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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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Background

Relacorilant, a selective glucocorticoid receptor antagonist, increases tumor sensitivity to chemotherapy. In the positive phase 3 ROSELLA study, the addition of relacorilant to nab-paclitaxel significantly prolonged progression-free survival (PFS) and showed a clinically meaningful improvement in overall survival (OS) in patients with PROC. We present a pre-planned analysis of the subgroup with prior exposure to a PARP inhibitor (prior PARPi), a population reported to exhibit a worse response to subsequent chemotherapy.

Methods

Patients were randomized 1:1 to relacorilant (150 mg the day before, of, and after nab-paclitaxel) + nab-paclitaxel (days 1, 8, and 15 of each 28-day cycle) or nab-paclitaxel alone. PFS assessed by blinded independent central review and OS are dual primary endpoints. Secondary and exploratory endpoints include PFS and OS in subgroups, and safety.

Results

381 patients were randomized (intent-to-treat population [ITT]) and 234 (61%) had received a PARPi in any prior line of therapy, of which 78% had radiographic progression during PARPi treatment. The baseline characteristics for the prior PARPi subgroup were similar to the ITT. A similar benefit was observed with the addition of relacorilant to nab-paclitaxel in this subgroup compared to the ITT (Table). The safety profile of the combination arm in this subgroup was comparable to the ITT, with similar rates of grade ≥ 3 (71.1% vs 74.5%) and serious (31.6% vs 35.1%) adverse events. Table: LBA45

Efficacy summary

	ITT Relacorilant + nab-paclitaxel N=188	Nab-paclitaxel N=193	Prior PARPi Relacorilant + nab-paclitaxel n=114	Nab-paclitaxel n=120	
Events, n (%)		113 (60.1)	121 (62.7)	66 (57.9)	72 (60.0)
Median, months		6.54	5.52	7.36	4.63
PFS (BICR)					

	ITT Relacorilant + nab-paclitaxel N=188	Nab-paclitaxel N=193	Prior PARPi Relacorilant + nab-paclitaxel n=114	Nab-paclitaxel n=120	
HR (95% CI)	0.70 (0.54-0.91)	0.60 (0.42-0.85)			
P-value (Log-rank)	P=0.0076	Nominal P=0.0035			
OS (Interim)	Events, n (%)	82 (43.6)	110 (57.0)	51 (44.7)	65 (54.2)
	Median, months	15.97	11.50	15.61	12.58
HR (95% CI)	0.69 (0.52-0.92)	0.77 (0.53-1.13)			
P-value (Log-rank)	P=0.0121	Nominal P=0.1834			

Conclusions

In patients with PROC previously exposed to a PARPi, relacorilant + nab-paclitaxel showed clinically meaningful improvements in PFS and OS. The median PFS of 7.36 months compares favorably to the median time from first to second subsequent therapy in patients who progressed while receiving a PARPi in the PAOLA1 trial (Ann Oncol 2025;36:185) and supports further exploration of relacorilant to improve outcomes for this population.

Clinical trial identification

NCT05257408, 2022-06-29; EU-CTR: 2024-514080-25-00.

Editorial acknowledgement

Farida F. Khan, Corcept Therapeutics Incorporated.

Legal entity responsible for the study

Corcept Therapeutics Incorporated.

Funding

Corcept Therapeutics Incorporated.

Disclosure

D. Lorusso: Financial Interests, Personal, Advisory Board, Participation in Advisory Boards and Invited Speakers: AstraZeneca, MSD; Financial Interests, Personal, Advisory Board, Participation in Advisory Boards and Invited Speaker: Clovis Oncology, GSK; Financial Interests, Personal, Advisory Board, Invited member of advisory board: Corcept, Oncoinvest, Sutro; Financial Interests, Personal, Advisory Board: Daiichi Sankyo; Financial Interests, Personal, Advisory Board, Invited member of advisory board and invited speaker: Genmab, Immunogen, Seagen; Financial Interests, Personal, Advisory Board, Invited Speaker of advisory board: Novocure; Financial Interests, Personal, Other, Consultancy: AstraZeneca, Clovis Oncology, GSK, Genmab, Immunogen, MSD, Novartis, Pharmamar, Seagen; Financial Interests, Personal, Other, Colsuntancy: Novartis; Financial Interests, Institutional, Funding, Clinical trial/contracted research: Alkermes, AstraZeneca, Clovis Oncology, GSK, MSD, Seagen, Corcept; Financial Interests, Institutional, Coordinating PI, ENGOT trial with institutional support for coordination: Clovis Oncology; Financial Interests, Institutional, Funding, Grant for founding academic trials: Clovis Oncology, GSK, MSD, Pharma&, Pharmamar; Financial Interests, Institutional, Coordinating PI, ENGOT trial with insitutional support for coordination: Genmab, MSD; Financial Interests, Institutional, Funding, Clinical trials/contracted research: Genmab, Immunogen, Incyte, Novartis, Roche; Non-Financial Interests, Principal Investigator, PI of several trials. No personal compensation received: AstraZeneca, Genmab, Cercept; Non-Financial Interests, Principal Investigator, PI of clinical trial. No personal compensation received: Clovis Oncology, Immunogen, Incyte, Roche; Non-Financial Interests, Principal Investigator, PI of several trials, no compensation received: GSK; Non-Financial Interests, Principal Investigator, PI in several trials. No personal compensation received: MSD; Non-Financial Interests, Principal Investigator, PI of several trials, no personal compensation received: Novartis; Non-Financial Interests, Principal Investigator, PI of clinical trials, no personal compensation received: PharmaMar; Non-Financial Interests, Principal Investigator, PI of clinical trial, no personal compensation received: Seagen; Non-Financial Interests, Member, Board of Directors: GCIG; Non-Financial Interests, Member, President Elected: MITO; Non-Financial Interests, Member, Coordinating: ENGOT; Other, Other, Grants for traveling: AstraZeneca, Menarini, Clovis Oncology, GSK. S. Quesada: Financial Interests, Personal, Advisory Board: GSK, AstraZeneca, Pharmaand, Eisai, MSD; Financial Interests, Institutional, Local PI: MSD; Financial Interests, Personal and Institutional, Local PI: AstraZeneca, GSK; Non-Financial Interests, Member, General Secretary of SFC (non-profit, non-governmental organization): Société Française du Cancer (SFC). J.K. Chan: Financial Interests, Personal, Funding: Denis Cobb Hale Chair, Angela Wang Johnson & The Fisher Family Funds; Financial Interests, Personal, Funding, Consortium trial participation:

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