2026 ASCO® ANNUAL MEETING

Overall survival subgroup analyses for prior taxane use in the phase 3 ROSELLA trial of 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)

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In collaboration with: GOG FOUNDATION, 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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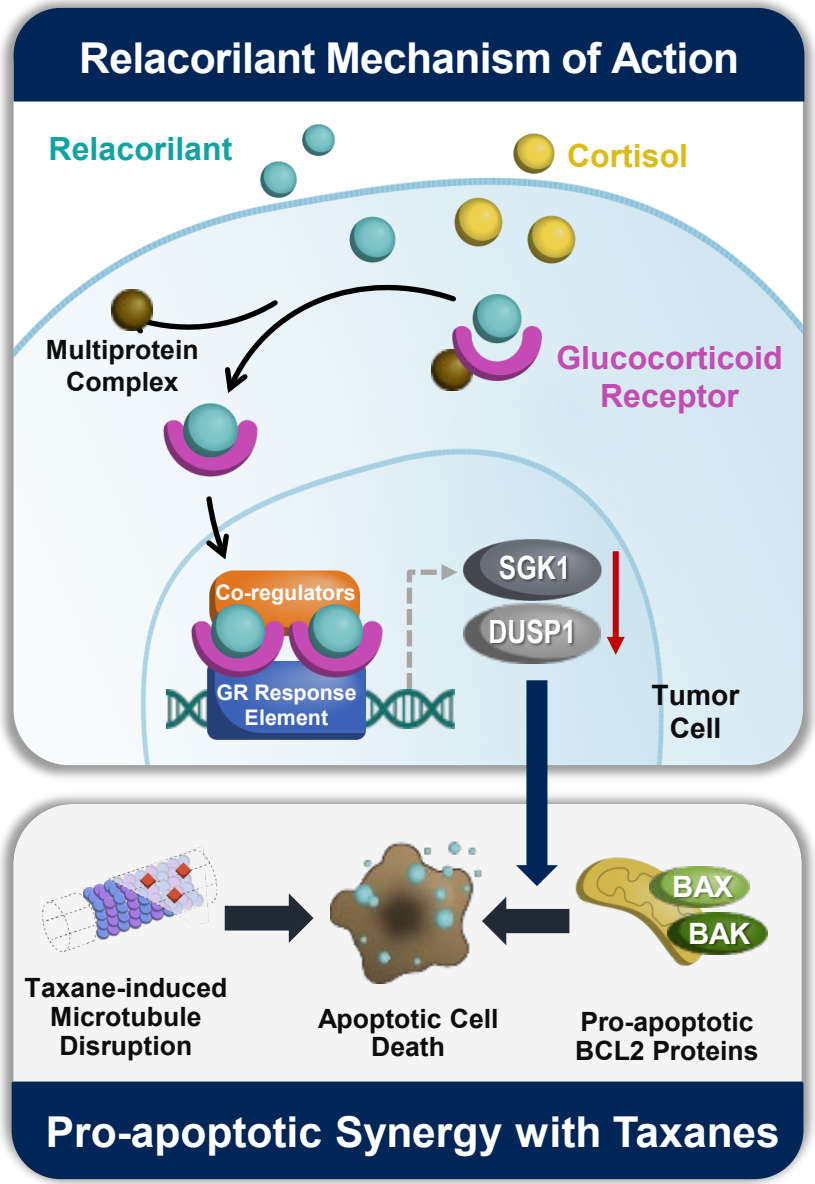
Background

- Patients with platinum-resistant ovarian cancer (PROC) have a poor prognosis with an overall survival of ~1 year[1]
- Cortisol-mediated survival signals through the glucocorticoid receptor (GR) reduce the sensitivity of tumor cells to chemotherapy[2,3]
- Relacorilant is a novel, selective GR antagonist (SGRA) that restores the sensitivity of cancers to cytotoxic chemotherapy[2,4-6]
- The addition of relacorilant to weekly nab-paclitaxel is associated with prolonged survival in trials of patients with PROC[5,6]
- Prior taxane use may influence outcomes to future taxane-based regimens.[7] Therefore, the survival benefit of relacorilant + nab-paclitaxel was evaluated in subgroups defined by prior taxane use



1. Martorana, et al. *Int J Gynecol Cancer*. 2025;35(1):100009. 2. Greenstein, et al. *Oncotarget*. 2021;12(13):1243-55. 3. Melhelm, et al. *Clin Cancer Res*. 2009;15(9):3196-3204. 4. Stringer-Reasor, et al. *Gynecol Oncol*. 2015;138(3):656-62. 5. Munster, et al. *Clin Cancer Res*. 2022;28(15):3214-24. 6. Colombo N, et al. *J Clin Oncol*. 2023;41(30):4779-4789. 7. Ghamande, et al. *Int J Gynecol Cancer* 2003;13(2):142-7.

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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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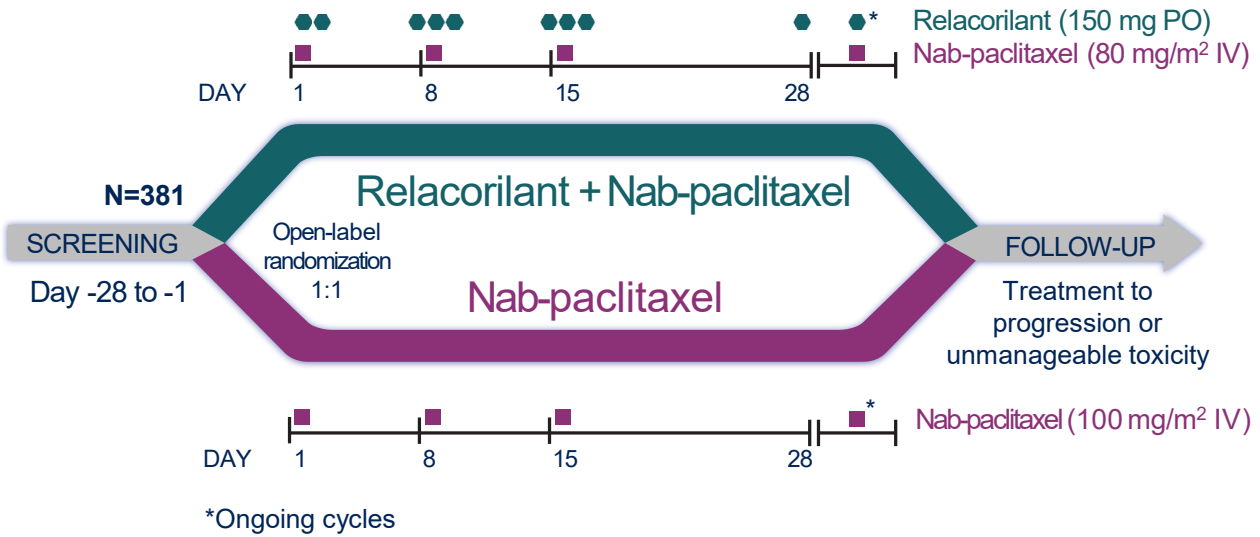

Stratification Factors

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

As nab-paclitaxel does not require steroid pre-treatment, it is a rational combination partner for relacorilant, a selective glucocorticoid receptor antagonist.

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.

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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	136 **(72.3)**	135 **(69.9)**
	Black or African-American	3 **(1.6)**	2 **(1.0)**
	Asian (92% Korean)	22 **(11.7)**	26 **(13.5)**
	Other / not reported	27 **(14.4)**	30 **(15.5)**
Ethnicity, n (%)	Hispanic	16 **(8.5)**	17 **(8.8)**
Region	North America	45 **(23.9)**	45 **(23.3)**
	Europe	107 **(56.9)**	109 **(56.5)**
	Korea, Australia, and Latin America	36 **(19.1)**	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	15 **(8.0)**	18 **(9.3)**
	2	92 **(48.9)**	89 **(46.1)**
	3	81 **(43.1)**	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 therapies, n (%)	Bevacizumab	188 **(100)**	193 **(100)**
	Taxanes	187 **(99.5)**	192 **(99.5)**
	Pegylated liposomal doxorubicin	121 **(64.4)**	125 **(64.8)**
	PARP inhibitor	114 **(60.6)**	120 **(62.2)**
Prior taxane in the platinum-resistant setting, n (%)	Yes	8 **(4.3)**	7 **(3.6)**
Taxane-free interval, n (%)	≤ 6 months	22 **(11.7)**	33 **(17.1)**
	> 6 months	165 **(87.8)**	159 **(82.4)**
Taxane in the last regimen, n (%)	Yes	35 **(18.6)**	38 **(19.7)**
	No	153 **(81.4)**	155 **(80.3)**

*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.

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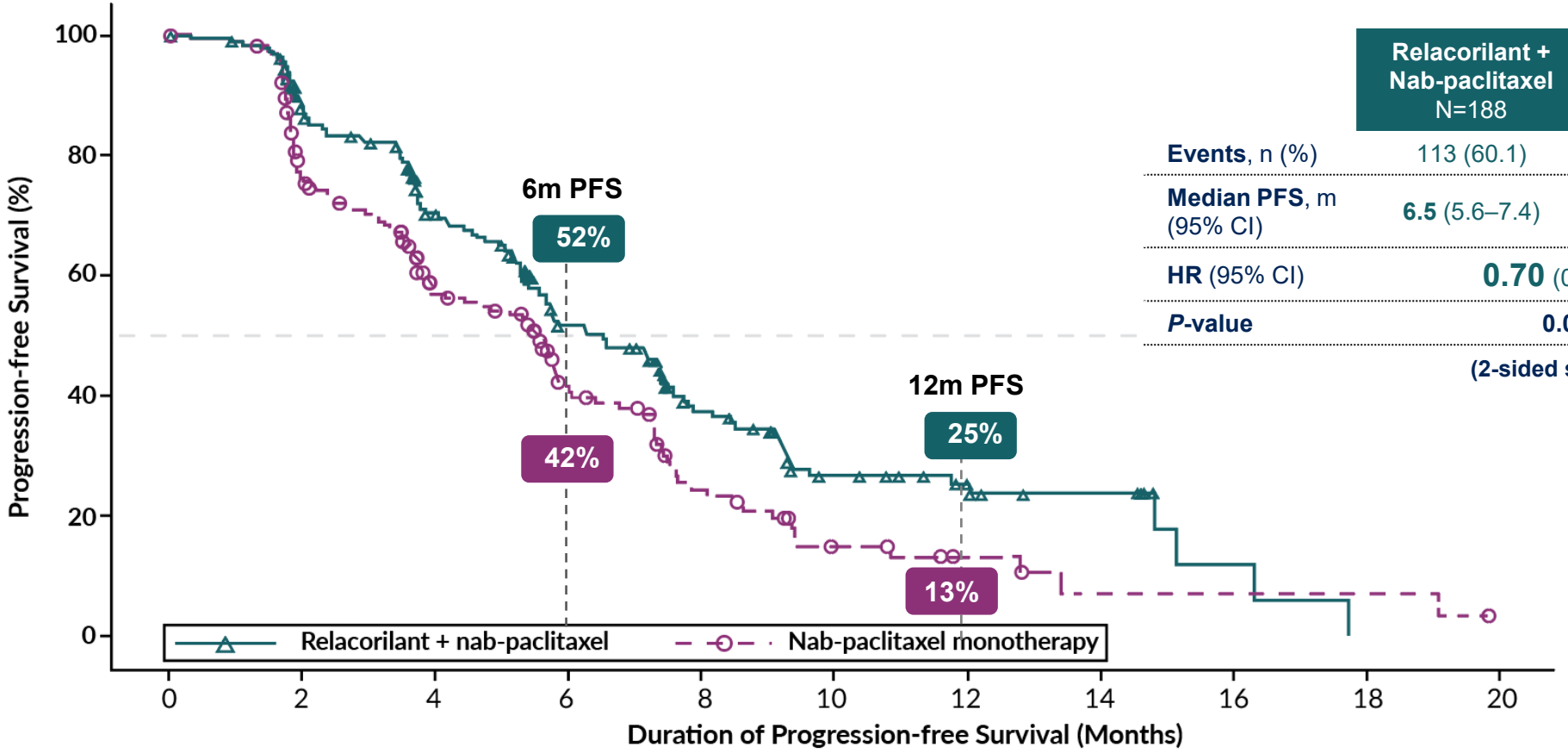
ROSELLA | Relacorilant Significantly Improved Progression-free Survival Assessed by Blinded Review at the Primary Analysis



	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)	0 (2/120)	0 (1/121)

Median follow-up time: 9.0 months; statistical significance threshold: $P \leq 0.04$. 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% CIs 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.

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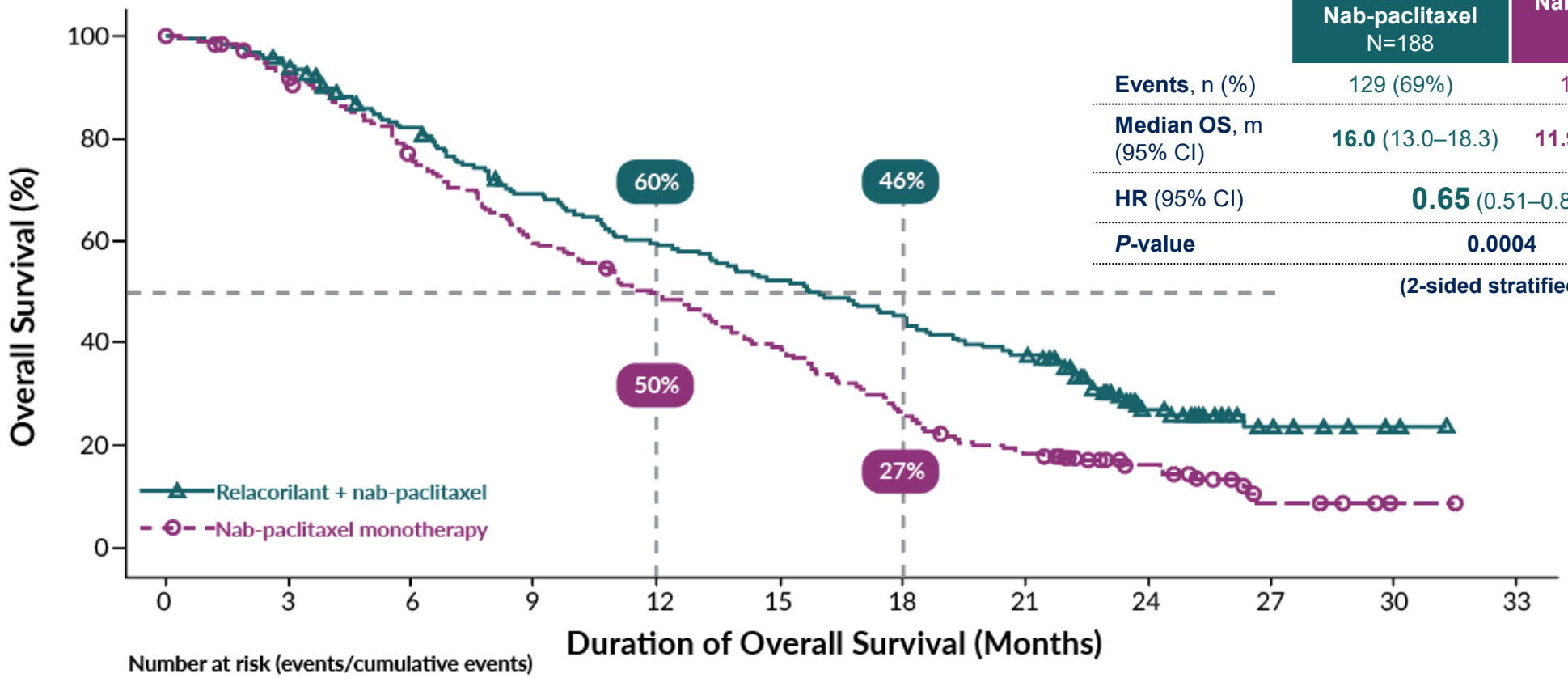
ROSELLA | Relacorilant Significantly Improved Overall Survival at the Final Analysis



	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: $P \leq 0.0499$. 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.

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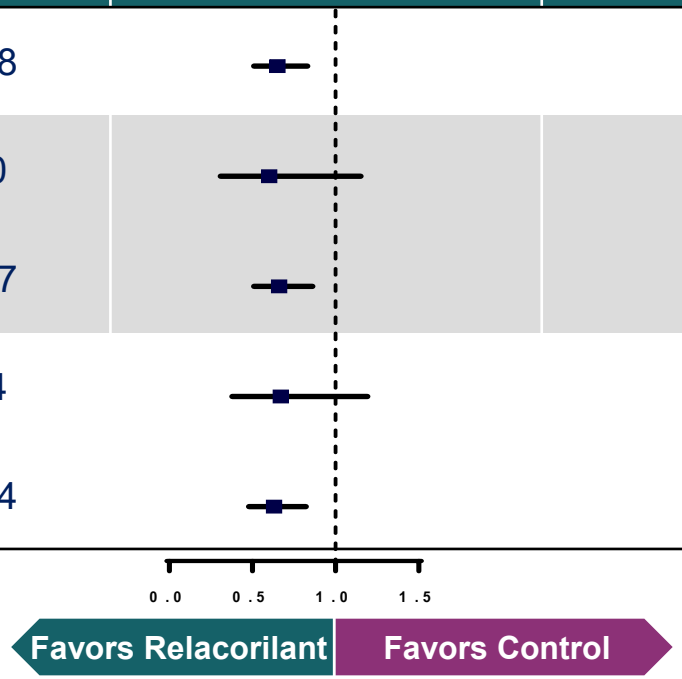
ROSELLA | Relacorilant Improved Overall Survival Across Prior Taxane Subgroups

Subgroup		Patients, n	Events, n	Hazard Ratio (95% CI)
All patients		381	288	0.65 (0.51–0.83)
Taxane-free interval	≤6 months	55	50	0.60 (0.31–1.15)
	>6 months	324	237	0.66 (0.51–0.86)
Taxane in the last regimen	Yes	73	64	0.67 (0.38–1.19)
	No	308	224	0.63 (0.48–0.82)



CI, confidence interval.

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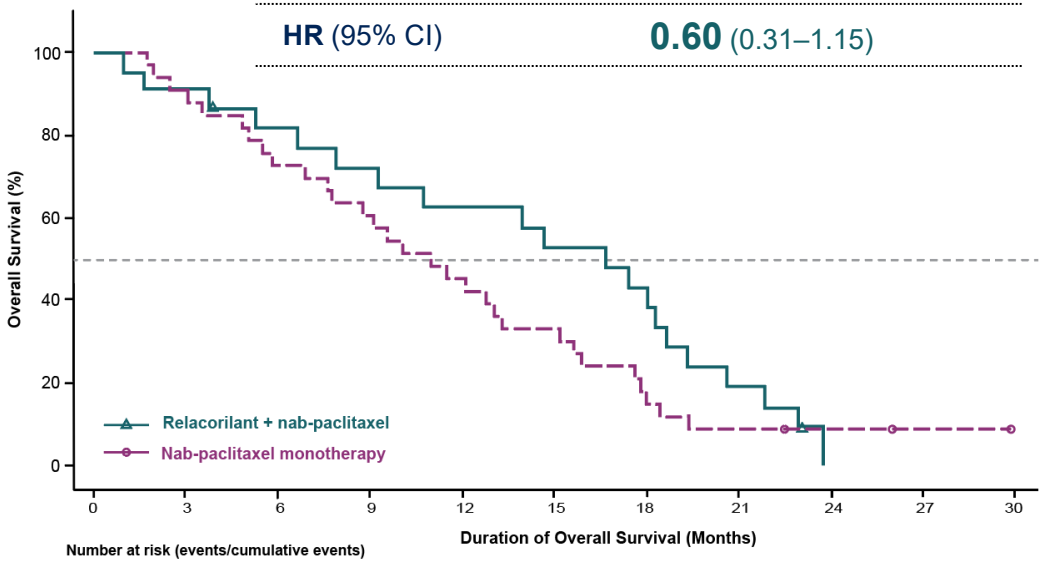
ROSELLA | Relacorilant + Nab-paclitaxel Showed Similar Overall Survival Benefits Irrespective of the Taxane-free Interval

Taxane-free Interval ≤6 Months

	Relacorilant + Nab-paclitaxel N=22	Nab-paclitaxel N=33
Events, n (%)	20 (91%)	30 (91%)
Median OS, m (95% CI)	**16.7** (7.9–18.7)	**11.0** (7.6–13.3)
HR (95% CI)	**0.60** (0.31–1.15)	

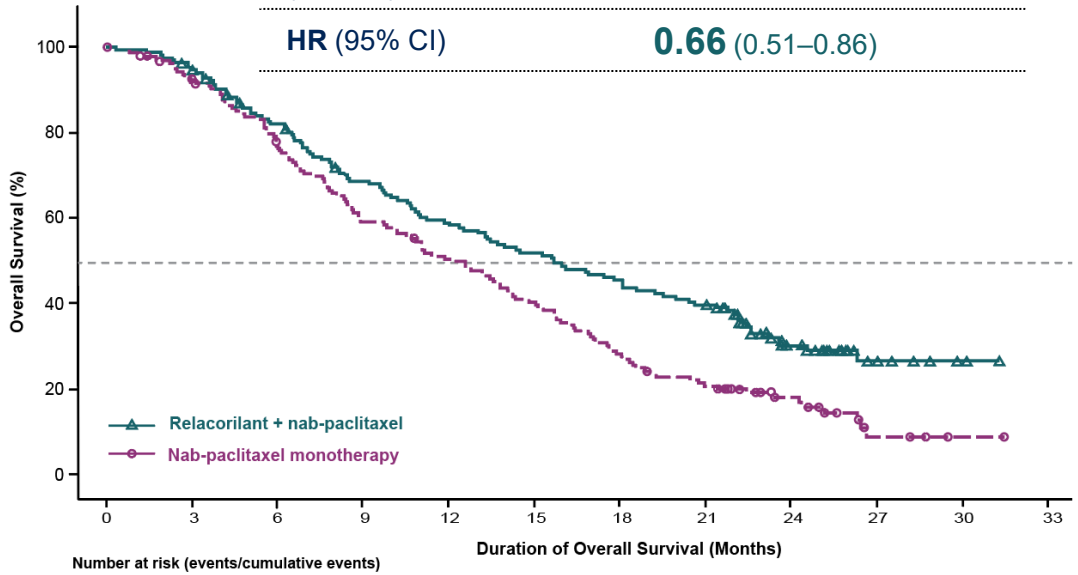


Number at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	22 (0/0)	20 (2/2)	17 (2/4)	15 (2/6)	13 (2/8)	11 (2/10)	9 (2/12)	4 (5/17)	0 (3/20)		
Nab-paclitaxel monotherapy	33 (0/0)	30 (3/3)	24 (6/9)	20 (4/13)	15 (5/18)	11 (4/22))	6 (5/27)	3 (3/30)	2 (0/30)	1 (0/30)	0 (0/30)

Taxane-free Interval >6 Months

	Relacorilant + Nab-paclitaxel N=165	Nab-paclitaxel N=159
Events, n (%)	109 (66%)	128 (81%)
Median OS, m (95% CI)	**15.7** (12.4–19.3)	**12.1** (9.8–14.3)
HR (95% CI)	**0.66** (0.51–0.86)	



Number at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	165 (0/0)	155 (9/9)	130 (20/29)	107 (21/50)	92 (15/65)	81 (11/76)	71 (10/86)	62 (9/95)	28 (12/107)	10 (2/109)	3 (0/109)	0 (0/109)
Nab-paclitaxel monotherapy	159 (0/0)	142 (12/12)	117 (22/34)	89 (28/62)	75 (13/75)	60 (15/90)	42 (18/108)	30 (11/119)	16 (3/122)	4 (6/128)	1 (0/128)	0 (0/128)

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.

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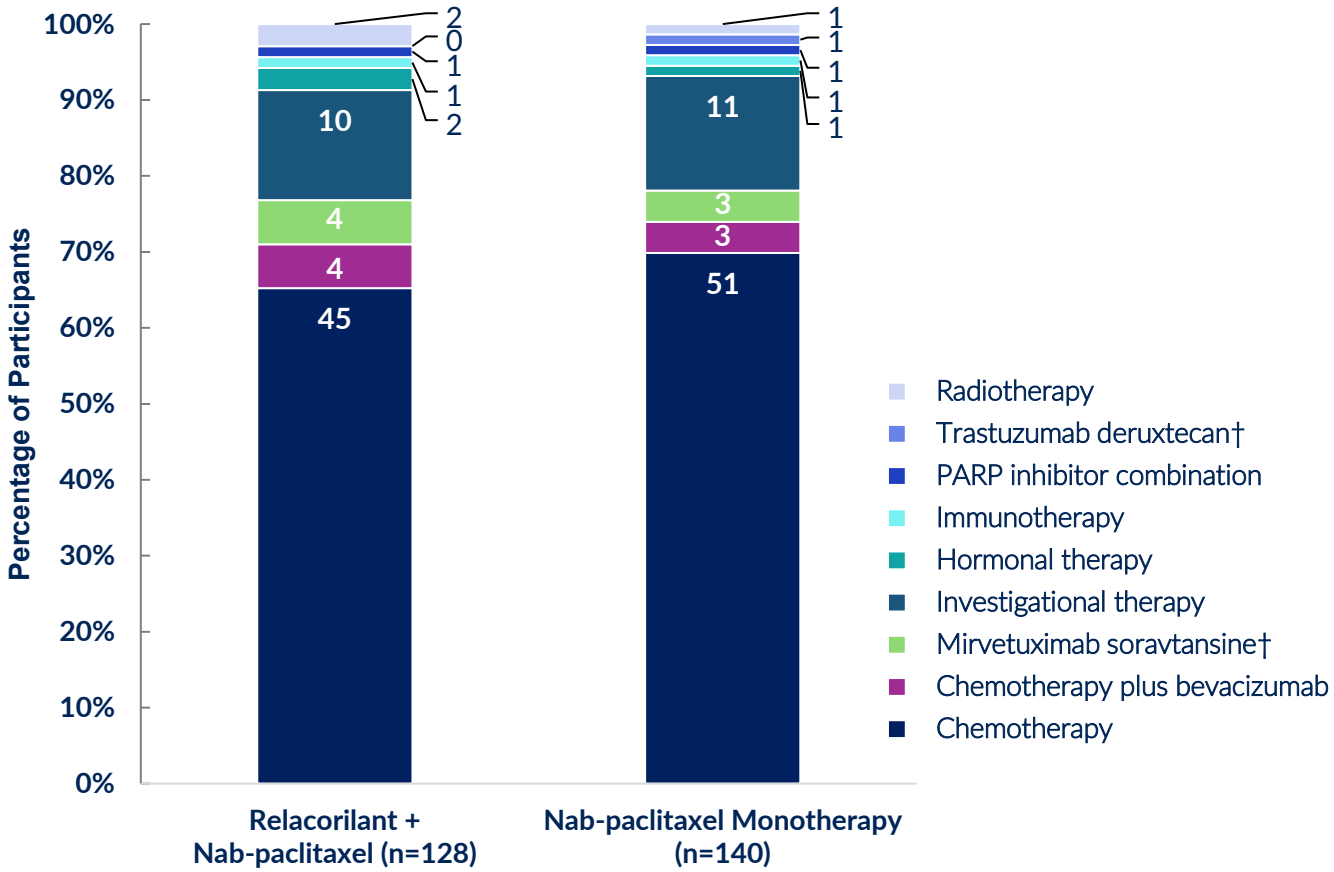
ROSELLA | First and All Subsequent Therapies Were Well Balanced

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.

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ROSELLA | Safety Summary

Relacorilant + Nab-paclitaxel was Well Tolerated, with a Favorable and Consistent 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)	**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.

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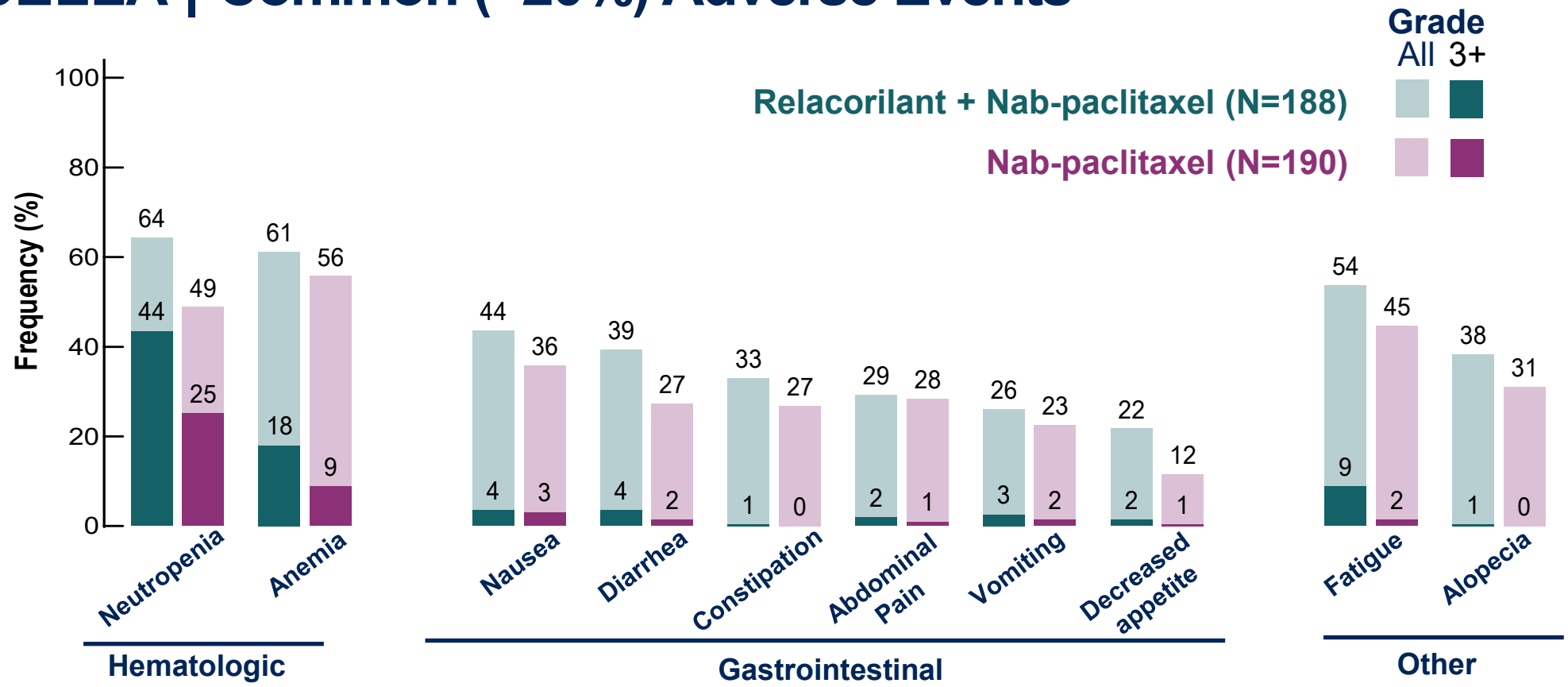
ROSELLA | Common (>20%) Adverse Events



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). *Comparing the relacorilant combination arm to the nab-paclitaxel monotherapy arm, respectively. SAEs, serious adverse events.

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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 favored the relacorilant combination arm across all prespecified subgroups, including participants with a short taxane-free interval and with taxane use in the most recent regimen.
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.

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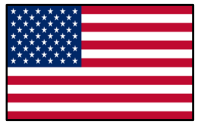
ROSELLA | Acknowledgments

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



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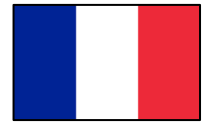

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THE LANCET

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

Domenica Lorusso, Laurence Gladieff, David M O'Malley, Jae-Weon Kim, Gabriel Garbaos, Anna Fagotti, Lucy Gilbert, Linda Mileshkin, Stanislas Quesada, Elizabeth Hopp, Yong Jae Lee, Ana Oaknin, Mariana Scaranti, Byoung-Gie Kim, Andrew Clamp, Christina Prillaman, Connie Diakos, Andrea Bagaméri, Aliza L Leiser, Vanda Salutari, Bradley J Monk, Philippe Follana, Emily McClung, Vittoria Carbone, Brian Slomovitz, Elena Giudice, Maria Chiara Cannizzaro, Laurène Gavoille, Alix Devaux, Paolo Scollo, Giuseppa Scandurra, Chiara Cassani, Grazia Artioli, Toon Van Gorp, Ana Santaballa, Lyndah K Dreiling, Amanda Kesner-Hays, Iulia Cristina Tudor, Adrian M Jubb, Nicoletta Colombo, Alexander B Olawaiye

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