# Efficacy and Safety of Relacorilant + Nab-paclitaxel in Patients Aged ≥65 Years With Platinum-Resistant Ovarian Cancer (PROC) in the Phase 3 ROSELLA Study (GOG-3073, ENGOT-OV72, APGOT-Ov10)

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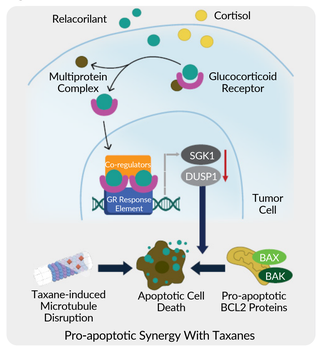
## SUMMARY AND CONCLUSIONS


- Relacorilant is a novel, selective glucocorticoid receptor antagonist (SGRA) that restores the sensitivity of cancers to cytotoxic chemotherapy
- In the phase 3 ROSELLA study, the addition of relacorilant to nab-paclitaxel demonstrated significant, clinically meaningful improvements in overall survival and progression-free survival in patients with platinum-resistant ovarian cancer (PROC) in the overall population and in the prespecified subgroup of patients aged ≥65 years
- Relacorilant + nab-paclitaxel was well tolerated, with a manageable safety profile, including in patients aged ≥65 years
- These findings position relacorilant + nab-paclitaxel as a potential new standard for patients with PROC of all age groups


## BACKGROUND AND OBJECTIVE

- Ovarian cancers express the glucocorticoid receptor (GR), and GR signaling has been associated with reduced sensitivity to chemotherapy[1-3]
- Relacorilant is a selective GR antagonist that increases tumor sensitivity to chemotherapy-induced apoptosis (**Figure 1**)[2,4,5]
- In the phase 3 ROSELLA study in patients with platinum-resistant ovarian cancer (PROC) (NCT05257408), the combination of relacorilant + nab-paclitaxel significantly improved overall survival (OS) and progression-free survival (PFS), with a manageable safety profile[6,7]
- Older patients may have a greater comorbidity burden and reduced tolerance to anticancer therapies, which may limit treatment benefit[8]
- We assessed the efficacy and safety of relacorilant + nab-paclitaxel in the prespecified ROSELLA subgroup of patients aged ≥65 years

**Figure 1. Relacorilant Mechanism of Action**

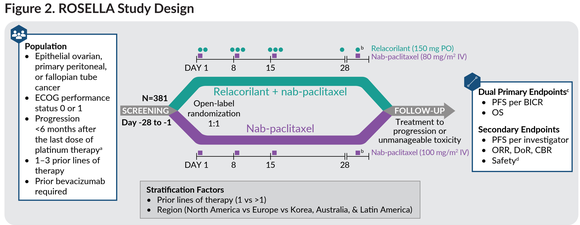



BCL2, B-cell lymphoma 2; BAK, BCL2 homologous antagonist/killer; BAX, BCL2-associated X protein; DUSP1, dual specificity phosphatase 1; GR, glucocorticoid receptor; SGK1, serum/glucocorticoid-regulated kinase 1.

## METHODS

- ROSELLA was an open-label, multicenter, global, phase 3 study in which patients with PROC were randomized 1:1 to receive relacorilant in combination with nab-paclitaxel or nab-paclitaxel monotherapy (**Figure 2**)

**Figure 2. ROSELLA Study Design**




[a]Excluding disease with no response to or progression ≤1 month after the last dose of front-line platinum therapy. [b]Ongoing cycles. [c]Time-to-event endpoints were estimated by Kaplan–Meier methods, and HRs were estimated using Cox regression, with treatment comparisons by stratified log-rank tests. [d]Safety was summarized descriptively in treated patients.
BICR, blinded independent central review; CBR, clinical benefit rate; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; HRs, hazard ratios; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PO, by mouth.

## RESULTS

- Of the 381 women randomized in ROSELLA, 152 (39.9%) were aged ≥65 years (**Table 1**)
  - Baseline demographic and disease characteristics in the ≥65 years subgroup were generally well balanced between treatment arms and consistent with those of the overall ITT population
  - This prespecified subgroup represented a heavily pretreated PROC population

**Table 1. Baseline Characteristics: Aged ≥65 Years Subgroup**

| | | 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**,[a] 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) |

[a]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.

### Efficacy

- In the overall ROSELLA population, relacorilant + nab-paclitaxel significantly improved OS vs nab-paclitaxel alone, reducing the risk of death by 35% and extending median OS by 4.1 months (**Figure 3A**)
- Relacorilant + nab-paclitaxel also significantly improved PFS assessed by blinded independent central review (BICR) vs nab-paclitaxel alone, reducing the risk of progression or death by 30% (HR, 0.70; *P*=0.0076)[6]
- In the aged ≥65 years subgroup, the addition of relacorilant to nab-paclitaxel resulted in a 42% reduction in the risk of death and a 7.3-month improvement in median OS vs nab-paclitaxel alone (**Figure 3B**)
- In this subgroup, relacorilant + nab-paclitaxel also improved BICR-assessed PFS vs nab-paclitaxel alone (HR, 0.61; median PFS, 7.4 vs 5.9 months; nominal *P*=0.0247)[9]

**Figure 3A. Overall Survival at the ROSELLA Final Analysis in the ITT Population[a]**

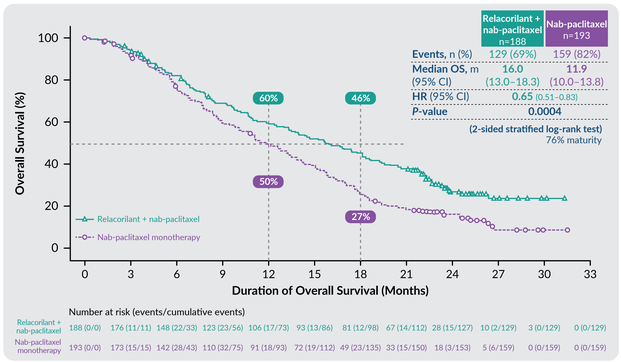
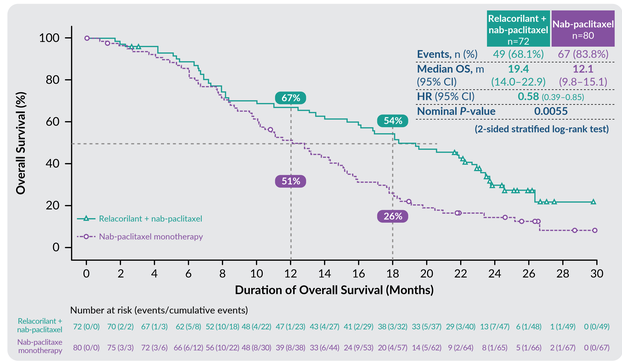



**Figure 3B. Overall Survival at the ROSELLA Final Analysis in Patients Aged ≥65 Years[b]**




[a]Median follow-up time: 24.8 months; statistical significance threshold at the final analysis: *P*≤0.0499. The HR and the associated 95% CI were estimated using a Cox regression model with treatment group as the main effect. ITT population includes all randomized patients.
[b]Median follow-up time: 25.3 months. The HR and the associated 95% CI were estimated using a stratified Cox regression model with treatment group as the main effect.
CI, confidence interval; HR, hazard ratio; m, months; OS, overall survival.

### Safety

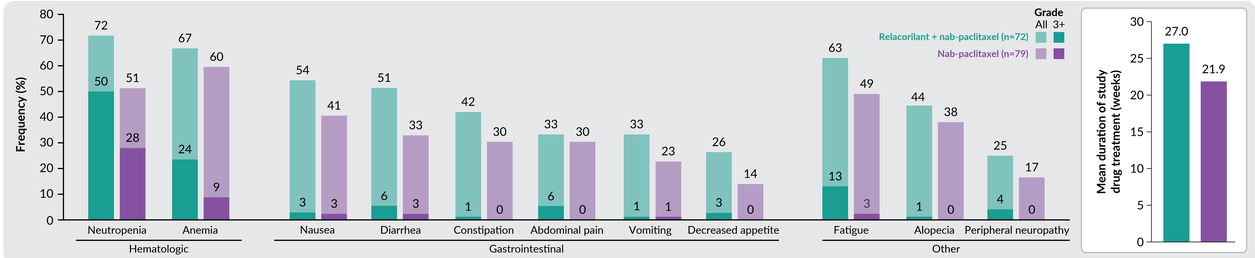
- The overall safety profile was similar between treatment arms in the aged ≥65 years subgroup and consistent with the overall ROSELLA safety population (**Table 2**)
  - In the aged ≥65 years subgroup, a similar frequency of serious adverse events (AEs) was observed compared to the overall population
  - In both study arms, nab-paclitaxel dose reductions, interruptions, and discontinuations were more frequent in this subgroup than in the overall safety population
- Grade ≥3 events were primarily hematologic, with neutropenia and anemia reported more frequently with relacorilant + nab-paclitaxel than with nab-paclitaxel alone (**Figure 4**)
- Exposure-adjusted incidence rates of common AEs in the aged ≥65 years subgroup was broadly similar to that observed in the overall safety population (**Figure 5**)

**Table 2. Safety Summary**

| Patients Who Received ≥1 Dose of Study Drug | Safety Population: Relacorilant + nab-paclitaxel (n=188) | Safety Population: Nab-paclitaxel (n=190) | ≥65 Years Subgroup: Relacorilant + nab-paclitaxel (n=72) | ≥65 Years Subgroup: Nab-paclitaxel (n=79) |
|---|---|---|---|---|
| Weeks of nab-paclitaxel therapy, mean (range) | **24.5** (0.1–102.4) | **19.1** (0.1–109.6) | **27.0** (0.1–97.3) | **21.9** (0.1–76.3) |
| Grade ≥3 TEAEs, n (%) | 141 (**75.0**) | 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 (%) | 14 (**7.4**) | — | 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 (%)[a] | 137 (**72.9**) | 105 (**55.3**) | 56 (**77.8**) | 47 (**59.5**) |
| Discontinuations of nab-paclitaxel (+ relacorilant) due to TEAEs, n (%)[a] | 18 (**9.6**) | 15 (**7.9**) | 12 (**16.7**) | 9 (**11.4**) |

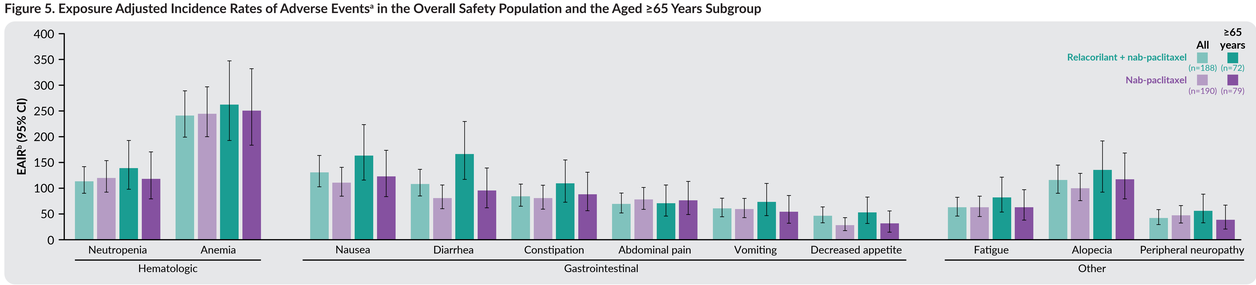
[a]Relacorilant was always interrupted or discontinued when nab-paclitaxel was interrupted or discontinued. Safety population includes all randomized patients who received ≥1 dose of study drug.
AEs, adverse events; TEAEs, treatment-emergent adverse events.

**Figure 4. TEAEs That Occurred in >20% of Patients Aged ≥65 Years**




Assessed in the safety population (all randomized patients who received ≥1 dose of study drug). 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).
TEAEs, treatment-emergent adverse events.

**Figure 5. Exposure Adjusted Incidence Rates of Adverse Events[a] in the Overall Safety Population and the Aged ≥65 Years Subgroup**




[a]Preferred terms are shown.
[b]EAIR 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. Assessed in the safety population (all randomized patients who received ≥1 dose of study drug).
CI, confidence interval; EAIR, exposure-adjusted incidence rate.


## References

**1.** Veneris JT, et al. *Gynecol Oncol*. 2017;146(1):153–160. **2.** Greenstein AE, Hunt HJ. *Oncotarget*. 2021;12(13):1243–1255. **3.** Melhem A, et al. *Clin Cancer Res*. 2009;15(9):3196–3204. **4.** Stringer-Reasor EM, et al. *Gynecol Oncol*. 2015;138(2):656–662. **5.** Munster PN, et al. *Clin Cancer Res*. 2022;28(15):3214–3224. **6.** Lorusso D, et al. *Lancet*. 2026;407(10538):1513–1524. **7.** Olawaiye AB, et al. *Lancet*. 2025;405(10496):2205–2216. **8.** Dotan E, et al. *J Natl Compr Canc Netw*. 2021;19(9):1006–1019. **9.** Olawaiye AB, et al. Presented at: International Society of Gynecologic Cancer 2025 Annual Global Meeting; November 5, 2025; Cape Town, South Africa.



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## Presenter Disclosure

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