ENGOT ov26 / PRIMA Study

Grupo Español de Investigación en Cáncer de Ovario

ENGOT European Network of Gynaecological Oncological Trial groups

GOG Gynecologic Oncology Group

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

Platinum responsive ovarian cancer
Stage III or IV ovarian
CR or PR with front line platinum-based chemotherapy
HRDpos or HRDneg/not determined (nd) tumor

pre-enrollment screening:
- **centralized HRD testing for all patients**
- **local sBRCA and/or gBRCA test results are allowed**

2:1 Randomization

Stratification factors:
- **Use of NACT: yes or no**
- **Best tumor response: CR or PR**
- **HRD status: pos or neg/nd**

Niraparib 300 mg

Placebo

- Patients with sBRAC or tBRCAmut will be stratified as HRDpos
- Patients with unknown or wild type BRCA will be stratified based on HRD test results

Endpoint assessment

Primary Endpoint	**PFS in HRDpos patients; hierarchical analysis for all patients regardless of HRD status**
Key Secondary Endpoints	**Overall survival (OS), patient reported outcomes (PRO's), time to first subsequent treatment, progression- survival-2 , time to CA-125 progression, safety and tolerability of study therapy**

HRD=homologous recombination deficiency; CR=complete response; PR=partial response; PFS=progression-free survival;

Ongoing Trials – status update

Trial name/Group name and number

Trial setting: Maintenance 1st line with Niraparib

Study Design: ENGOT MODEL C

Sponsor(s): TESARO

Lead Group: GEICO (PI: A. González-Martín)

Planned No. of patients: 330

Current accrual: 246

Expected to end recruitment by Q2 2018