

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

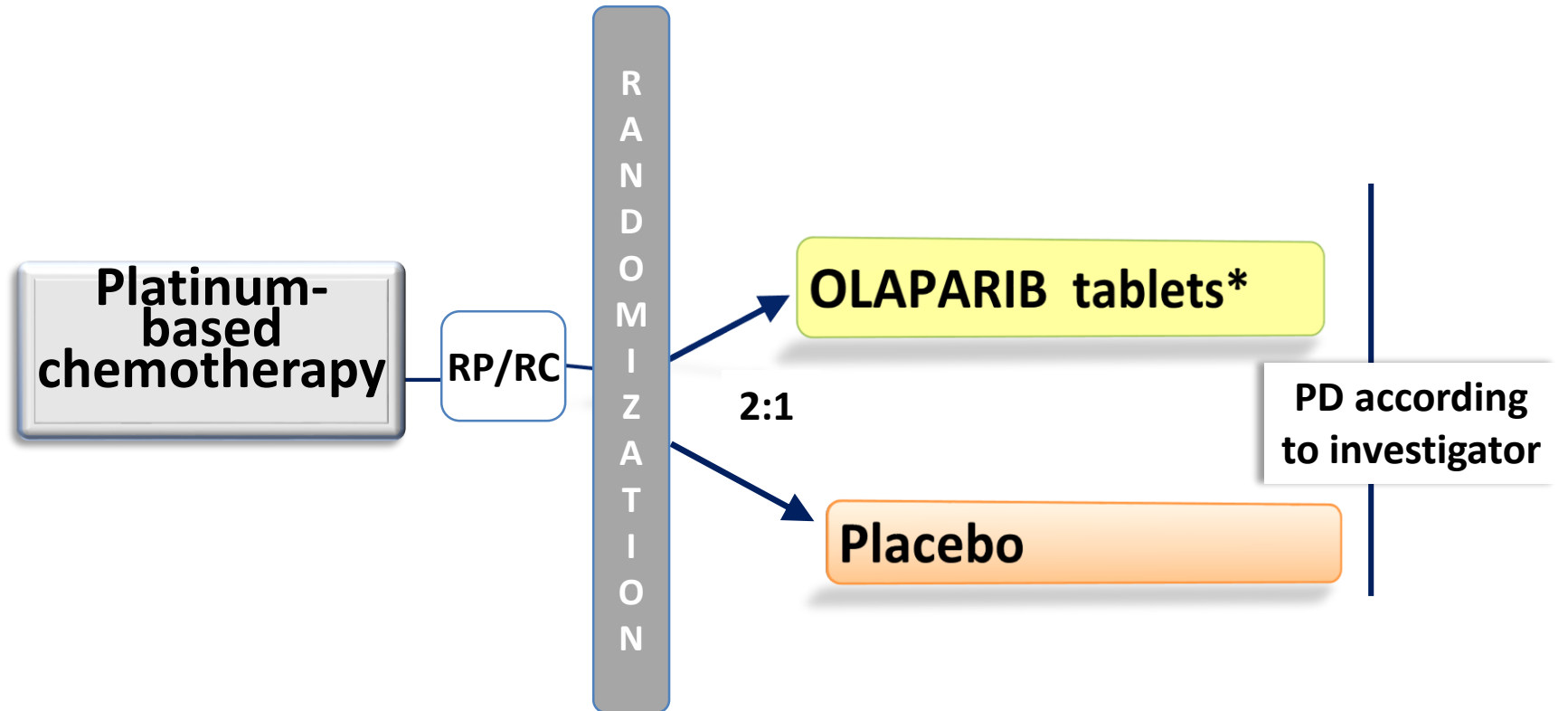
Double-blind phase IIIb study design

OC in RELAPSE

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

Stratification factors

- Prior Bevacizumab
- \leq 3 vs \geq 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