OReO study

Olaparib Re-treatment in platinum sensitive recurrent Ovarian cancer

Sponsor: ASTRA-ZENECA

Lead group: GINECO
Co-lead group : ISGO (Pr J Korach)

OReO trial

- Objective: to generate robust data to submit allowing retreatment with olaparib, if shown beneficial for the patient

Oreo Study design

Double-blind phase IIIb study design

OC in RELAPSE

- Previous treatment with consecutive PARPi ≥ 6 months
- Whatever the line and the PARPi

Platinum-based chemotherapy

RP/RC

RANDOMIZATION

2:1

OLAPARIB tablets*

Placebo

PD according to investigator

Stratification factors

- Prior Bevacizumab
- ≤ 3 vs ≥ 4 chemo lines

*300mg bid or last tolerable dose

Main Endpoints

PFS (primary) / Powered for OS (secondary)

- **PFS (primary):** HR=0.5, mPFS 4 mo → 8 mo; 80% power; alpha=0.05 (two-sided). Analysis after 66 PFS events, ~16 mo after FSI

  supported by PRO/safety and TTST

- **OS (secondary):** HR=0.7 (UCV = 0.77), mOS 11 mo → 15.7 mo (14.3 mo) 80% power; alpha=0.05 (two-sided); Analysis after 247 OS events, ~42 mo after FSI

- **Sample size:** 338 (370 allowing for 10% drop out)

Study status

- Interested groups to date : AGO, ISGO, GEICO, BGOG...
- First draft Protocol received
- Feasibility questionnaire to be sent to the groups for site selection in the following weeks
- First TSC to organize