OReO study

Olaparib Re-treatment in platinum sensitive recurrent Ovarian cancer

ENGOT model C (AZ)
Lead group: GINECO
Co-lead group : ISGO (Pr J Korach)

GINECO

The Israeli Society of Gynecologic Oncology
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ENGOT
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GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

Rationale

- On
- In c

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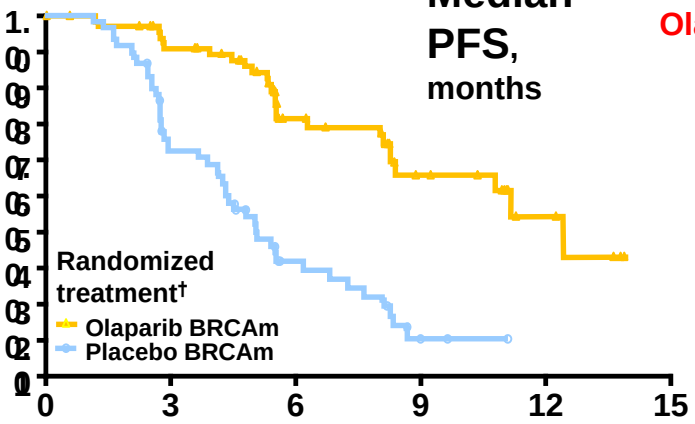
ola

IN LONG RESPONDERS, WE WOULD LIKE TO REUSE OLAPARIB!



Ledermann J, et al. *N Engl J Med.* 2012;366(15):1382-

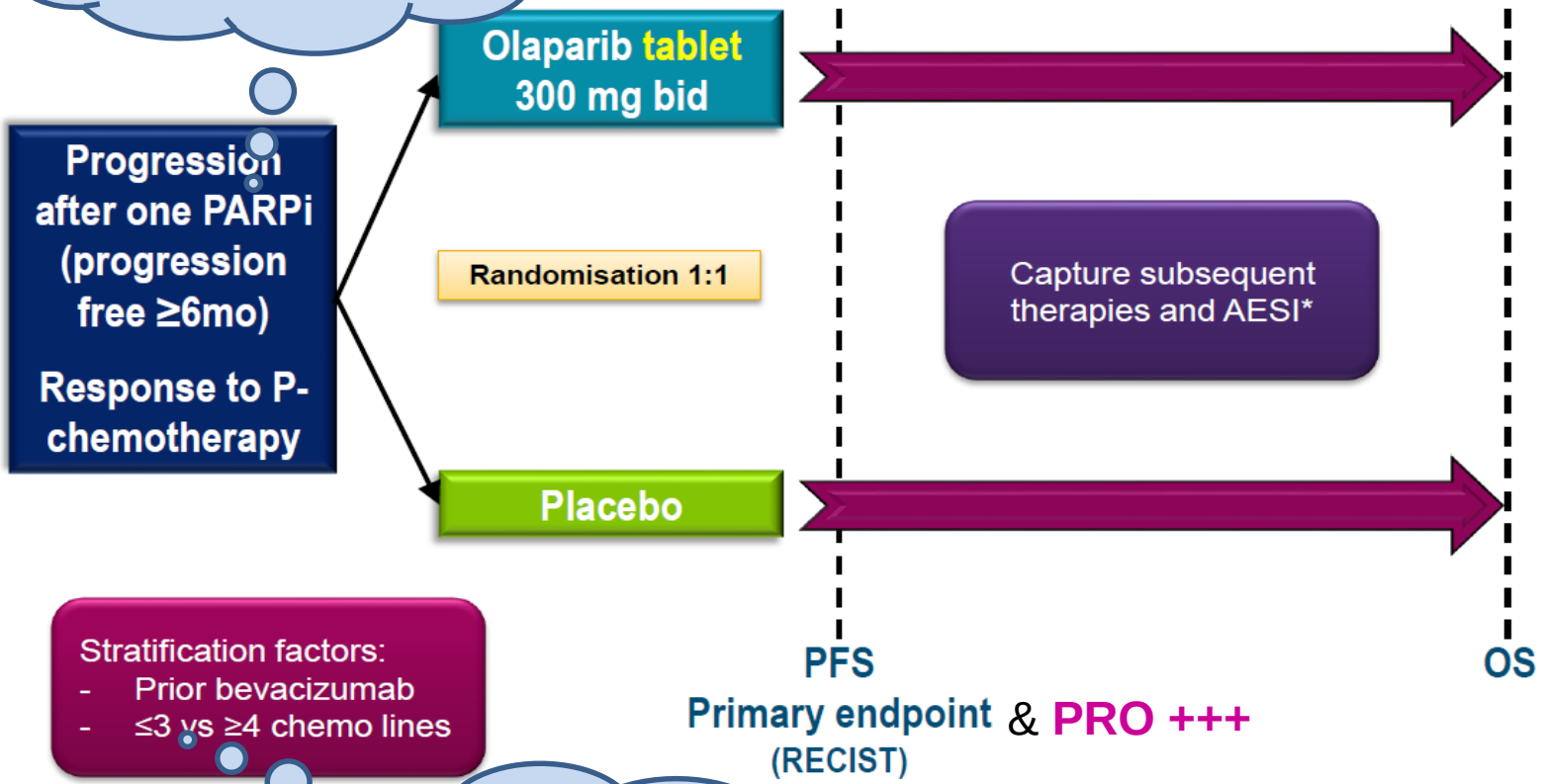
OReO trial

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

OReO Study

Pr… …d double-blind phase IIIb study design

6 months of treatment whatever the PARP and the line



*Adverse events of special interest

No matter the N° of lines between PARP first treatment and OReO

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Safety/Tolerability – data capture plan

- Collection of AEs, SAEs, events leading to discontinuation of study drug (DAEs) from randomisation to 30 days post follow-up
- AESIs: MDS/AML, pneumonitis
- Collection of clinical chemistry/haematology parameters as per local labelling

Statistics: 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
- **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)

Assumptions: 1:1 randomisation; 24 mo non-linear recruitment, 42 mo study duration

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THANK YOU!

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