

# ROSELLA (GOG3073, ENGOTov72, APGOT-OV10): Relacorilant + Nab-Paclitaxel in the Subgroup of Patients With Platinum-Resistant Ovarian Cancer (PROC) Previously Exposed to a PARP Inhibitor

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# DECLARATION OF INTERESTS

## **Lorusso, Domenica**

Grants or contracts from AstraZeneca, Clovis, Genmab, GSK, Immunogen, Incyte, MSD, Novartis, PharmaMar, Seagen, and Roche

Consulting fees from AstraZeneca, Clovis Oncology, Genmab, GSK, Immunogen, MSD, PharmaMar, Seagen, and Novartis

Payment or honoraria from AstraZeneca, Clovis, Corcept, Genmab, GSK, Immunogen, MSD, Oncoinvest, PharmaMar, Seagen, and Sutro

Support for attending meetings and/or travel from GSK, AstraZeneca, Clovis, and MSD

Participation on a Data Safety Monitoring or Advisory Board for AstraZeneca, Clovis, Corcept, Genmab, GSK, Immunogen, MSD, Oncoinvest, PharmaMar, Seagen, and Sutro

# BACKGROUND

- Patients with ovarian cancer who progress on a PARP inhibitor have poor outcomes:
  - In PAOLA-1, patients who progressed on a PARP inhibitor had a 6.1-month median TTSST (HR 2.1) vs patients who progressed after a PARP inhibitor<sup>1</sup>
- Relacorilant is a novel, selective glucocorticoid receptor antagonist (SGRA) that restores the sensitivity of cancers to cytotoxic chemotherapy<sup>2,3,4</sup>
- Phase 2: The addition of relacorilant to nab-paclitaxel extended PFS (HR 0.66, P=0.038) and showed a trend to improved OS (HR 0.67, P=0.066) in patients with platinum-resistant ovarian cancer (PROC)<sup>5</sup>
- Phase 3 (**ROSELLA**): Relacorilant + nab-paclitaxel showed improvements in the dual primary endpoints of PFS (HR 0.70, P=0.0076) and OS (HR 0.69, P=0.0121) in patients with PROC<sup>6</sup>

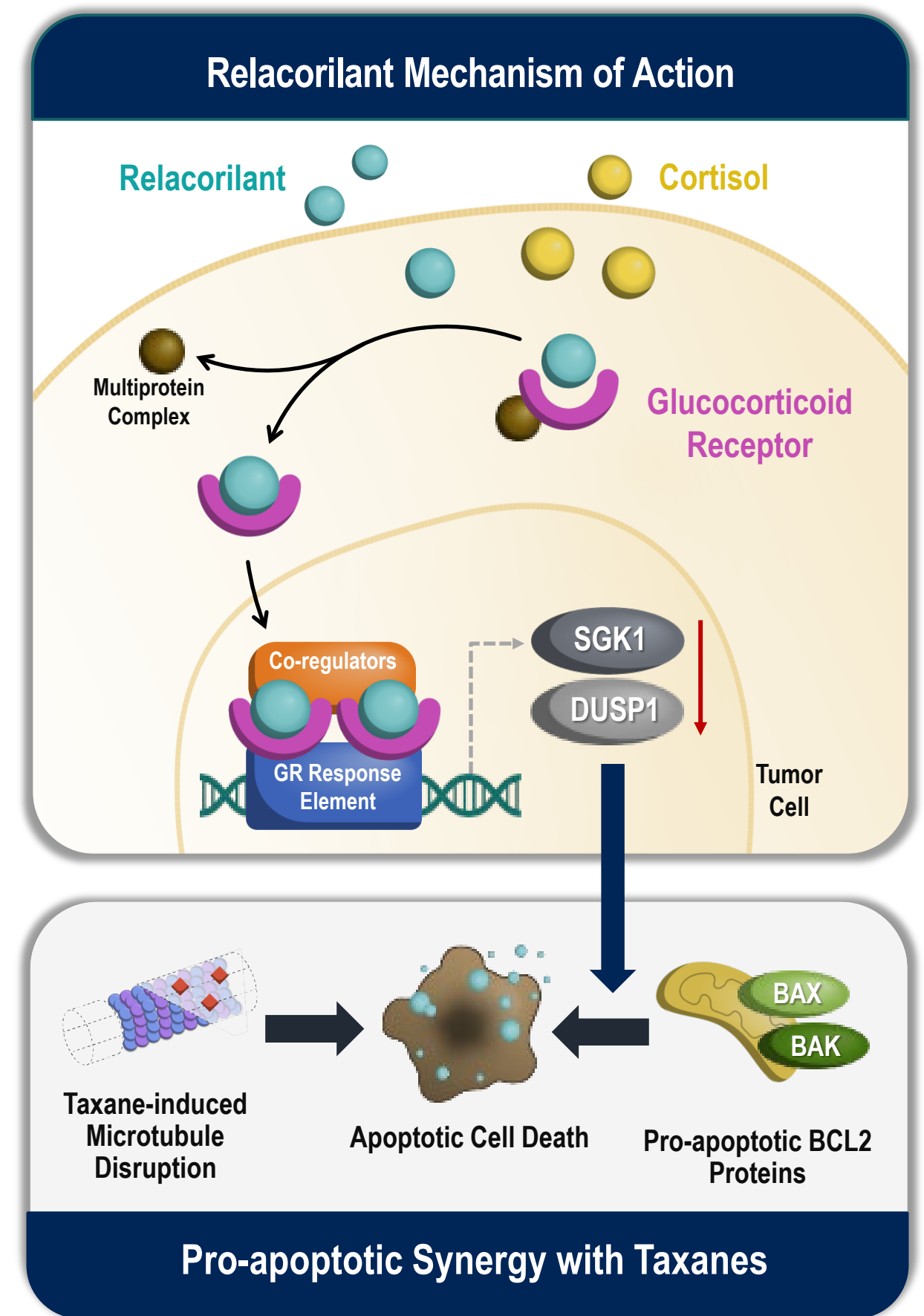
This pre-planned subgroup analysis of ROSELLA assessed the benefit of relacorilant + nab-paclitaxel in patients who had received a PARP inhibitor.

HR, hazard ratio; OS, overall survival; PARP, poly(ADP-ribose) polymerase; PFS, progression-free survival; TTSST, time to second subsequent therapy.

1. Harter, et al. *Ann Oncol.* 2025;36(2):185-96. 2. Greenstein, et al. *Oncotarget.* 2021;12(13):1243-55. 3. Stringer-Reasor, et al. *Gynecol Oncol.* 2015;138(3):656-62. 4. Munster, et al. *Clin Cancer Res.* 2022;28(15):3214-24. 5. Colombo, et al. *J Clin Oncol.* 2023;41(30):4779-89. 6. Olawaiye, et al. *Lancet.* 2025; 405(10496):2205-2216.

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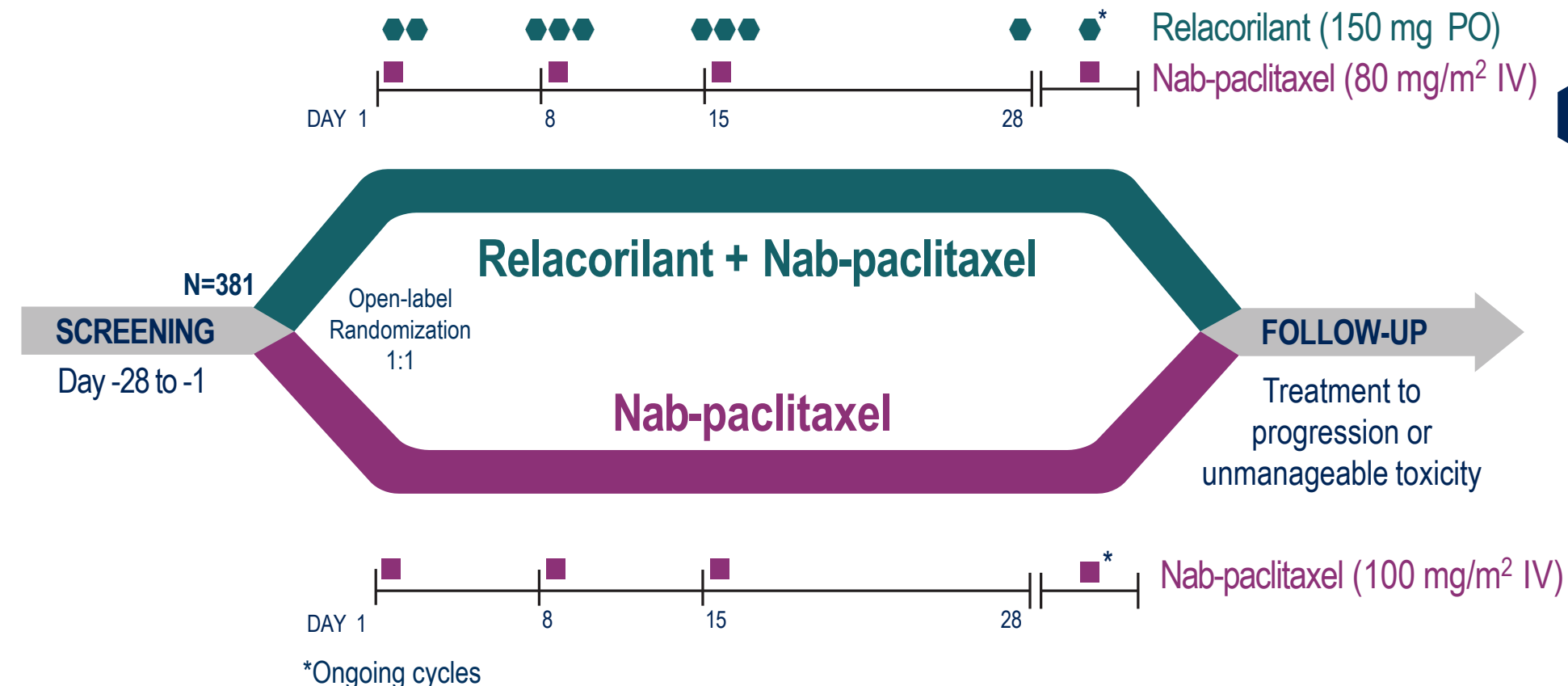


# ROSELLA | PHASE 3 TRIAL IN PLATINUM-RESISTANT OVARIAN CANCER

## Population

- Epithelial ovarian, primary peritoneal or fallopian tube cancer
- ECOG performance status 0 or 1
- Progression >1 to <6 months after the last dose of platinum therapy<sup>†</sup>
- 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

- PFS by RECIST v1.1 assessed by BICR
- OS

## Secondary Endpoints

- PFS by RECIST v1.1 assessed by Investigator
- Safety

Data cutoff: Feb 24, 2025

<sup>†</sup>Excluding disease with no response or progression ≤1 month after last dose of platinum therapy in first-line treatment.

ECOG, Eastern Cooperative Oncology Group; IV, intravenous; OS, overall survival; PFS, progression-free survival; PO, by mouth; RECIST, Response Evaluation Criteria in Solid Tumors.

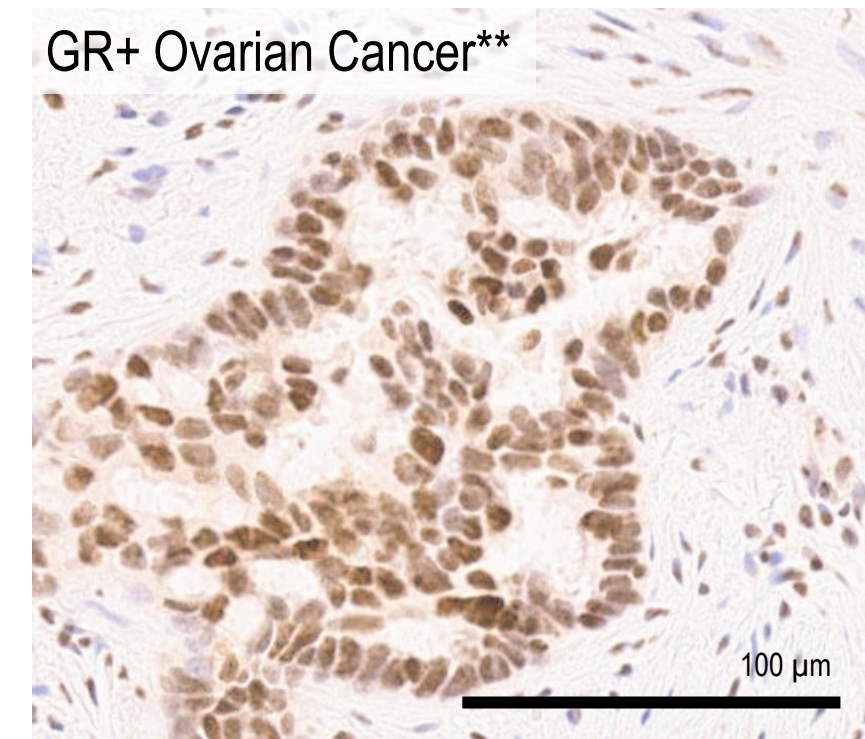
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# PHASE 2 EXPLORATORY ANALYSIS | THE ADDITION OF RELACORILANT TO NAB-PACLITAXEL BENEFITED PATIENTS AT ALL TUMOR GR EXPRESSION LEVELS

Treatment Arm	Patients Enrolled	Patients with GR Immunohistochemistry Data
Intermittent Relacorilant + Nab-paclitaxel	60	38
Nab-paclitaxel Monotherapy	60	49

GR Immunohistochemistry H-Score Tertile (Range)	PFS Hazard Ratio* (95% CI)
<b>Lowest</b> [0–100)	<b>0.64</b> (0.25–1.64)
<b>Middle</b> [100–180)	<b>0.67</b> (0.30–1.50)
<b>Highest</b> [180–300]	<b>0.80</b> (0.31–2.12)
<b>All Patients</b>	<b>0.66</b> (0.44–0.98)



>95% of ovarian cancers expressed GR in tumor cell nuclei.

Similar results were observed for different levels of tumor GR mRNA expression evaluated by NanoString.

Immunohistochemistry was performed with a CLIA-certified assay on the Techmate platform with the rabbit monoclonal anti-GR antibody clone D8H2 (Cell Signaling Inc.).

\*Comparing patients who were randomized to intermittent relacorilant + nab-paclitaxel to those who were randomized to nab-paclitaxel monotherapy.

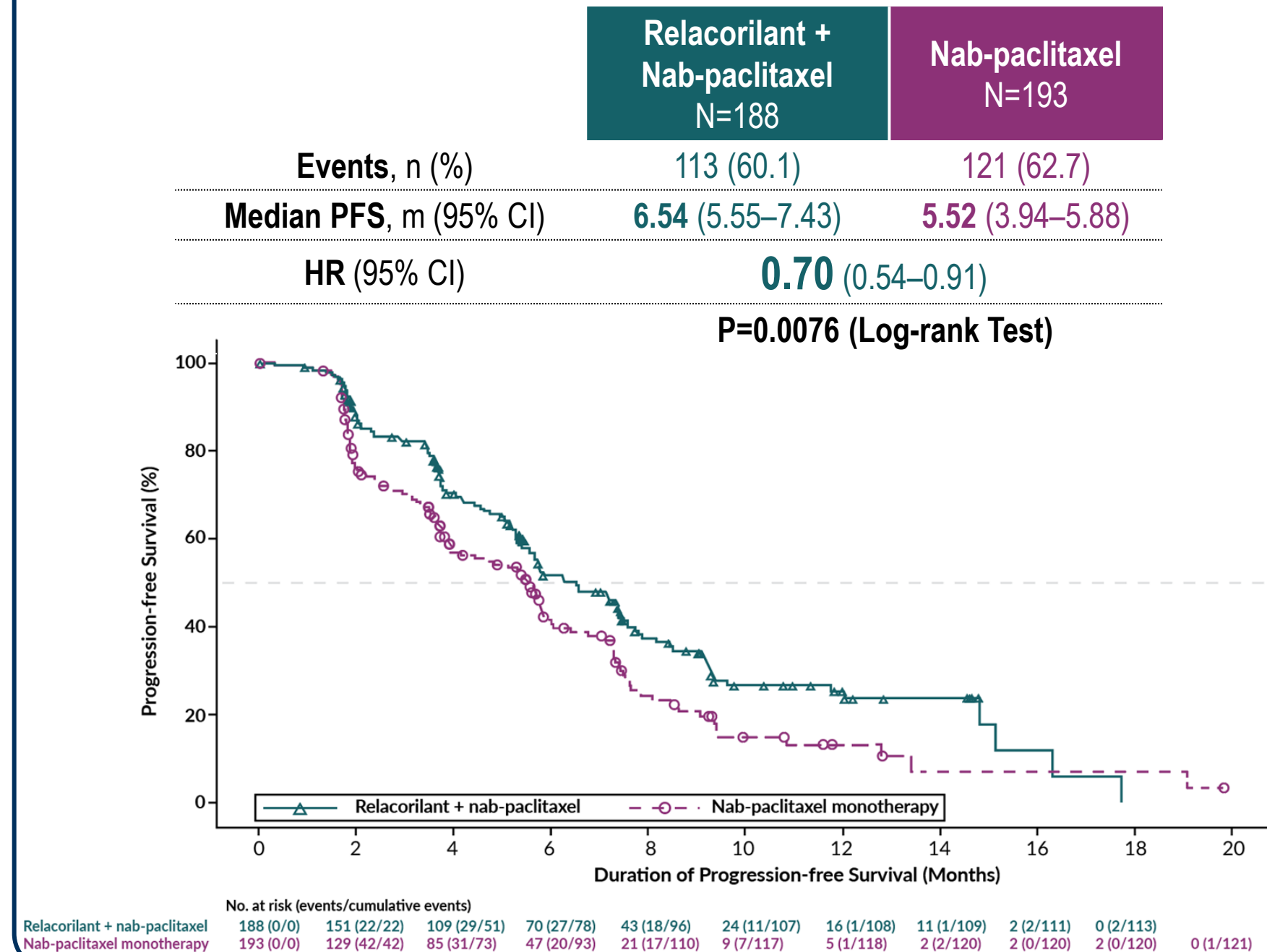
\*\*Immunoreactivity for GR is indicated by brown chromogen deposition in the nuclei of malignant and stromal cells with a blue nuclear hematoxylin counterstain.

CI, confidence Interval; GR, glucocorticoid receptor; PFS, progression-free survival.

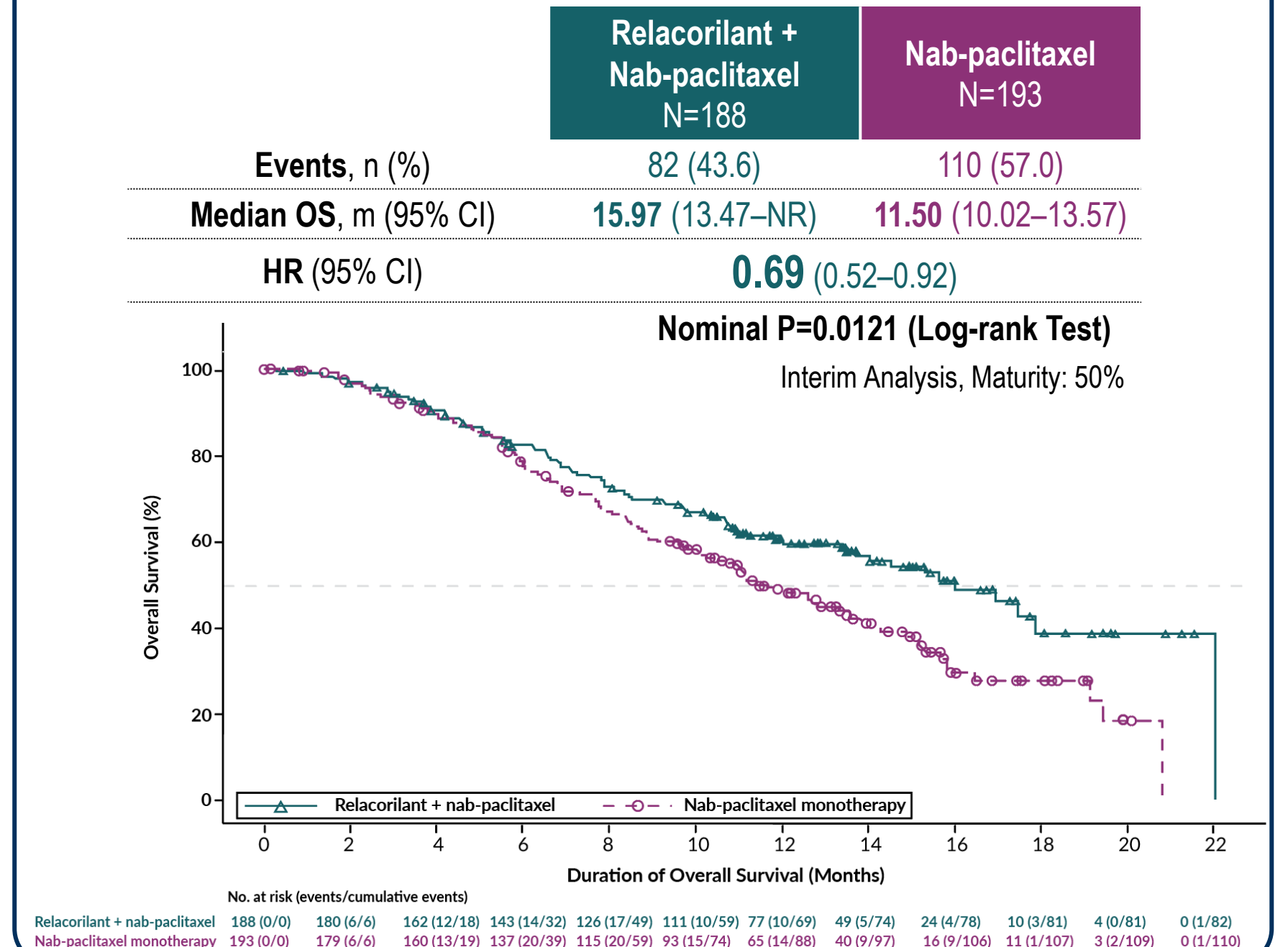
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# ROSELLA | Relacorilant Improved PFS Assessed by BICR in the ITT Population<sup>1</sup>



# ROSELLA | Relacorilant Improved OS at an Interim Analysis in the ITT Population<sup>1</sup>



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. BICR, blinded-independent central review; CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; m, months; OS, overall survival; PFS, progression-free survival.

Data cutoff: Feb 24, 2025

1. Olawaiye, et al. *Lancet*. 2025; 405(10496):2205-2216.

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# ROSELLA | BASELINE CHARACTERISTICS OF PATIENTS WHO RECEIVED PRIOR PARP INHIBITOR TREATMENT

Prior PARP Inhibitor Treatment, N=234 of 381 Randomized (61.4%)		Relacorilant + Nab-paclitaxel (N=114)	Nab-paclitaxel (N=120)
<b>Age, median (range), years</b>		<b>60 (41–79)</b>	<b>61 (33–77)</b>
<b>Race, n (%)</b>	White	83 (72.8)	86 (71.7)
	Black or African-American	1 (0.9)	1 (0.8)
	Asian	10 (8.8)	14 (11.7)
	Other / Not Reported	20 (17.5)	19 (15.8)
<b>Region</b>	North America	24 (21.1)	25 (20.8)
	Europe	75 (65.8)	78 (65.0)
	Republic of Korea, Australia, & Latin America	15 (13.2)	17 (14.2)
<b>ECOG Performance Status, n (%)*</b>	1 or 2	25 (21.9)	29 (24.2)
<b>BRCA1/2 Mutation, n (%)</b>	Yes	20 (17.5)	22 (18.3)
	No / Unknown	74 (64.9) / 20 (17.5)	69 (57.5) / 29 (24.2)
<b>Prior Lines of Therapy, n (%)</b>	1	1 (0.9)	6 (5.0)
	2	58 (50.9)	59 (49.2)
	3	55 (48.2)	55 (45.8)
<b>Prior Therapies, n (%)</b>	Bevacizumab	114 (100)	120 (100)
	Taxanes	113 (99.1)	120 (100)
	Pegylated Liposomal Doxorubicin	76 (66.7)	75 (62.5)
	Gemcitabine	53 (46.5)	48 (40.0)
<b>Radiographic Progression on a PARP Inhibitor, n (%)</b>		<b>86 (75.4)</b>	<b>97 (80.8)</b>

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\*In the nab-paclitaxel monotherapy arm, 1 patient had an ECOG performance status of 2. BRCA, Breast Cancer Gene; ECOG, Eastern Cooperative Oncology Group; PARP, poly(ADP-ribose) polymerase.

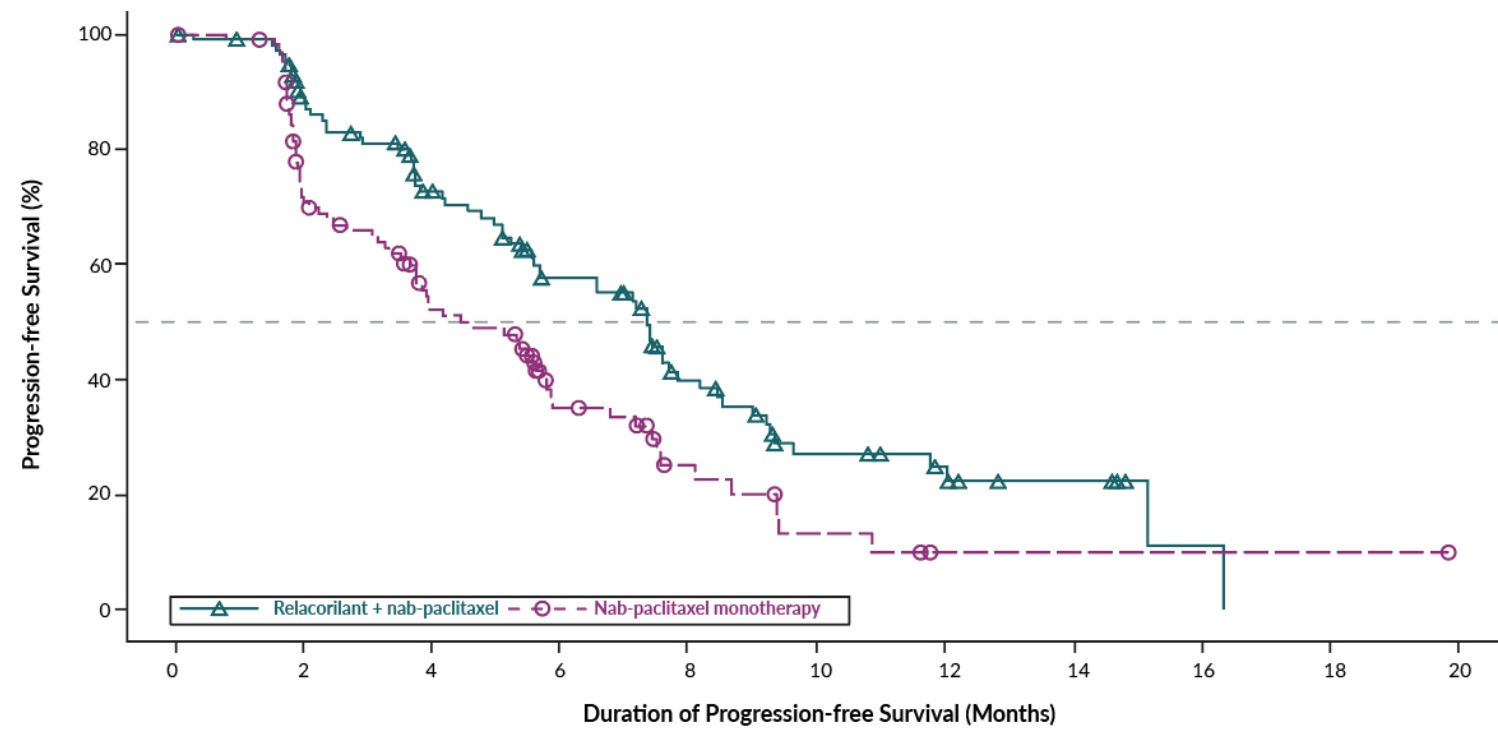
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# ROSELLA | Relacorilant Improved PFS Assessed by BICR in the Subgroup of Patients Who Received Prior PARP Inhibitor Treatment

	<b>Relacorilant + Nab-paclitaxel</b> N=114	<b>Nab-paclitaxel</b> N=120
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<b>Events, n (%)</b>	66 (57.9)	72 (60.0)
<b>Median PFS, m (95% CI)</b>	<b>7.36 (5.59–8.18)</b>	<b>4.63 (3.55–5.72)</b>
<b>HR (95% CI)</b>	<b>0.60 (0.42–0.85)</b>	

Nominal P=0.0035 (Log-rank Test)



	0	2	4	6	8	10	12	14	16	18	20
Relacorilant + nab-paclitaxel	114 (0/0)	90 (12/12)	66 (16/28)	46 (13/41)	27 (13/54)	15 (8/62)	10 (1/63)	6 (1/64)	6 (1/65)	0 (1/66)	0 (0/72)
Nab-paclitaxel monotherapy	120 (0/0)	74 (30/30)	47 (19/49)	22 (13/62)	10 (5/67)	4 (4/71)	1 (1/72)	1 (0/72)	1 (0/72)	1 (0/72)	0 (0/72)

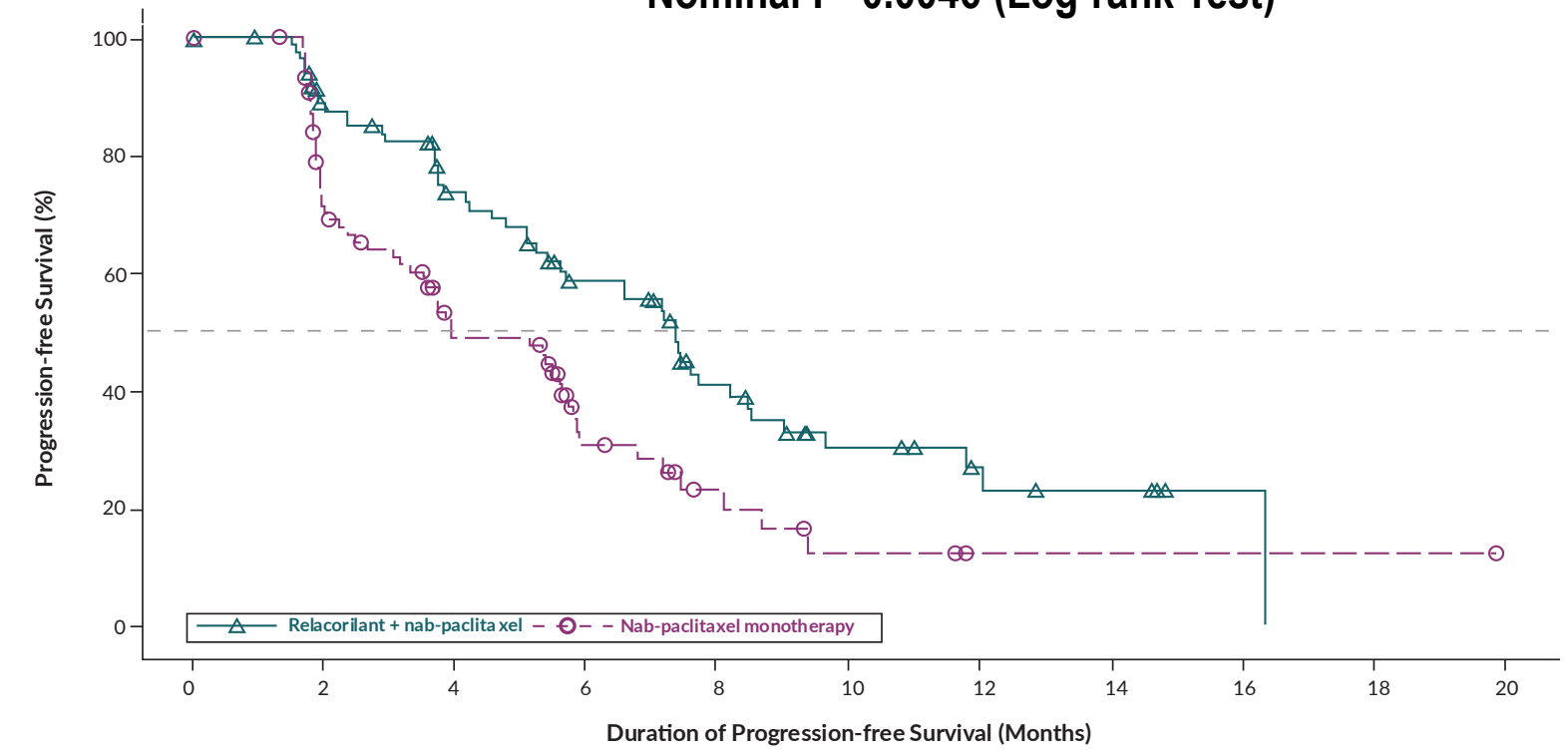
**ORR (Investigator): 39.5% (45/114) vs 30.8% (37/120)**

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

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

Nominal P=0.0046 (Log-rank Test)



	0	2	4	6	8	10	12	14	16	18	20
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)	0 (0/57)
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)**

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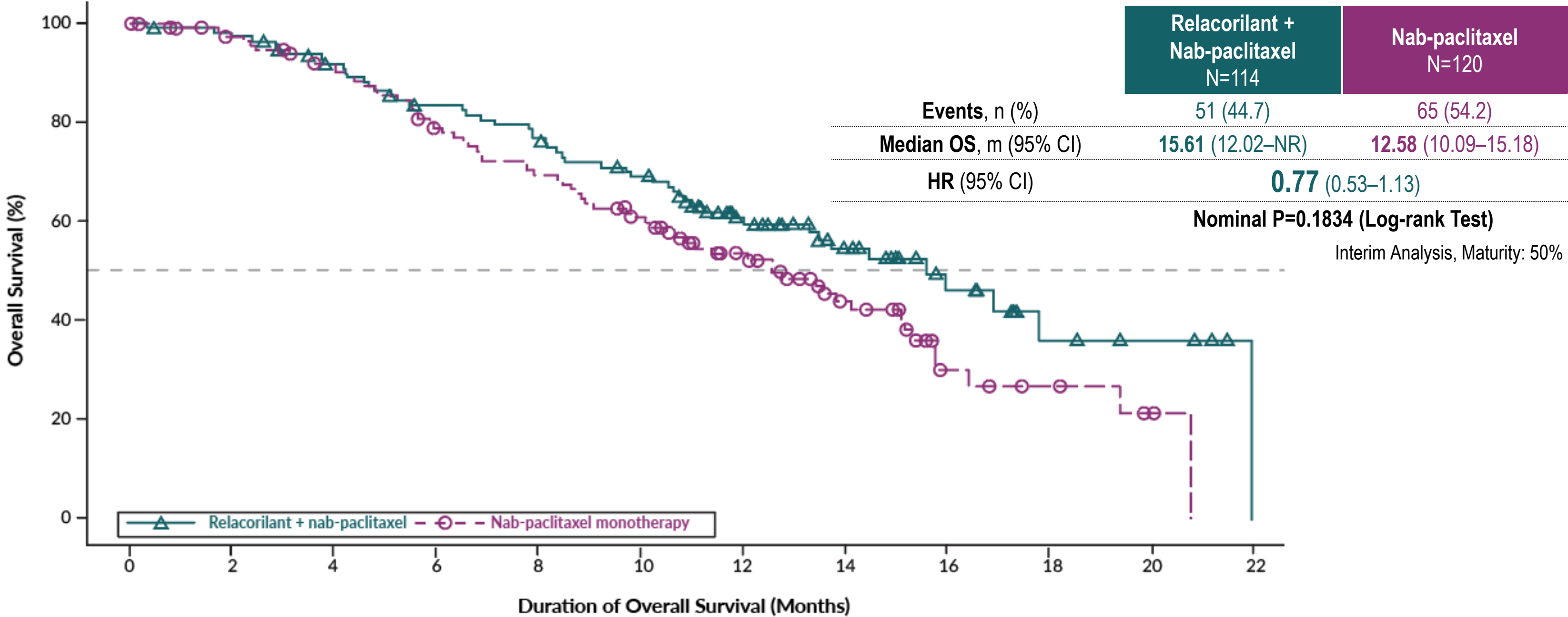
The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% confidence intervals (CI) for progression-free survival in each treatment arm. The HR and the associated 95% CI were estimated using a Cox regression model with treatment group as the main effect and stratification 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.

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# ROSELLA | RELACORILANT SHOWED A TREND TO IMPROVED OVERALL SURVIVAL IN THE SUBGROUP OF PATIENTS WITH PRIOR PARP INHIBITOR TREATMENT



	No. at risk (events/cumulative events)											
Relacorilant + nab-paclitaxel	114 (0/0)	109 (3/3)	99 (6/9)	88 (9/18)	81 (7/25)	71 (8/33)	48 (8/41)	31 (4/45)	14 (3/48)	6 (2/50)	4 (0/50)	0 (1/51)
Nab-paclitaxel monotherapy	120 (0/0)	110 (3/3)	99 (6/9)	83 (14/23)	73 (10/33)	61 (9/42)	45 (7/49)	26 (7/56)	9 (6/62)	6 (1/63)	3 (1/64)	0 (1/65)

The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% confidence intervals (CI) 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.

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# ROSELLA | SAFETY SUMMARY

## *Relacorilant + Nab-paclitaxel Was Well Tolerated, With a Favorable and Consistent Safety Profile*

Patients Who Received at Least One Dose of Study Drug	Safety Population		Prior PARP Inhibitor Subgroup	
	Relacorilant + Nab-paclitaxel (N=188)	Nab-paclitaxel (N=190)	Relacorilant + Nab-paclitaxel (N=114)	Nab-paclitaxel (N=117)
Any TEAEs, n (%)	188 (100)	189 (99.5)	114 (100)	117 (100)
Grade ≥3 TEAEs, n (%)	140 (74.5)	113 (59.5)	81 (71.1)	75 (64.1)
Serious AEs, n (%)	66 (35.1)	45 (23.7)	36 (31.6)	25 (21.4)
Dose Reductions of Relacorilant Due to TEAEs, n (%)	13 (6.9)	—	8 (7.0)	—
Dose Reductions of Nab-paclitaxel Due to TEAEs, n (%)	91 (48.4)	60 (31.6)	53 (46.5)	34 (29.1)
Interruptions of Nab-paclitaxel (+ Relacorilant) Due to TEAEs, n (%)*	137 (72.9)	104 (54.7)	83 (72.8)	68 (58.1)
Discontinuations of Nab-paclitaxel (+ Relacorilant) Due to TEAEs, n (%)*	17 (9.0)	15 (7.9)	10 (8.8)	8 (6.8)

**There were no relacorilant-related fatal AEs.  
The safety profile of the prior PARP inhibitor subgroup was comparable to the overall safety population.**

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

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# CONCLUSIONS



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1

## ROSELLA met its primary endpoint of improving PFS

Relacorilant, a **first-in-class, oral, SGRA**, in combination with nab-paclitaxel extended progression-free survival by BICR (HR 0.70, log-rank test  $P=0.0076$ ) compared to nab-paclitaxel monotherapy in patients with platinum-resistant ovarian cancer.

At the interim overall survival analysis, the addition of relacorilant to nab-paclitaxel showed a clinically meaningful 4.5-month median improvement in overall survival (median 16.0 vs 11.5 months, HR 0.69, nominal log-rank test  $P=0.0121$ ).

2

## Consistent benefit in the PARPi-progressor subgroup

Relacorilant + nab-paclitaxel showed a PFS benefit in subgroups of patients with prior PARP inhibitor treatment (HR 0.60, nominal log-rank test  $P=0.0035$ ) and progression while on a PARP inhibitor (HR 0.56, nominal log-rank test  $P=0.0046$ ), with a median PFS of 7.36 months for both subgroups.

3

## Well-tolerated, favorable safety profile

The safety profile in the prior PARP inhibitor exposed subgroup was comparable to the overall safety population.

Relacorilant + nab-paclitaxel was well-tolerated, with a favorable safety profile that was comparable between treatment arms when adjusted for duration of study treatment.

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

**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, Anna Lam, Sachin Pai, Nina Pashova, William Guyer, Abhijit Ramachandran, Don Pham, Alan Arroyo, Bhagyashree Yadav, 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, Nikoletta Toth, and Bhagyashree Yadav. **Publications Support:** Farida Khan and Tina Schlafly.

BICR, blinded independent central review; HR, hazard ratio; PARPi, poly(ADP-ribose) polymerase inhibitor; PFS, progression-free survival; PROC, platinum-resistant ovarian cancer; SGRA, selective glucocorticoid receptor antagonist.

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