ENGOT-OV24 - NSGO / AVANOVA

Niraparib and niraparib-bevacizumab combination against bevacizumab alone in Women with Homologous Recombination Deficient (HRD) platinum-sensitive epithelial ovarian, fallopian tube, or peritoneal cancer.

Part 1: AVANOVA1 - A phase I study to evaluate the safety and tolerability of bevacizumab-niraparib combination therapy and determine the Recommended Phase 2 Dose (RP2D) in Women with platinum-sensitive epithelial ovarian, fallopian tube, or peritoneal cancer.

Part 2: AVANOVA2 - A three-arm, open-label, phase II randomized study to evaluate the efficacy of niraparib and/or niraparib-bevacizumab combination against bevacizumab alone in Women with HRD platinum-sensitive epithelial ovarian, fallopian tube, or peritoneal cancer.

Sponsor: NSGO

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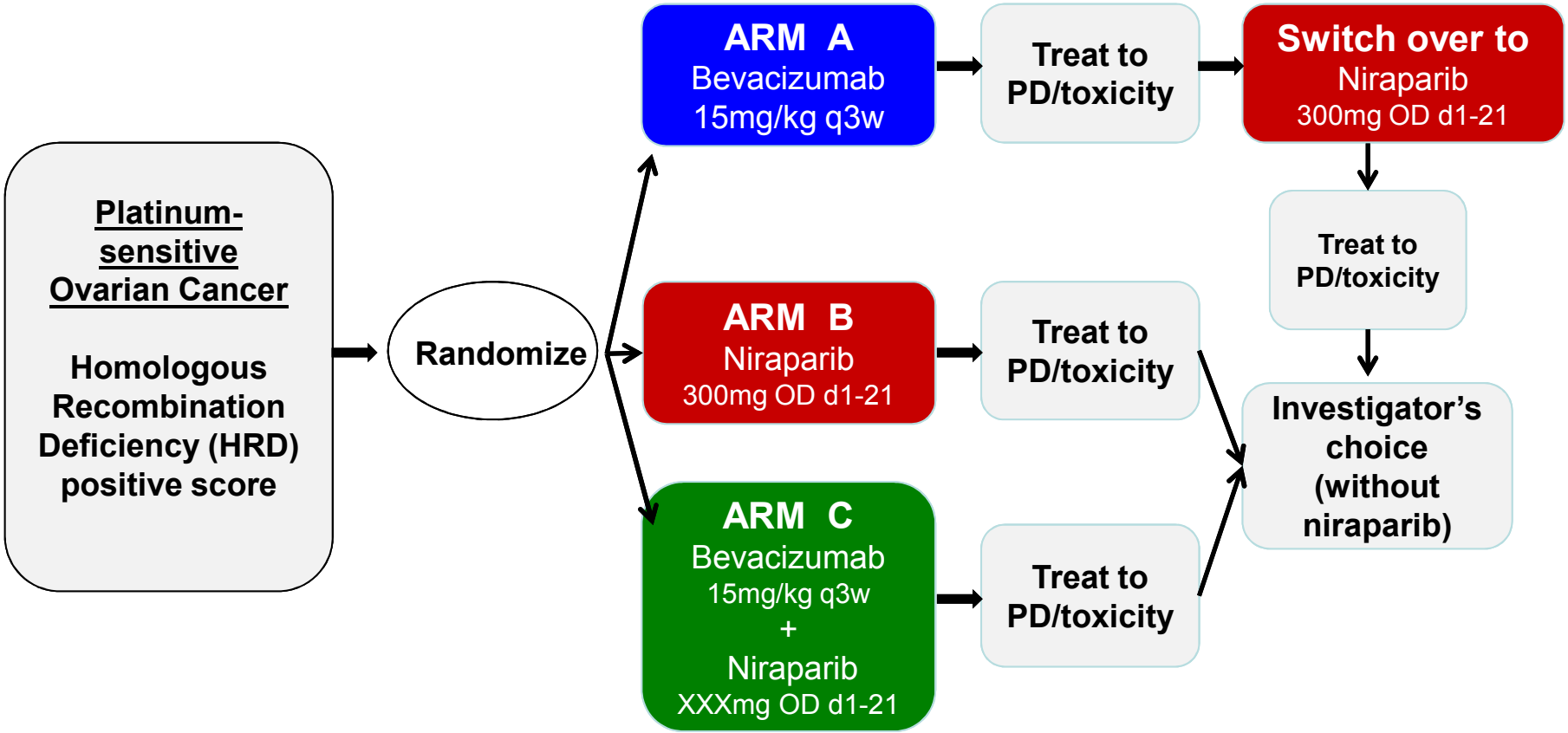
Phase 2 design



Randomization: 1:1:1
n=132

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Study Population Phase 2

Study population

- Recurrent platinum-sensitive epithelial ovarian, fallopian tube, or peritoneal cancer (platinum sensitivity defined as no recurrence within 6 months of last receipt of platinum/chemotherapy).
- High-grade serious or high-grade endometrioid histology. Other histological types are allowed if documented BRCA mutation.
- Patient consents to perform HRD test.
- HRD test positive.
- Prior line of therapy: Patients must have received platinum-containing therapy for primary disease.
    - No limits on number of platinum-based therapies. Population of patients who has previously received ≥ 3 lines of therapy for relapsed disease will be capped at 40%.
    - Up to one non-platinum-based line of therapy in recurrent setting.
    - Patients who are treated with bevacizumab just prior to entering in the trial must not have progressed under or within 3 months after bevacizumab.

End-Points Phase 2

Primary:

Progression-Free Survival (PFS) of patients treated with:

- A: Niraparib alone against bevacizumab alone
- B: Niraparib-bevacizumab combination against bevacizumab alone

Secondary:

- PFS in each group according to trial stratification factors
- PFS comparison of sequential versus concomitant bevacizumab and niraparib
- PFS2 (Progression Free Survival 2)
- TFST (Time to First Subsequent Therapy)
- TSST (Time to Second Subsequent Therapy)
- Objective Response Rate (ORR)
- Overall response according to GCIG criteria (CA125 response; best overall response in patients without initial measurable disease and who are evaluable by CA125; best overall response with measurable disease and who are also evaluable by CA125)
- Disease control rate (DCR) (CR+PR+SD)
- Patient Reported Outcomes (PROs)
- Safety and tolerability
- Overall survival in each group according to trial stratification factors (exploratory end point)

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Status

Phase 1 to finish on November 10, 2015

Phase 2 to start in December 2015

Groups are invited to participate in Part 2

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