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PATIENTS • PURPOSE • PROGRESS

Poster number: 1241

ROSELLA
Relacorilant with Nab-paclitaxel in Ovarian Cancer

GOG-3073, ENGOT-OV72/MITO: A Phase 3 Study of Relacorilant + Nab-paclitaxel vs. Nab-paclitaxel in Advanced, Platinum-resistant Ovarian Cancer

PRESENTER:
Alexander B. Olawaiye, MD
Contact: olawaiyea@upmc.edu

Alexander B. Olawaiye[1], Toon Van Gorp[2], Bradley J. Monk[3], Zoltán Novák[4], David O'Malley[5], Ana Oaknin[6], Thomas J. Herzog[7], Laurence Gladieff[8], Edwin Alvarez[9], Jacob Korach[10], John Chan[11], Shibani Nicum[12], Erin Bishop[13], Anita Chudecka-Glaz[14], Allan Covens[15], Carolyn Muller[16], Gina Westhoff[17], David Fishman[18], Lyndah Dreiling[19], Hristina I. Pashova[19], Iulia Cristina Tudor[19], Domenica Lorusso[20]

Summary & Conclusions

- There remains a large unmet need for effective treatments for platinum-resistant ovarian cancer.
- A phase 2 study of the selective glucocorticoid receptor modulator relacorilant + nab-paclitaxel in patients with advanced ovarian cancer showed meaningful improvements in PFS, DOR, and OS with minimal added toxicity compared to nab-paclitaxel alone.
- Here we introduce ROSELLA, a confirmatory phase 3 study comparing relacorilant + nab-paclitaxel to nab-paclitaxel monotherapy in patients with advanced, platinum-resistant ovarian cancer.

DOR, duration of response; PFS, progression-free survival; OS, overall survival.

The authors want to thank all those who are participating in this study: The study patients and their families, the investigators, and the sponsor team.

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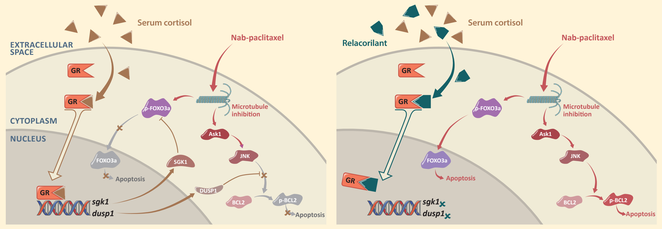
Background

- Platinum resistance occurs in virtually all patients with recurrent ovarian cancer.
- Single agent chemotherapies are commonly used in this setting, but outcomes are generally poor, leaving a large unmet need for treatments.
- Cortisol, which acts by binding to the glucocorticoid receptor (GR), can reduce the efficacy of chemotherapies by suppressing the apoptotic pathways used by cytotoxic agents.
- The GR is abundantly expressed in ovarian tumors and high GR expression is associated with poor outcomes.[1]
- Preclinical and clinical data indicate that modulation of GR signaling with relacorilant, a selective GR modulator, can reverse the anti-apoptotic effects of cortisol, thereby enhancing chemotherapy efficacy.[2-7]



- A phase 2 study of relacorilant* + nab-paclitaxel in patients with recurrent, platinum-resistant/refractory ovarian cancer showed:[4,5]
  - Improved PFS (HR 0.66; *P*=0.038; median PFS 5.6 vs. 3.8 months)
  - Improved DOR (HR 0.36; *P*=0.006; median DOR 5.6 vs. 3.7 months)
  - Trend toward improved OS (HR 0.67; median OS 13.9 vs. 12.2 months)
  - Even greater improvement was seen in patients with 1-3 prior lines of therapy (including prior bevacizumab) and without primary platinum-refractory disease.[6,7]
- The phase 3 ROSELLA study aims to confirm the findings of the phase 2 study in a larger patient population.

*Relacorilant dosed intermittently on the day before, day of, and day after nab-paclitaxel infusion; compared to nab-paclitaxel monotherapy. DOR, duration of response; HR, hazard ratio; OS, overall survival; PFS, progression-free survival.

1 Study Design

- ROSELLA (NCT05257408, EudraCT 2022-000662-18) is a confirmatory, phase 3, randomized, 2-arm, open-label, multicenter study of relacorilant + nab-paclitaxel compared to nab-paclitaxel monotherapy in patients with recurrent, platinum-resistant, high-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancer.
- The study is being conducted globally in collaboration with GOG FOUNDATION and ENGOT European Network of Gynaecological Oncological Trial groups

See ClinicalTrials.gov for more details:

ROSELLA
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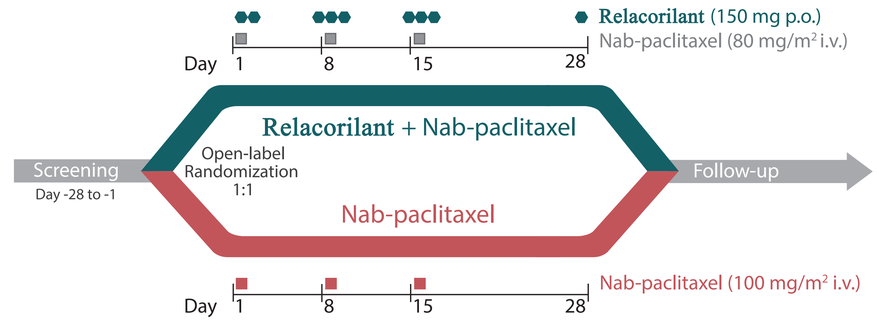

- Approximately 360 patients randomized 1:1 to:
  - Relacorilant (150 mg the day before, day of, and day after nab-paclitaxel infusion) + nab-paclitaxel (80 mg/m² on days 1, 8, and 15 of each 28-day cycle)
  - or
  - Nab-paclitaxel monotherapy (100 mg/m² on days 1, 8, and 15 of each 28-day cycle).

Primary Endpoint

- Progression-free survival by BICR per RECIST v1.1

Key Secondary & Exploratory Endpoints

- Overall survival per RECIST v1.1
- Safety, pharmacodynamics, pharmacokinetics, and patient-reported outcomes

BICR, blinded independent central review; RECIST, Response Evaluation Criteria in Solid Tumors.

2 Key Inclusion & Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• ≥18 years old	
• Diagnosis: ○ High-grade (grade 3) serous, epithelial ovarian, primary peritoneal, or fallopian tube carcinoma	• Diagnosis: ○ Low-grade endometrioid, clear-cell carcinoma, mucinous or sarcomatous histology, or mixed tumors containing any of these histologies, or low-grade or borderline ovarian tumor
• Platinum-resistant disease (progression <6 months from completion of a platinum-containing therapy)	• Primary platinum-refractory disease
• Prior therapies: ○ 1-3 lines of prior systemic anticancer therapy ○ ≥1 prior line of platinum chemotherapy and prior bevacizumab required	• Prior therapies: ○ Chemotherapy and other treatments for disease under study within 28 days before the first dose
• ECOG performance score of 0 or 1 • Adequate organ function: ○ Absolute neutrophil count ≥1500 cells/mm³ ○ Platelet count ≥100,000/mm³ ○ Hemoglobin ≥9 g/dL ○ AST or ALT ≤2.5 × ULN or ≤5 × ULN in context of liver metastases ○ Total bilirubin ≤1.5 × ULN ○ Albumin ≥3 g/dL ○ Creatinine clearance ≥40 mL/min/1.73 m²	• Clinically relevant toxicity from prior systemic anticancer therapies or radiotherapy that has not resolved to grade ≤1 • Any major surgery within 4 weeks prior to randomization • Treatment with chronic or frequently used corticosteroids ○ A short course of steroids for hypersensitivity reactions due to chemotherapy (eg, paclitaxel) is allowed

ALT, alanine aminotransferase; AST, aspartate aminotransferase; ECOG, Eastern Cooperative Oncology Group; ULN, upper limit of normal.

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Presenter Disclosures

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Author Affiliations

[1] University of Pittsburgh School of Medicine & Magee Women's Hospital, GOG, Pittsburgh, PA, USA; [2] University Hospital Leuven, Leuven Cancer Institute, BGOG, Leuven, Belgium; [3] HonorHealth, Creighton University, University of Arizona, GOG, Phoenix, AZ, USA; [4] National Institute of Oncology, CEEGOG, Budapest, Hungary; [5] The Ohio State University and the James Cancer Center, GOG, Columbus, OH, USA; [6] Vall d'Hebron Institute of Oncology (VHIO), Hospital Universitari Vall d'Hebron, GEICO, Barcelona, Spain; [7] University of Cincinnati Cancer Center, GOG, Cincinnati, OH, USA; [8] Institut Claudius Regaud-IUCT Oncopole, GINECO, Toulouse, France; [9] University of California, San Francisco (UCSF), GOG, San Francisco, CA, USA; [10] Sheba Medical Center, Sackler School of Medicine, Tel Aviv University, ISGO, Tel Aviv, Israel; [11] California Pacific Medical Center, GOG, San Francisco, CA, USA; [12] University College London Cancer Institute, NCRI, London, UK; [13] Medical College of Wisconsin, GOG, Milwaukee, WI, USA; [14] Pomeranian Medical University, PGOG, Szczecin, Poland; [15] University of Toronto, Sunnybrook Health Sciences Centre, GOG, Toronto, Canada; [16] University of New Mexico Comprehensive Cancer Center, GOG, Albuquerque, NM, USA; [17] Legacy Medical Group, GOG, Portland, OR, USA; [18] New York Presbyterian Queens, Cornell Medical School, GOG, New York City, NY, USA; [19] Corcept Therapeutics, Menlo Park, CA, USA; [20] Fondazione Policlinico Universitario a Gemelli IRCCS and Catholic University of Sacred Heart, MITO, Rome, Italy.