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Phase 3 ROSELLA (GOG-3073, ENGOT-ov72) Trial of Relacorilant + Nab-paclitaxel vs Nab-paclitaxel in Platinum-resistant Ovarian Cancer: Primary Results and Outcomes in Older Patients

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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

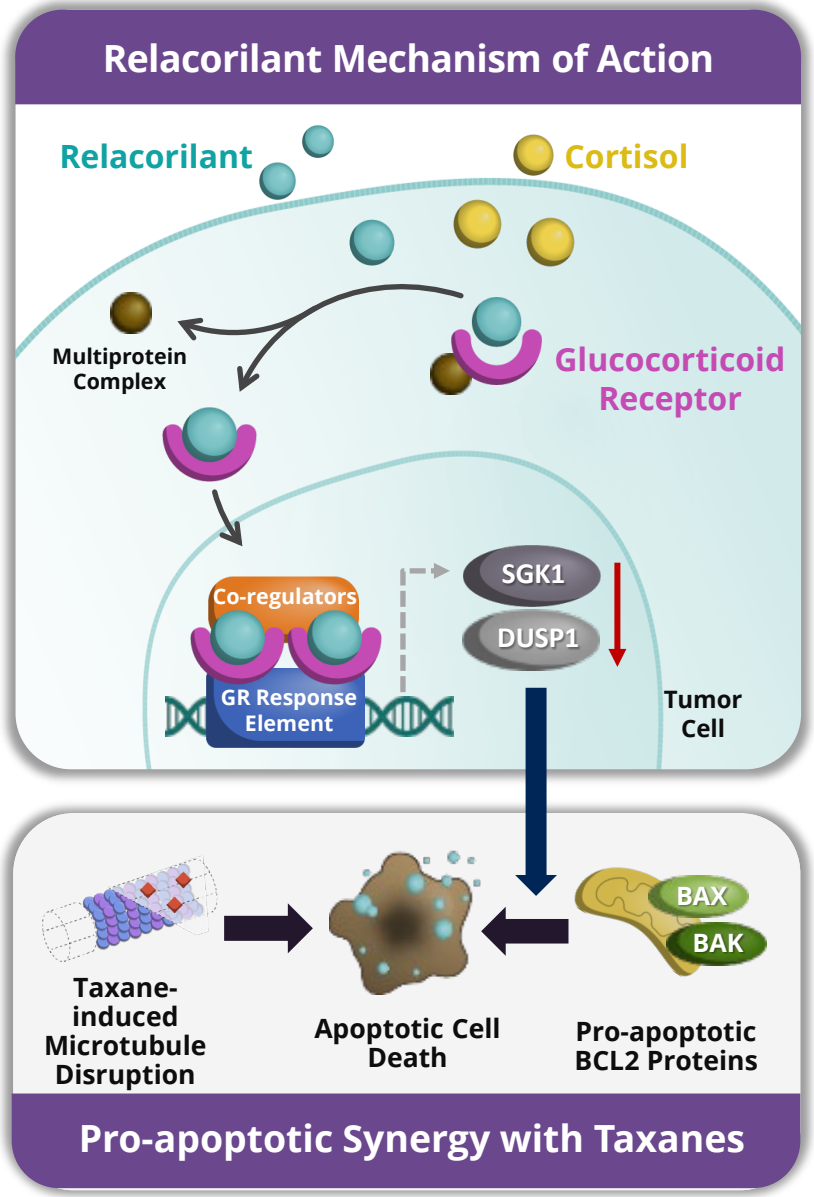
Disclosures

	No, nothing to disclose
X	Yes, please specify:

Company Name	*Honoraria/ Expenses*	*Consulting/ Advisory Board*	*Funded Research*	*Royalties/ Patent*	*Stock Options*	*Ownership/ Equity Position*	*Employee*	*Other (please specify)*
AstraZeneca			x					
Merck		x						
Corcept		x	x					
Eli Lilly		x						
GSK		x						
Genmab		x						

Background

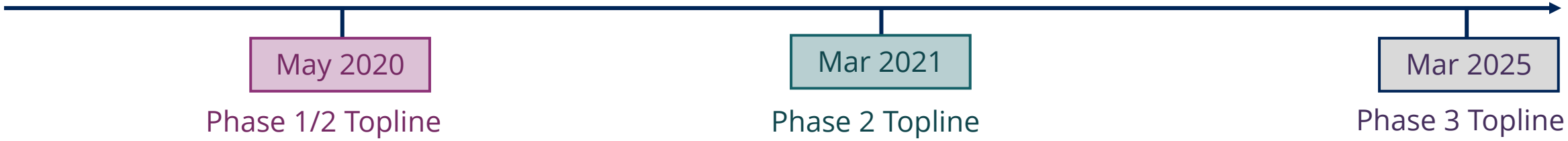
- Patients with platinum-resistant ovarian cancer have an overall survival of ~1 year and need new treatments[1]
- Ovarian cancers express the glucocorticoid receptor (GR), a marker of poor prognosis[2]
- GR signaling reduces sensitivity to chemotherapy[3,4]
- Relacorilant is a novel, selective GR antagonist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

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

39% durable (≥16 weeks) disease control in patients with ovarian cancer

29% 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 PFS (HR 0.66, P=0.038) and showed a trend to improved OS (HR 0.67, P=0.066)

Phase 3 | ROSELLA[5]

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

HR, hazard ratio; OS, overall survival; PFS, progression-free survival.

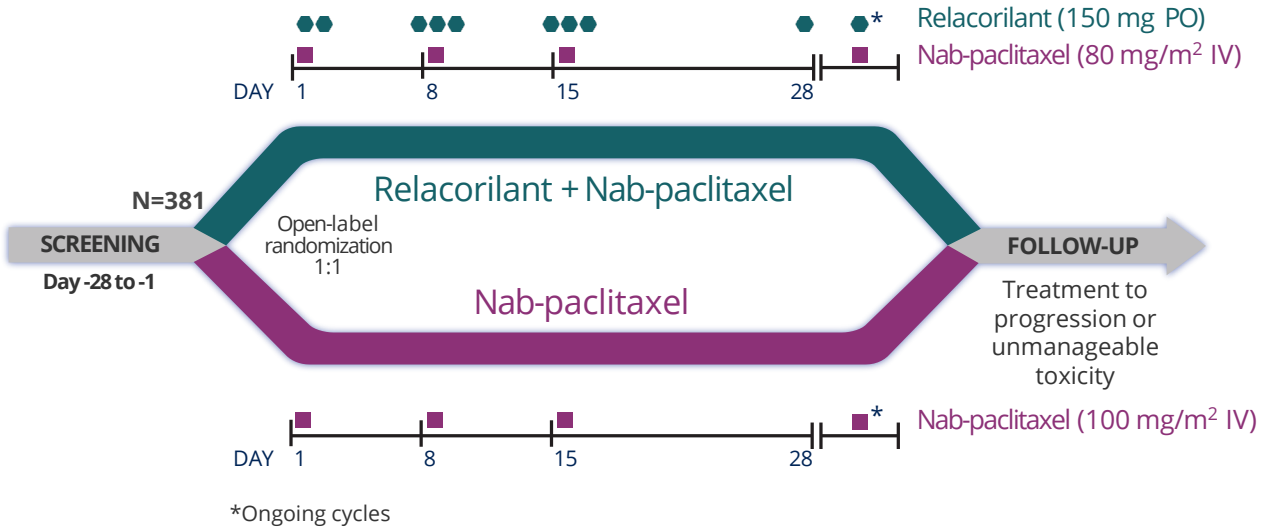
1. Martorana, et al. *Int J Gynecol Cancer.* 2025;35:100009. 2. Colombo, et al. *J Clin Oncol*. 2023;41(30):4779-89. 3. Coleman, et al. *Gynecol Oncol.* 2011;122:111-15. 4. Munster, et al. *Clin Cancer Res*. 2022;28(15):3214-24. 5. Olawaiye, et al. *Lancet.* 2025; 405(10496):2205-2216.

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†
- 1–3 prior lines of therapy
- Prior bevacizumab required

NCT05257408



*Ongoing cycles

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 per blinded independent central review
- 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
Data cutoff: Feb 24, 2025
Conducted at 117 sites in 14 countries.

†Excluding disease with no response to or progression ≤1 month after the last dose of front-line platinum therapy.

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; OS, overall survival; PFS, progression-free survival; PO, by mouth; RECIST, Response Evaluation Criteria in Solid Tumors.

ROSELLA | Baseline Characteristics Were Well Balanced

ITT

		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)**
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 No / Unknown	23 **(12.2)** 133 **(70.7)** / 32 **(17.0)**	24 **(12.4)** 128 **(66.3)** / 41 **(21.2)**
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)**

Data cutoff: Feb 24, 2025

*In the nab-paclitaxel monotherapy arm, 1 patient had an ECOG performance status of 2. †Progressed 1–3 months after the last dose of platinum from their first line platinum. 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; ITT, intent-to-treat; PARP, poly(ADP-ribose) polymerase.

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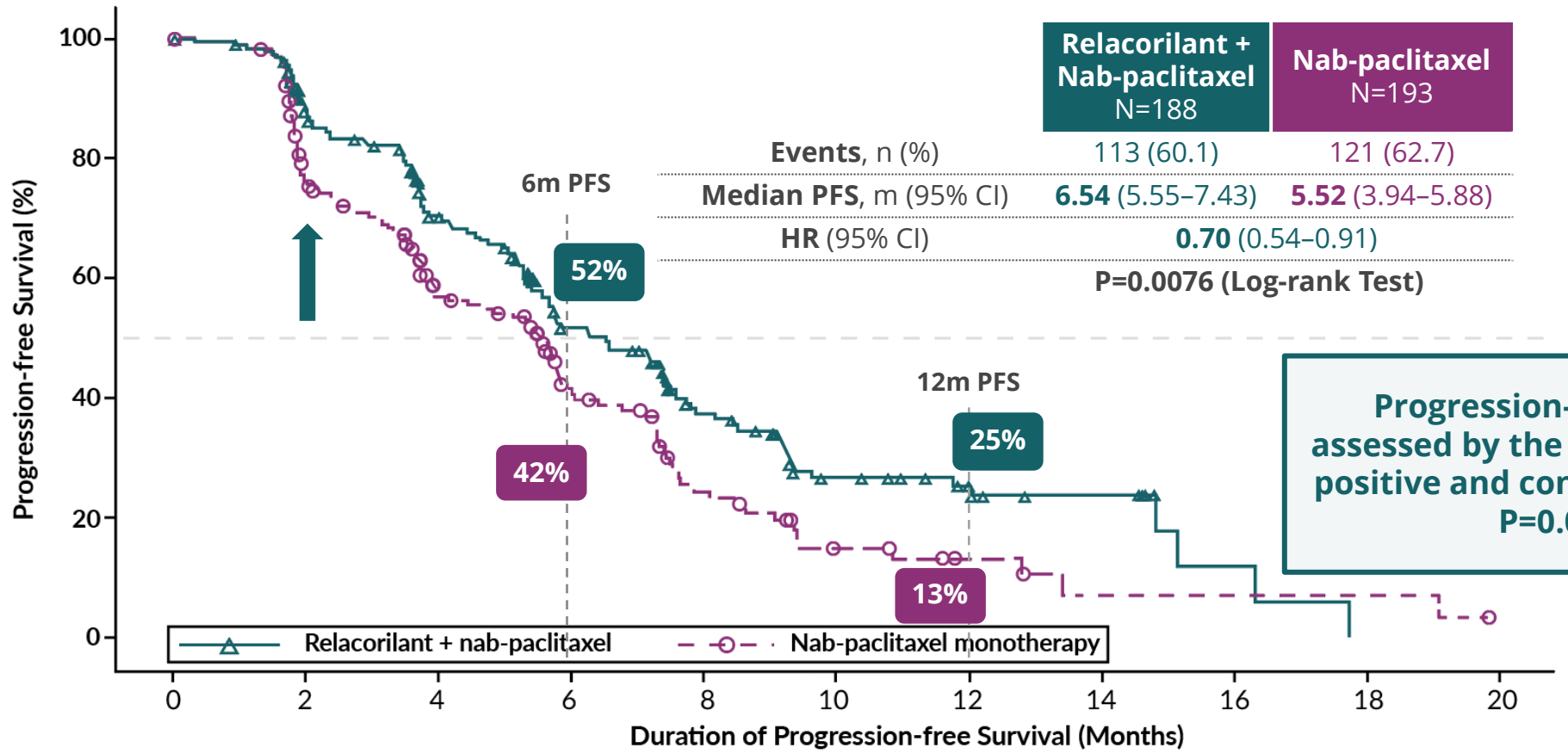
ROSELLA | Relacorilant Significantly Improved Progression-Free Survival Assessed by Blinded Independent Central Review (BICR)



	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 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.
CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; m, months; PFS, progression-free survival.

Data cutoff: Feb 24, 2025

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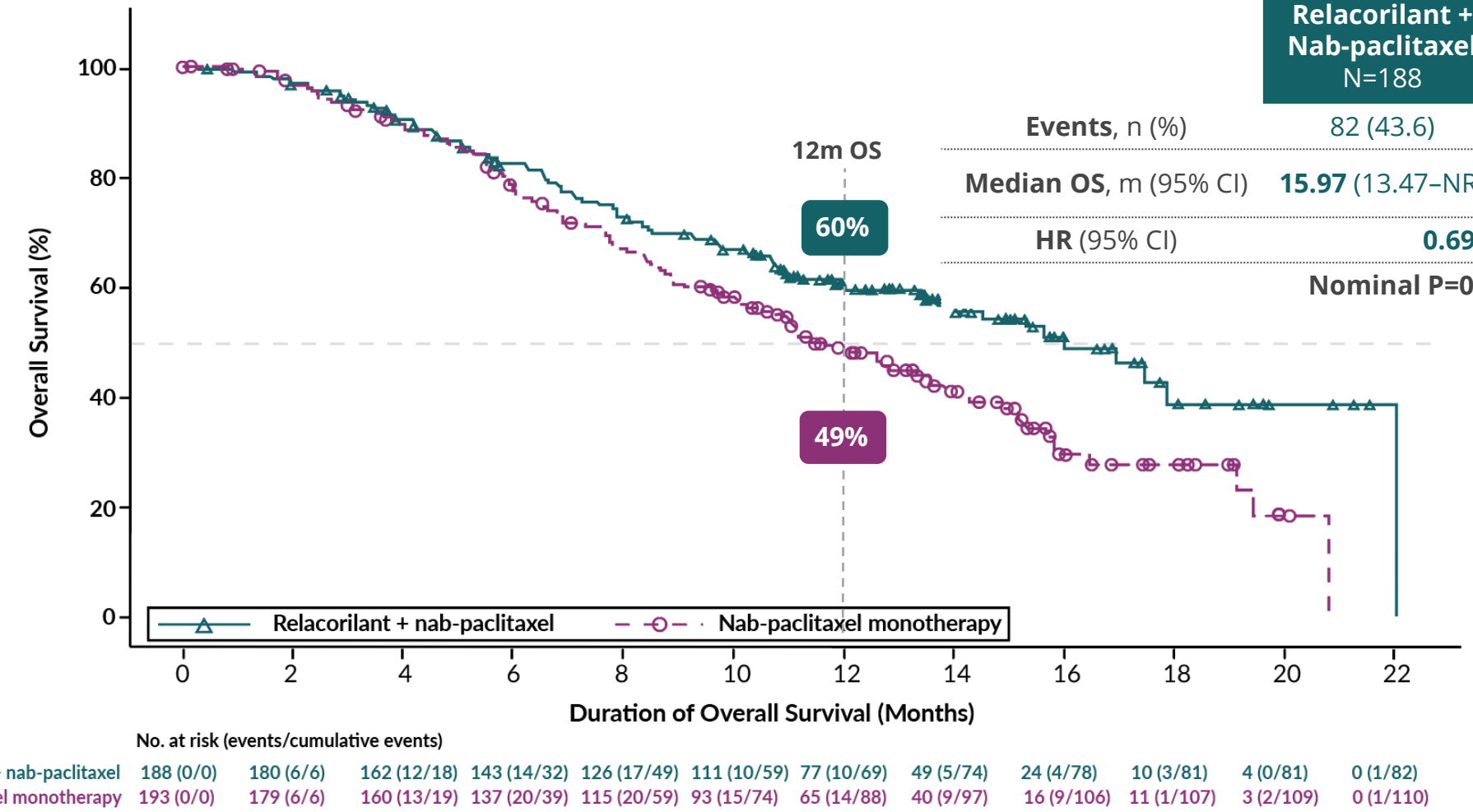
ROSELLA | Relacorilant Improved Overall Survival at This Interim Analysis



	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; ITT, intent-to-treat; m, months; NR, not reached; OS, overall survival.

Data cutoff: Feb 24, 2025

ROSELLA | Baseline Characteristics of Patients ≥ 65 Years

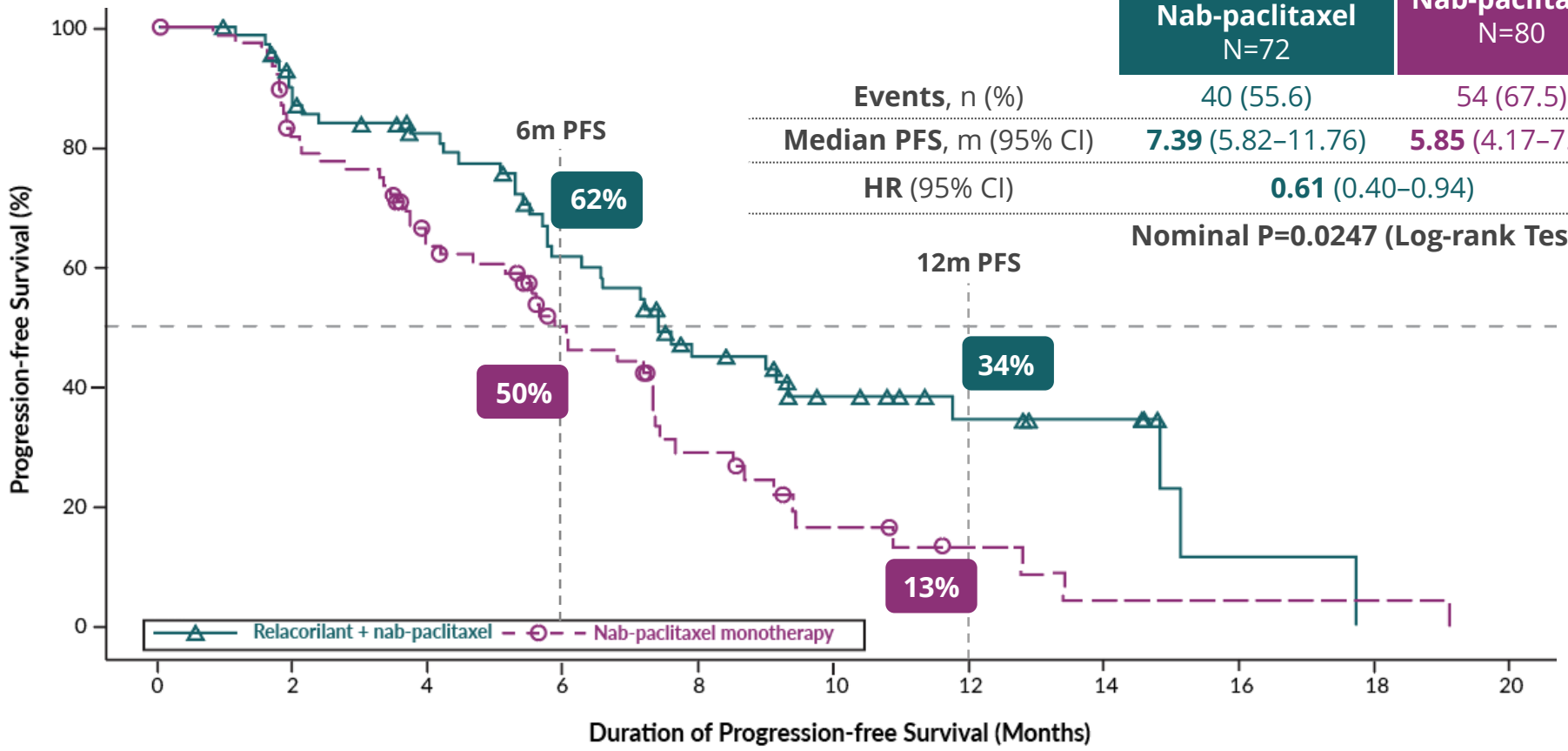
Patients ≥ 65 years, N=152 of 381 Randomized (40%)		**Relacorilant + Nab-paclitaxel** (N=72)	**Nab-paclitaxel** (N=80)
Age, median (range), years		**70.0** (65–85)	**70.5** (65–86)
Race, n (%)	White	52 **(72.2)**	54 **(67.5)**
	Black or African-American	2 **(2.8)**	0 **(0)**
	Asian	5 **(6.9)**	10 **(12.5)**
	Other / Not Reported	13 **(18.1)**	16 **(20.0)**
Region	North America	18 **(25.0)**	17 **(21.3)**
	Europe	44 **(61.1)**	50 **(62.5)**
	Korea, Australia and Latin America	10 **(13.9)**	13 **(16.3)**
ECOG Performance Status, n (%)*	1 or 2	26 **(36.1)**	33 **(41.3)**
BRCA1/2 Mutation, n (%)	Yes	3 **(4.2)**	6 **(7.5)**
	No / Unknown	54 **(75.0)** / 15 **(20.8)**	57 **(71.3)** / 17 **(21.3)**
Prior Lines of Therapy, n (%)	1	8 **(11.1)**	9 **(11.3)**
	2	27 **(37.5)**	39 **(48.8)**
	3	37 **(51.4)**	32 **(40.0)**
Prior Lines of Therapy in the Platinum-resistant Setting, n (%)	≥1	29 **(40.3)**	29 **(36.3)**
Prior Therapies, n (%)	Bevacizumab	72 **(100)**	80 **(100)**
	Taxanes	72 **(100)**	79 **(98.8)**
	Pegylated Liposomal Doxorubicin	49 **(68.1)**	49 **(61.3)**
	PARP Inhibitor	38 **(52.8)**	42 **(52.5)**

*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.

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)	



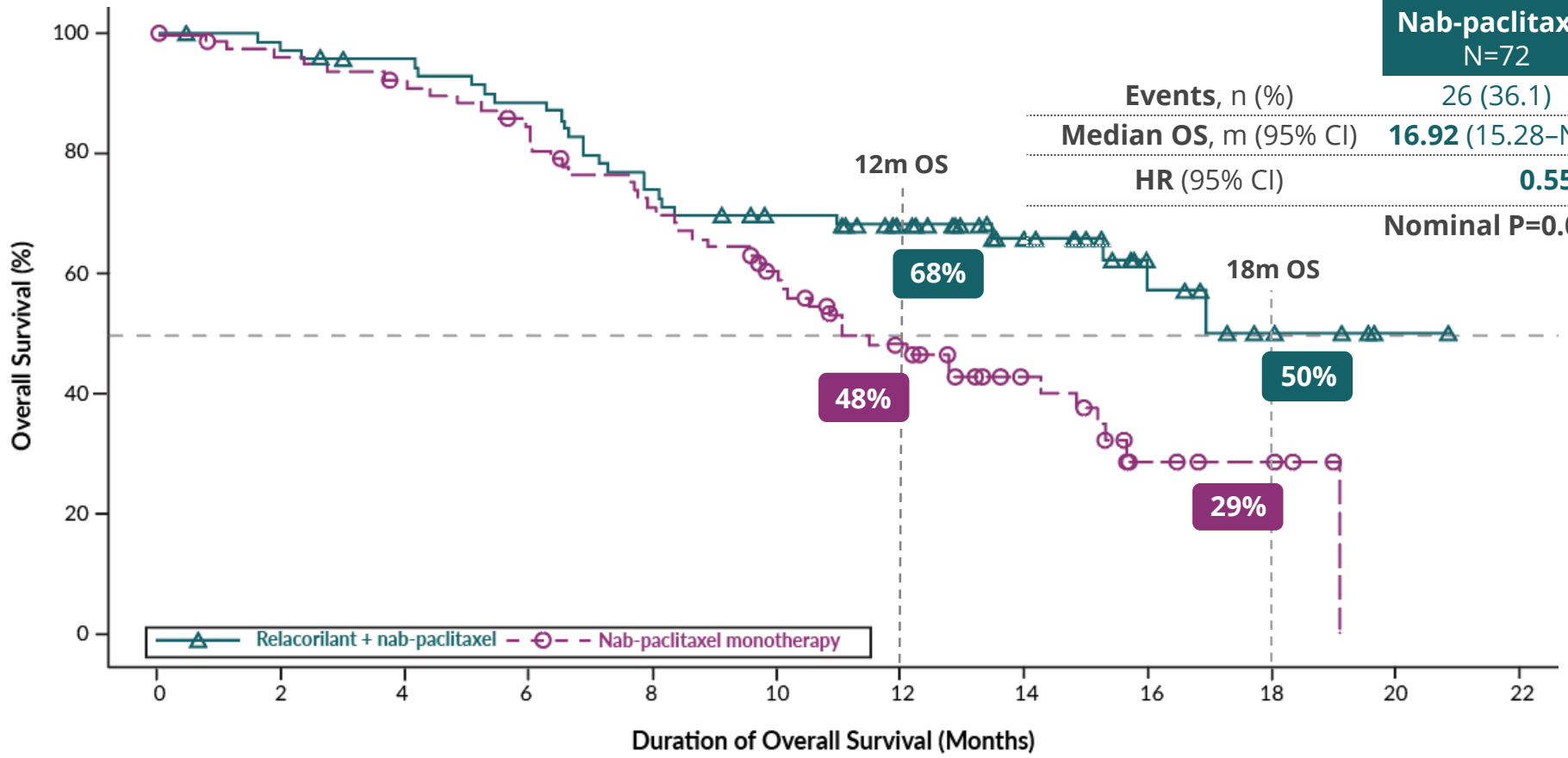
No. at risk (events/cumulative events)										
Relacorilant + nab-paclitaxel	72 (0/0)	59 (9/9)	49 (3/12)	35 (12/24)	22 (9/33)	14 (3/36)	9 (1/37)	7 (0/37)	1 (2/39)	0 (1/40)	
Nab-paclitaxel monotherapy	80 (0/0)	60 (14/14)	43 (13/27)	26 (8/35)	13 (10/45)	6 (5/50)	3 (1/51)	1 (2/53)	1 (0/53)	1 (0/53)	0 (1/54)

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 in Patients Aged ≥65 Years



	Relacorilant + Nab-paclitaxel N=72	Nab-paclitaxel N=80
Events, n (%)	26 (36.1)	47 (58.8)
Median OS, m (95% CI)	**16.92** (15.28–NR)	**11.07** (9.72–14.82)
HR (95% CI)	**0.55** (0.34–0.89)	

Nominal P=0.0143 (Log-rank Test)

Maturity: 50%

No. at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	72 (0/0)	69 (2/2)	66 (1/3)	61 (5/8)	51 (10/18)	45 (3/21)	38 (1/22)	25 (1/23)	11 (2/25)	5 (1/26)	1 (0/26)	0 (0/26)
Nab-paclitaxel monotherapy	80 (0/0)	75 (3/3)	71 (3/6)	64 (6/12)	53 (10/22)	42 (8/30)	29 (8/38)	17 (3/41)	6 (5/46)	4 (0/46)	0 (1/47)	

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 | Safety Summary

Relacorilant + Nab-paclitaxel Has a Favorable Safety Profile in the Overall Safety Population and in the ≥65 Years Subgroup

Patients Who Received at Least One Dose of Study Drug	Safety Population		≥65 Years Subgroup	
	Relacorilant + Nab-paclitaxel (N=188)	Nab-paclitaxel (N=190)	Relacorilant + Nab-paclitaxel (N=72)	Nab-paclitaxel (N=79)
Median duration of study drug treatment, weeks	**19.6**	**15.1**	**23.2**	**20.1**
Any TEAEs, n (%)	188 **(100)**	189 **(99.5)**	72 **(100)**	78 **(98.7)**
Grade ≥3 TEAEs, n (%)	140 **(74.5)**	113 **(59.5)**	59 **(81.9)**	46 **(58.2)**
Serious AEs, n (%)	66 **(35.1)**	45 **(23.7)**	25 **(34.7)**	20 **(25.3)**
Dose Reductions of Relacorilant Due to TEAEs, n (%)	13 **(6.9)**	—	6 **(8.3)**	—
Dose Reductions of Nab-paclitaxel Due to TEAEs, n (%)	91 **(48.4)**	60 **(31.6)**	46 **(63.9)**	31 **(39.2)**
Interruptions of Nab-paclitaxel (+ Relacorilant) Due to TEAEs, n (%)*	137 **(72.9)**	104 **(54.7)**	56 **(77.8)**	47 **(59.5)**
Discontinuations of Nab-paclitaxel (+ Relacorilant) Due to TEAEs, n (%)*	17 **(9.0)**	15 **(7.9)**	11 **(15.3)**	9 **(11.4)**

The ≥65 years subgroup had similar rates of serious adverse events compared to the overall population.

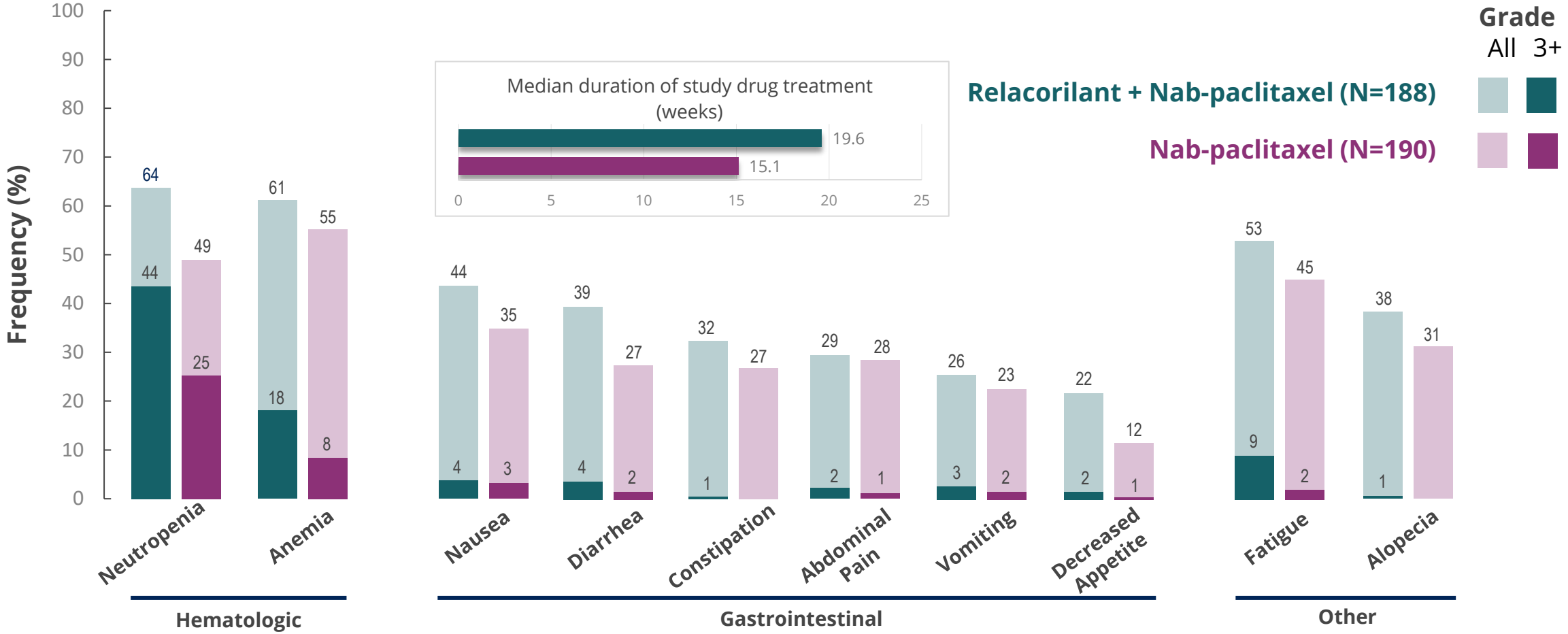
A slightly higher incidence of nab-paclitaxel dose reductions, interruptions and discontinuations is seen in both study arms, in part due to an 18-33% longer treatment duration with nab-paclitaxel than the overall safety population.

Data cutoff: Feb 24, 2025

Alexander B. Olawaiye, MD

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

ROSELLA | Common (>20%) Adverse Events

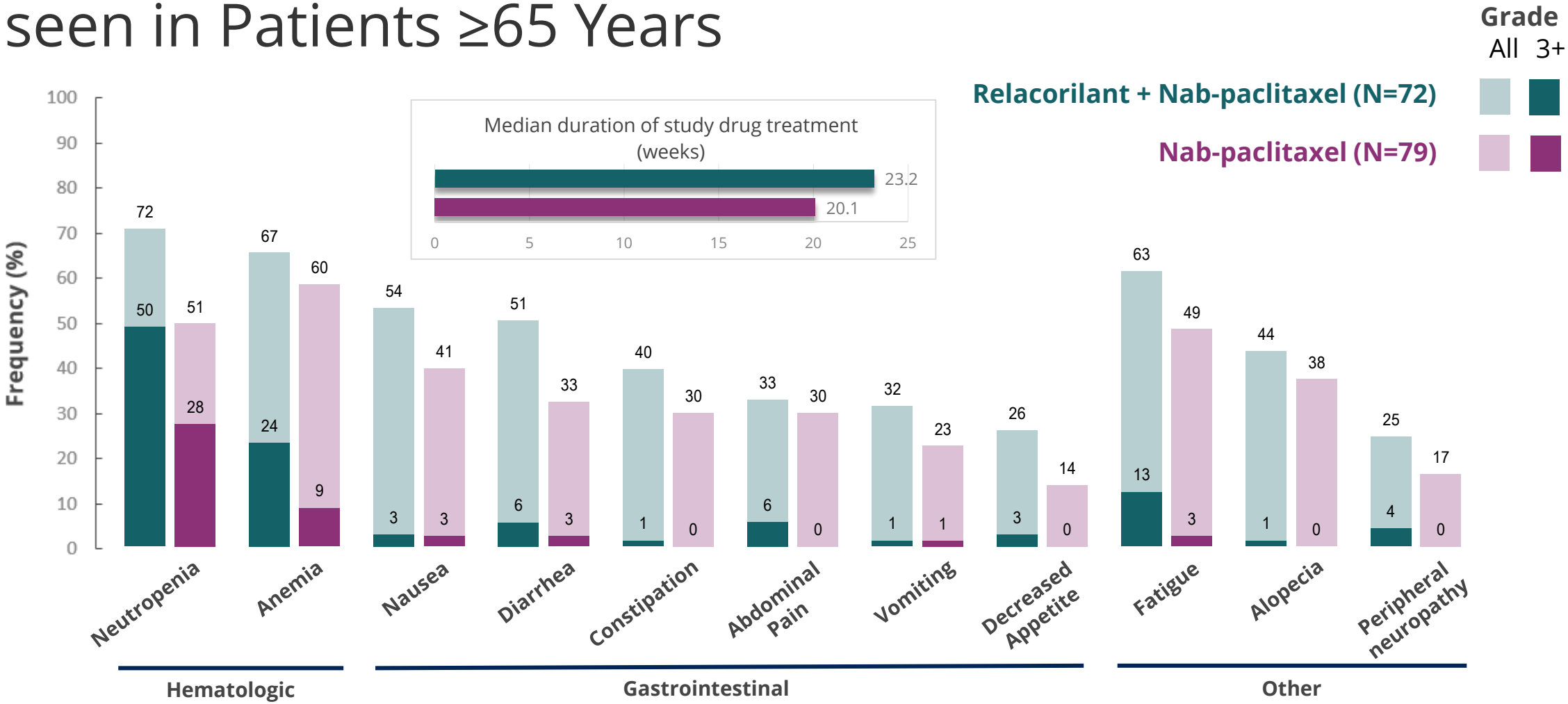


Peripheral neuropathy occurred with similar frequency in both arms (19.1% and 17.4%).
5 SAEs of febrile neutropenia were reported, 4 (2.1%) with relacorilant + nab-paclitaxel and 1 (0.5%) with nab-paclitaxel monotherapy.
5 SAEs of sepsis were reported, 3 (1.6%) with relacorilant + nab-paclitaxel and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

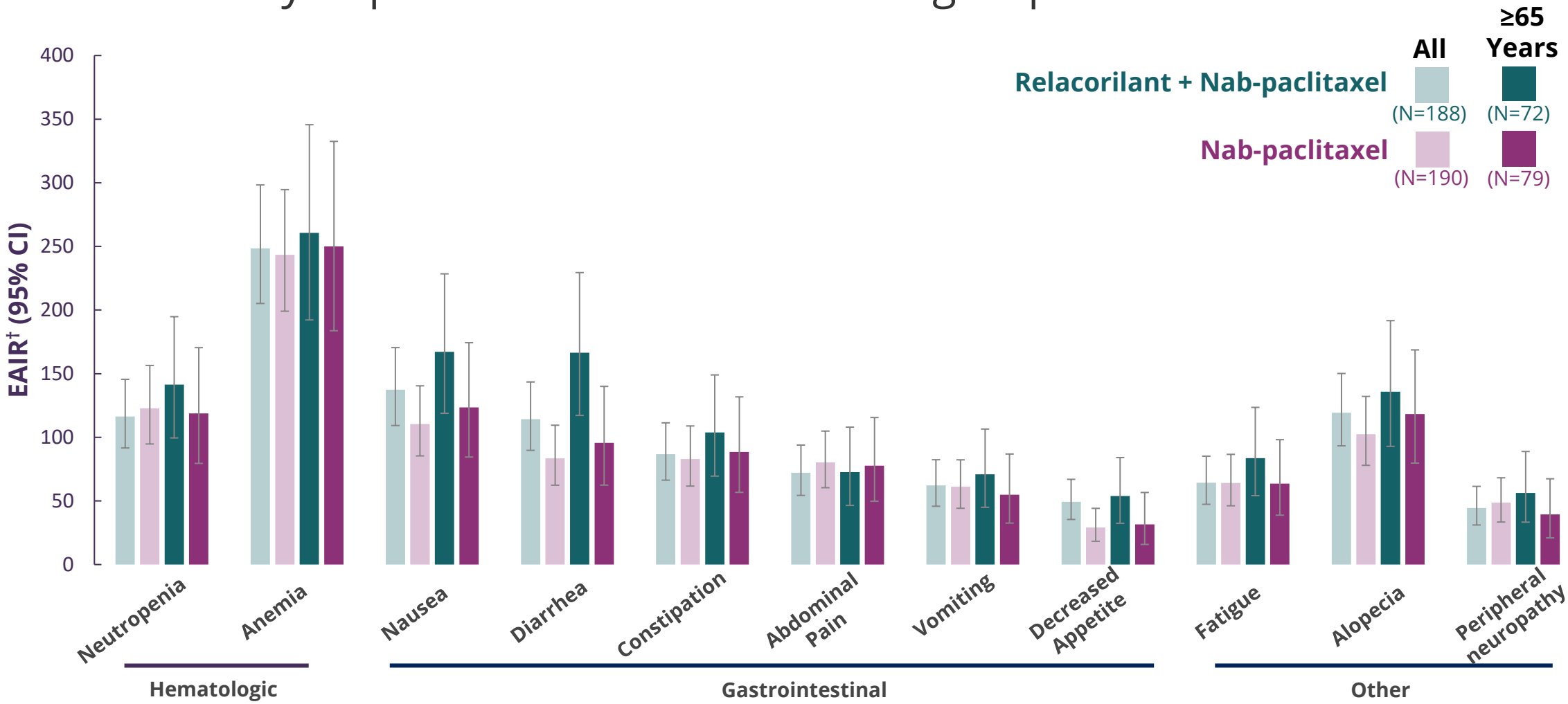
ROSELLA | A Similar Pattern of Adverse Events is seen in Patients ≥65 Years



2 (2.8%) SAEs of febrile neutropenia were reported, both in the relacorilant + nab-paclitaxel arm, and 1 (1.3%) SAE of sepsis was reported in the nab-paclitaxel monotherapy arm.

TEAEs that occurred in >20% of patients. Assessed in the safety population of patients who received at least one dose of study drug, N=151. 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.

ROSELLA | Exposure Adjusted Incidence Rates of Adverse Events* in Overall Safety Population and ≥65 Years Subgroup



*Preferred terms are shown.

†Exposure Adjusted Incidence Rate (EAIR) is defined as Event Incidence rate per 100 PYE: (Total number of patients with an event/Total PYE)*100. Exact 95% confidence interval based on Poisson distribution.

ROSELLA | Conclusions

1 ROSELLA met its primary endpoint of improving PFS	Relacorilant, **a first-in-class, oral, selective glucocorticoid receptor antagonist (SGRA), extended PFS** by BICR (HR 0.70, log-rank test P=0.0076) compared to nab-paclitaxel monotherapy in patients with platinum-resistant ovarian cancer
2 Median survival prolonged by 4.5 months	**The addition of relacorilant to nab-paclitaxel showed a clinically meaningful improvement in overall survival at this interim analysis** (HR 0.69, nominal log-rank test P=0.0121, median 16.0 vs 11.5 months)
3 Consistent benefit in older patients	**The addition of relacorilant to nab-paclitaxel showed a benefit in patients ≥65 years,** (PFS HR 0.61, nominal log-rank test P=0.0247; OS HR 0.55, nominal log-rank test P=0.0143)
4 Well-tolerated, favorable safety profile	Relacorilant plus nab-paclitaxel has a well-tolerated, favorable safety profile in the overall safety population and in the subgroup of patients ≥65 years.

BICR, blinded independent central review; HR, hazard ratio; OS, overall survival; PFS, progression-free survival; 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.

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
Knowles
Lee
Leiser
LyBarger
McClung
McCollum
Modesitt
Monk
Muller
Munro
Nguyen
Olawaiye
Randall
Salinas
Salyer
Sharma
Slomovitz
Stany
Taylor
Tenney
Ulm
Wilmott
Yeku

Barlow
Clamp
Cook
Herbertson
Khalique
Nicum

Lorusso
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Palaia
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Kim
Kim
Lee
Lim
Park
Shin

Diakos
Goss
Matos
Mileshkin

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de la Cueva Sapiña
Guillens
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Oaknin

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Sipőcz
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Cohen
Safra
Segev

Covens
Gilbert

Bellier
Derquin
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Bodnar
Pikiel
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