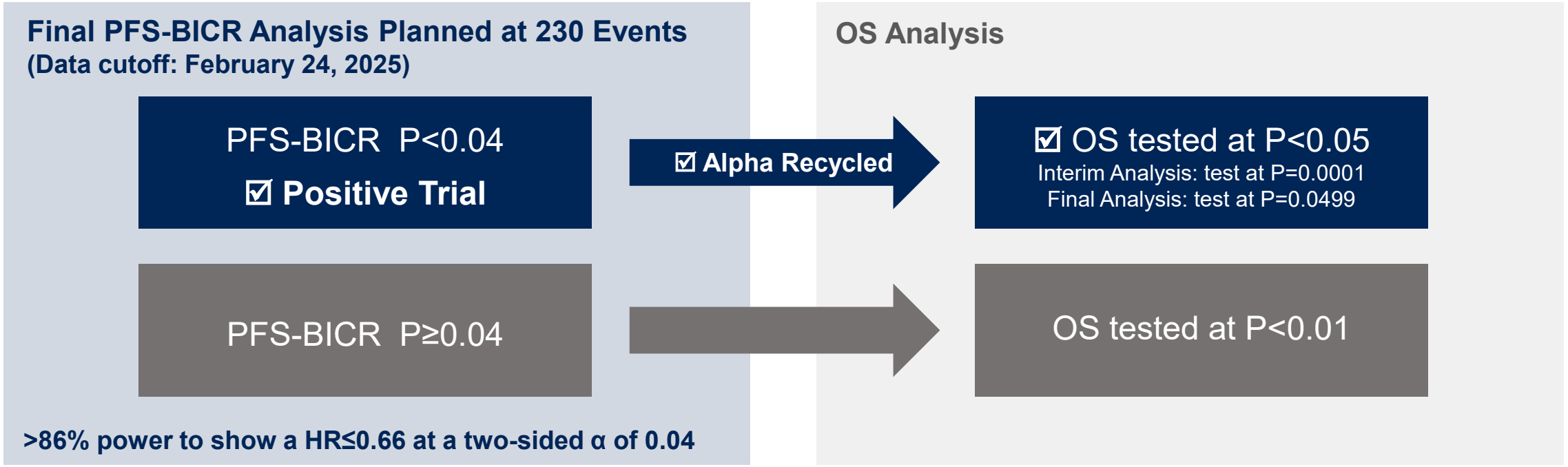
- PFS by RECIST v1.1 per Investigator
- ORR, DoR, CBR (RECIST v1.1)
- Response by CA-125 GCIG criteria
- Combined response (RECIST v1.1 and CA-125 GCIG criteria)
- Safety

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.

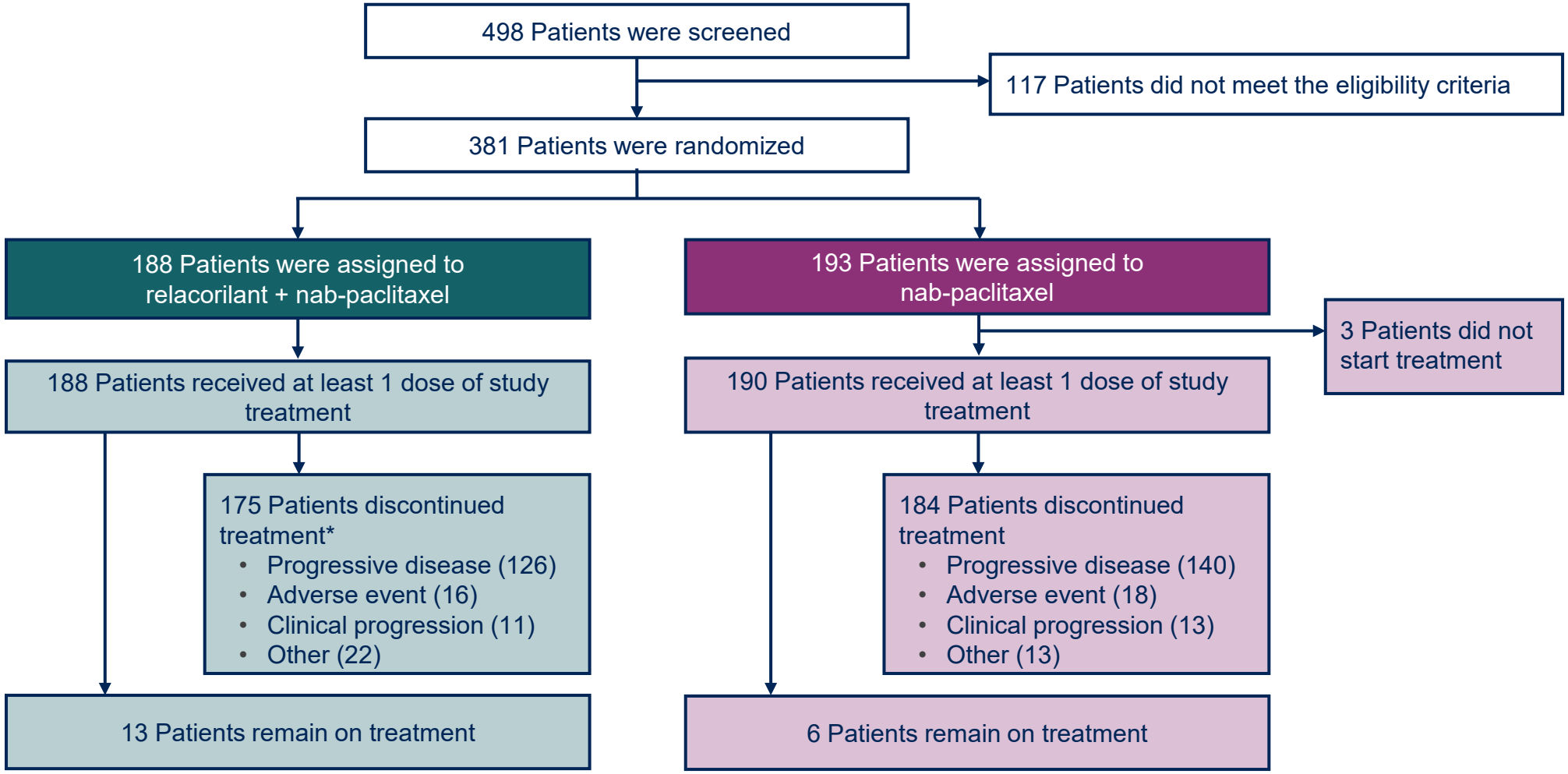
ROSELLA | Statistical Plan for Dual Primary Endpoints

If the P-value (stratified log-rank test) for either PFS-BICR (α=0.04) or OS (α=0.01) is less than the respective, pre-specified alpha boundary, the trial is positive.



Efficacy endpoints were assessed in the intent-to-treat population (all randomized patients). A group-sequential weighted Holm procedure was used for the dual primary endpoints PFS and OS.
BICR, blinded independent central review; HR, hazard ratio; OS, overall survival; PFS, progression-free survival.

ROSELLA | Patient Disposition



*Numbers shown are for nab-paclitaxel discontinuations. Progressive disease refers to radiographic progression.

Data cutoff: Feb 24, 2025

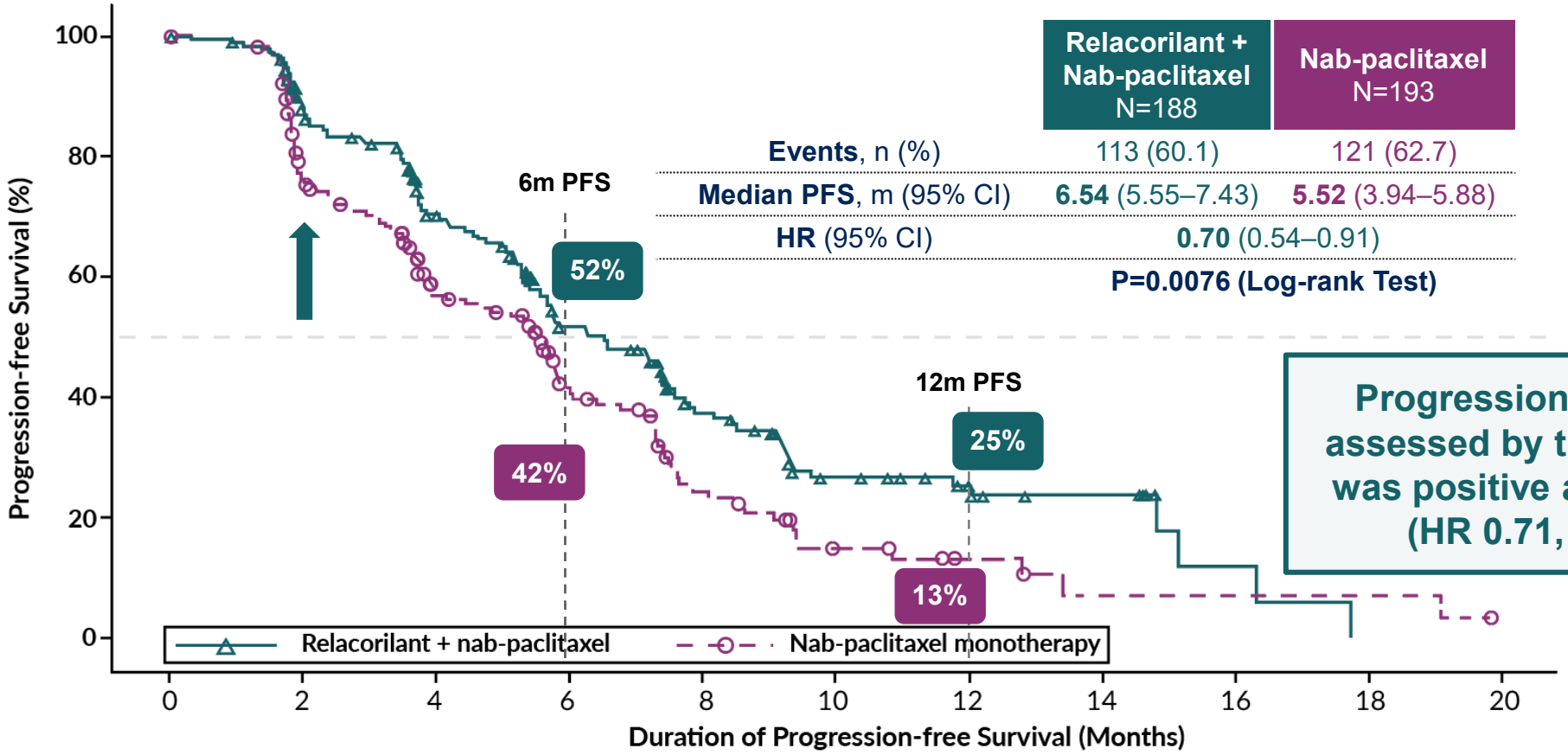
ROSELLA | Baseline Characteristics Were Well Balanced

		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.

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)

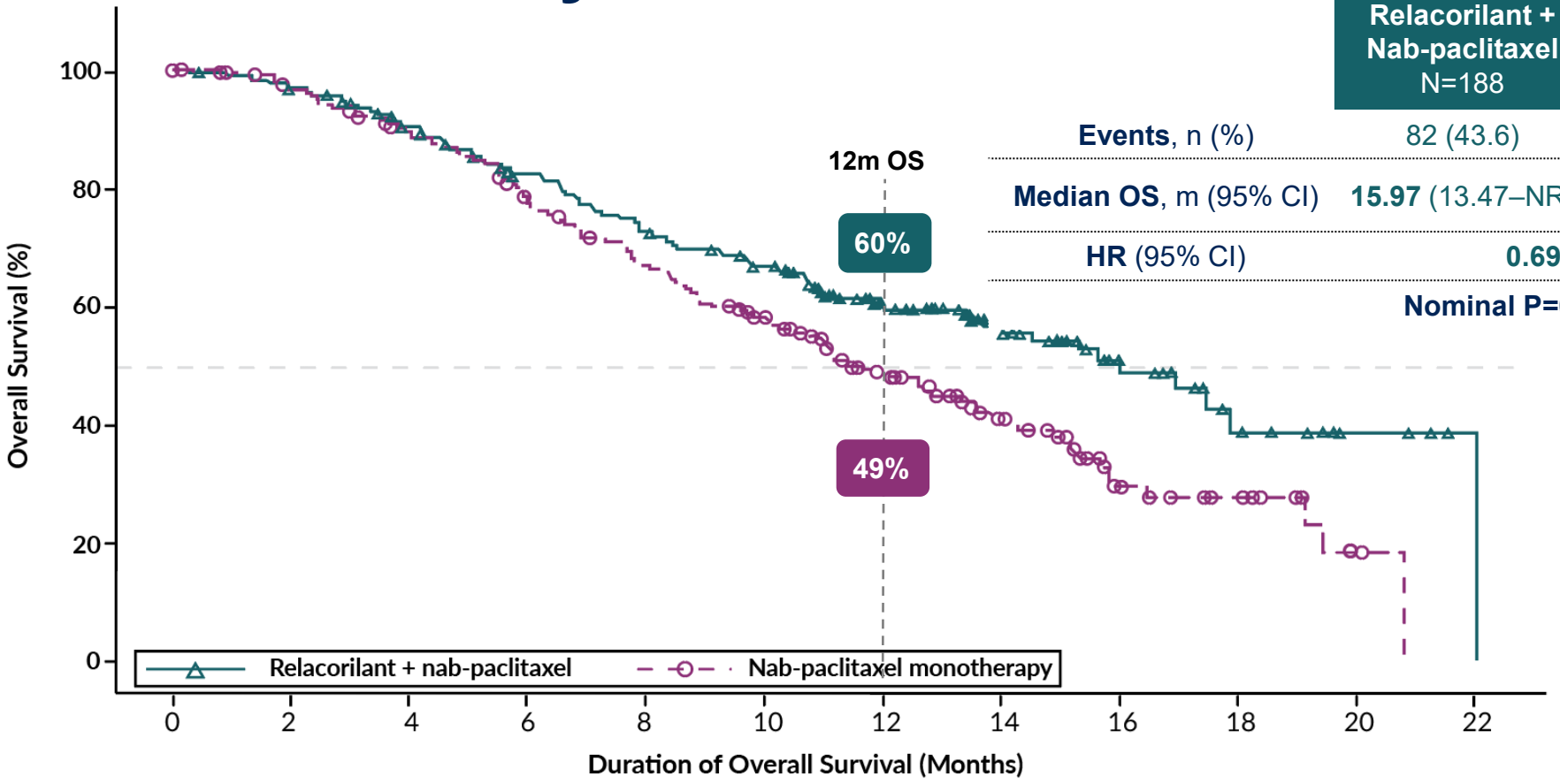
No. at risk (events/cumulative events)

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.

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.

Data cutoff: Feb 24, 2025

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.

ROSELLA | Relacorilant + Nab-Paclitaxel Was Associated with High Objective Response and Clinical Benefit Rates (by Investigator)

Endpoint	Relacorilant + Nab-paclitaxel	Nab-paclitaxel
Objective Response Rate, n (%)	69 **(36.9)**	58 **(30.1)**
	6.8% improvement P=0.17 (Stratified Cochran-Mantel-Haenszel Test)	
Complete Response, n (%)	6 **(3.2)**	4 **(2.1)**
Partial Response, n (%)	63 **(33.7)**	54 **(28.0)**
Stable Disease, n (%)	77 **(41.2)**	68 **(35.2)**
Progressive Disease, n (%)	32 **(17.1)**	52 **(26.9)**
Not Evaluable, n (%)	9 **(4.8)**	15 **(7.8)**
Clinical Benefit Rate, n (%) (Response or stable disease maintained for 24 weeks)	96 **(51.1)**	75 **(38.9)**
	12.2% improvement P=0.016 (Stratified Cochran-Mantel-Haenszel Test)	

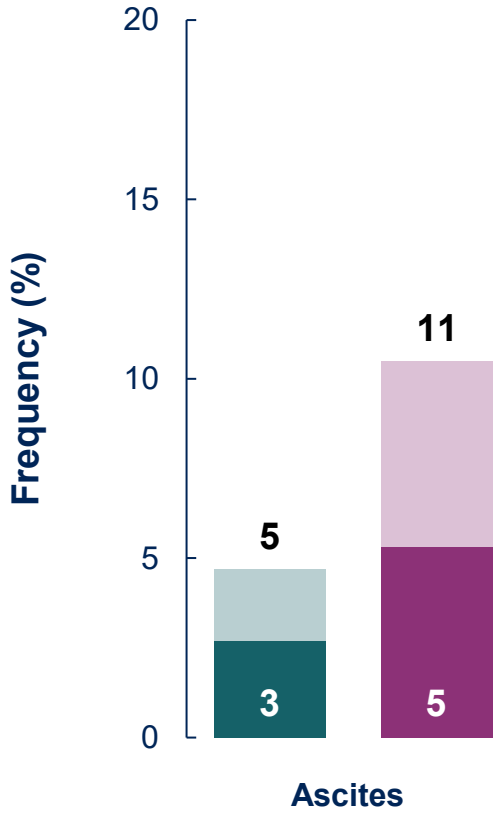
Objective response rate was assessed in the subset of intent-to-treat population with measurable disease at baseline, per investigator assessment (n=380 patients). Clinical Benefit Rate was assessed in the intent-to-treat population (n=381 patients). Per RECIST v1.1 guidelines confirmatory scans were not required for this randomized controlled trial.

RECIST, Response Evaluation Criteria in Solid Tumors.

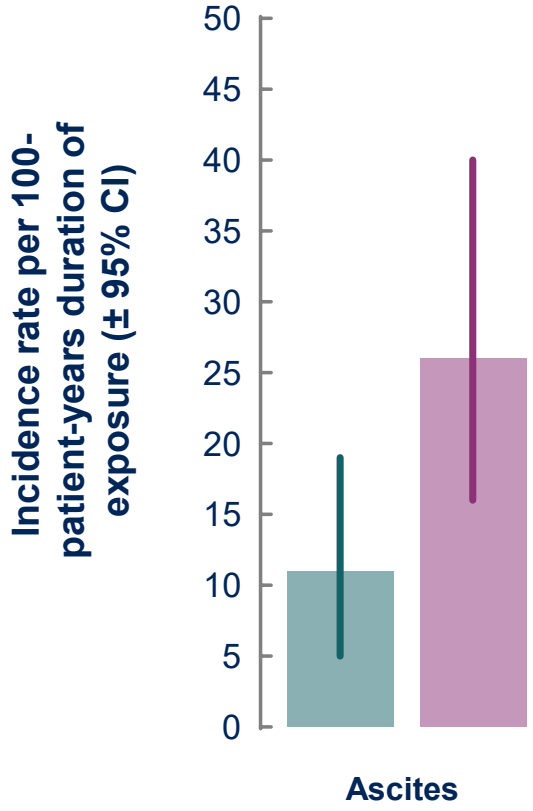
Data cutoff: Feb 24, 2025

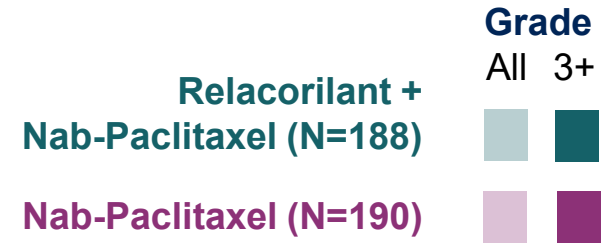
ROSELLA | Lower Incidence of Ascites with Relacorilant + Nab-paclitaxel

Unadjusted Incidence Rate



Exposure-Adjusted Incidence Rate
(Incidence normalized to the duration of exposure)





Ascites was less common in patients who received relacorilant.

Abdominal paracenteses were also less common in patients receiving the relacorilant combination compared to nab-paclitaxel monotherapy: 7.4% vs 13.2%.

Data cutoff: Feb 24, 2025

ROSELLA | Safety Summary

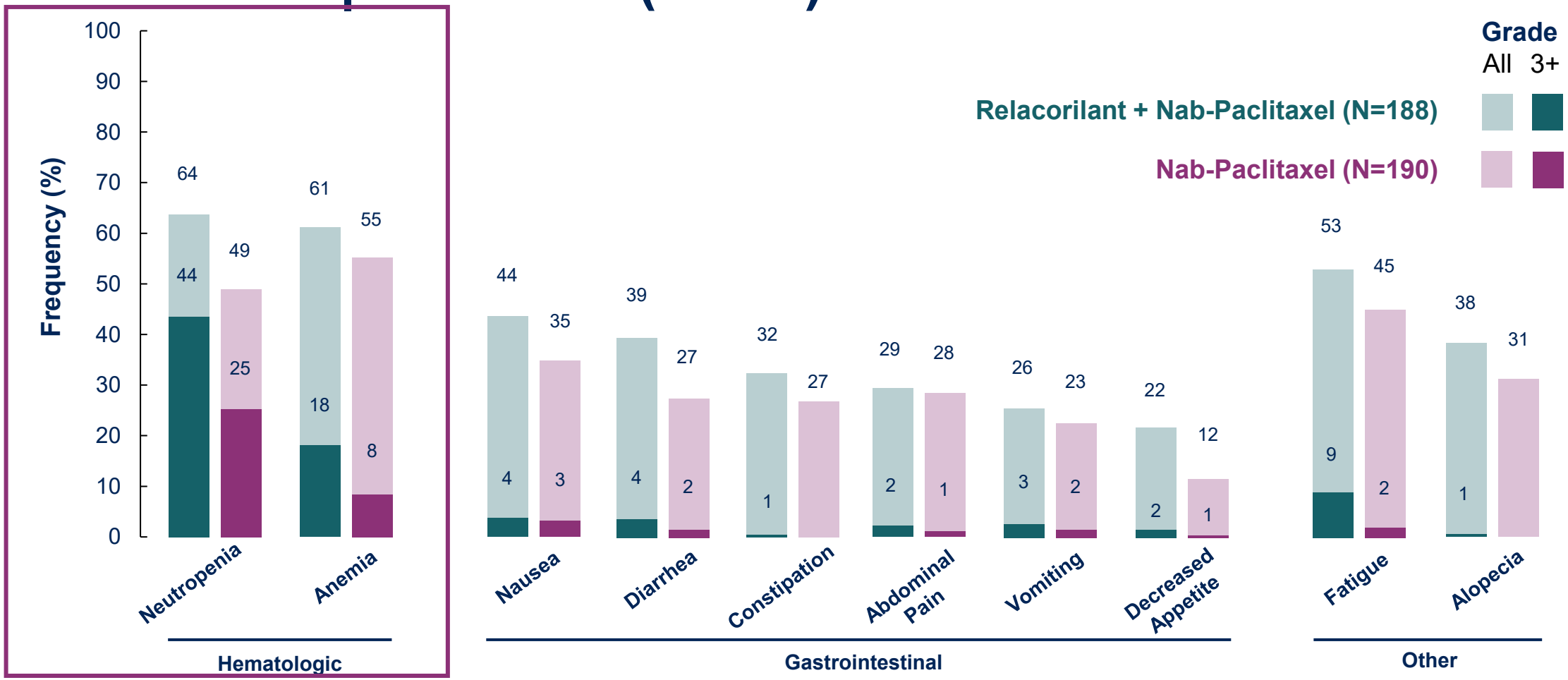
Relacorilant + Nab-Paclitaxel was Well-Tolerated, with a Favorable Safety Profile

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.

ROSELLA | Common (>20%) Adverse Events



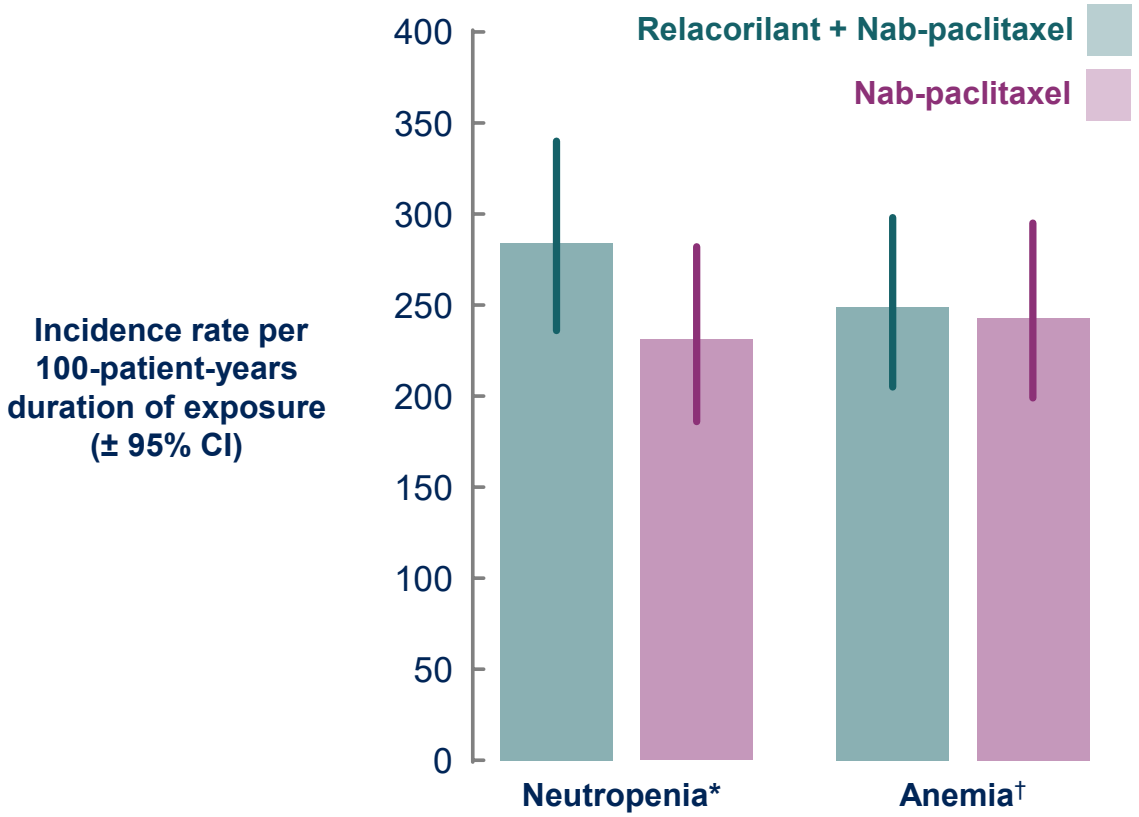
Peripheral neuropathy occurred with similar frequency in both arms (19.1% and 17.4%).
5 SAEs of febrile neutropenia were reported, 4 (2.1%) with relacorilant + nab-paclitaxel and 1 (0.5%) with nab-paclitaxel monotherapy.
5 SAEs of sepsis were reported, 3 (1.6%) with relacorilant + nab-paclitaxel and 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.

Data cutoff: Feb 24, 2025

ROSELLA | Selected Exposure-Adjusted Adverse Events

Exposure-Adjusted Incidence Rate
(AE incidence normalized to the duration of exposure)



When adjusted for duration of exposure, the incidence rates of neutropenia and anemia were comparable between study arms.

*Combined term including anemia, decreased red blood cell count, and decreased hemoglobin. †Combined term including neutropenia, decreased neutrophil count, and febrile neutropenia. Assessed in the safety population of patients who received at least one dose of study drug, N=378. AE, adverse event; CI, confidence interval. Exposure-Adjusted Incidence Rate (EAIR) is defined as Event Incidence rate per 100 patient-years-exposure (PYE): (Total number of patients with an event/Total PYE)*100. Exact 95% confidence interval based on Poisson distribution for EAIR. The total PYE to a treatment is the sum of individual patient's PYE within the treatment exposure period and is defined as: (i) For patients with an event within the exposure period: (First event start date-first dose date+1)/365.25; (ii) For patients with no event within the exposure period: (Study participation end date- first dose date +1)/365.25.
EAIR difference: [(Relacorilant + Nab-paclitaxel) - Nab-paclitaxel Monotherapy]. The exact confidence interval for difference of EAIR between two treatment arms is based on two independent Poisson distributions.

Data cutoff: Feb 24, 2025

ROSELLA | Conclusions

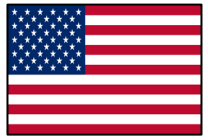
1 ROSELLA met its primary endpoint of improving PFS	Relacorilant, **a first-in-class, oral, SGRA, extended progression-free survival** by BICR (log-rank test P=0.0076, HR 0.70) compared to nab-paclitaxel monotherapy in patients with platinum-resistant ovarian cancer, in a population including patients who progressed within 1–3 months after their primary platinum regimen
2 Median survival prolonged by 4.5 months	**At this interim overall survival analysis, the addition of relacorilant to nab-paclitaxel showed a clinically meaningful improvement in overall survival** (nominal log-rank test P=0.0121, HR 0.69, median 16.0 vs 11.5 months)
3 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. The safety profile was consistent with previously reported data; no new signals were identified
4 A new standard for PROC	Intermittently dosed 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.

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.



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Relacorilant and nab-paclitaxel in patients with platinum-resistant ovarian cancer (ROSELLA): an open-label, randomised, controlled, phase 3 trial

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