FIRST CLINICAL TRIAL

Trial in progress

A Phase 3 Comparison of Platinum-based Therapy With Dostarlimab (TSR-042) and Niraparib Versus Standard of Care (SoC) Platinum-based Therapy as First-line Treatment of Stage III or IV Non-mucinous Epithelial Ovarian Cancer

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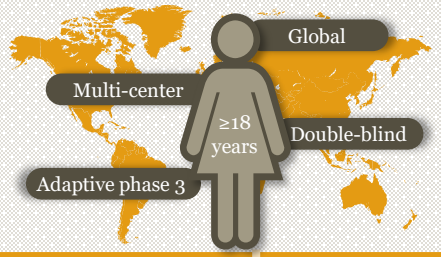
Background and Study Design

- ENGOT-OV44/FIRST (NCT03602859) has an adaptive design for modification of the control arm to follow the evolution of the SoC in the first line treatment of non-mucinous epithelial ovarian, fallopian tube, or primary peritoneal cancer that is stage III or IV, according to FIGO or tumor, node, and metastasis staging criteria.
- Status: Recruiting



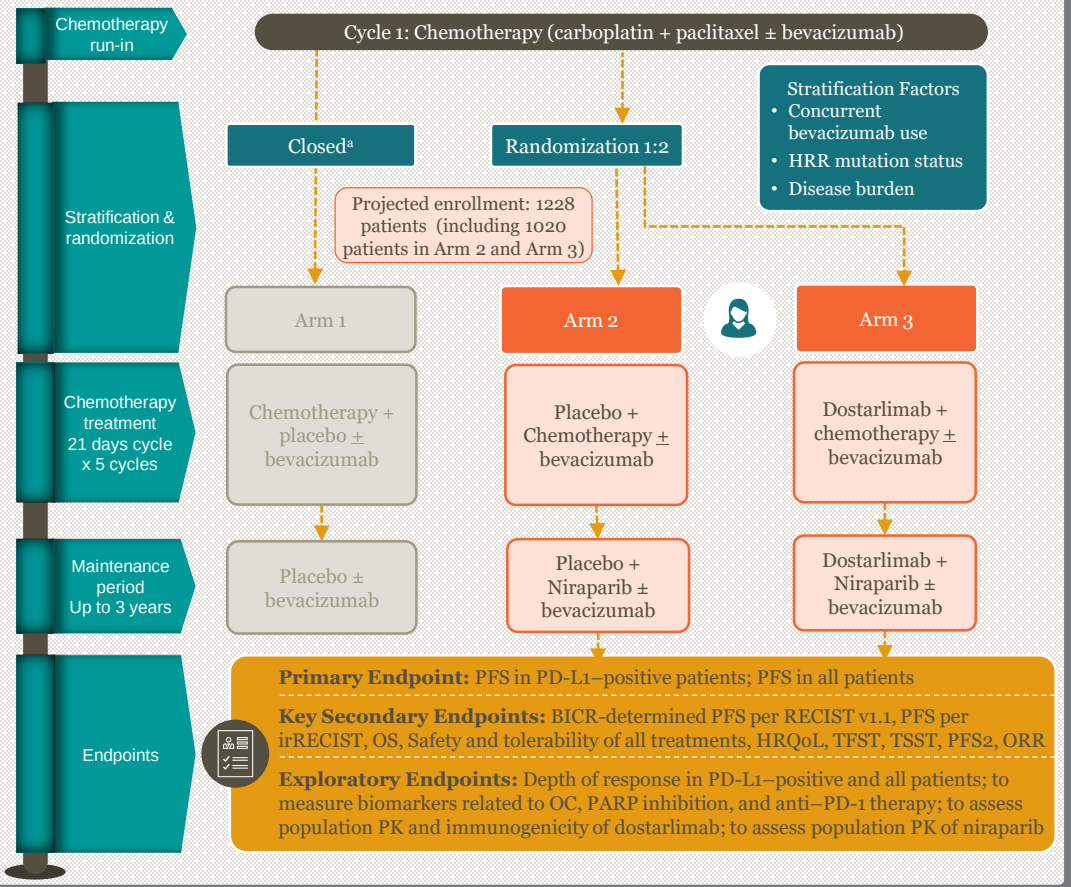
Key Inclusion Criteria

- Patients with Stage IV disease
- Patients who undergo PDS or receive NACT
- Patients with Stage III disease are eligible if they meet one or more of the following criteria:
  - Patients are stage IIIC CCO with ≥ 5-cm extra-pelvic disease following PDS
  - Inoperable stage III disease
  - Macroscopic residual tumor following PDS
  - NACT is planned
- ECOG score of 0 or 1

Key Exclusion Criteria

- Mucinous, germ cell, transitional cell, or undifferentiated tumor
- Low-grade or grade ≤ 1 epithelial OC
- Diagnosed and/or treated with any therapy for invasive cancer <5 years from enrollment
- Completed adjuvant chemotherapy and/or targeted therapy < 3 years from enrollment, or completed adjuvant hormonal therapy < 4 weeks from enrollment
- Investigational therapy administered within 4 weeks or within a time interval of < 5 half-lives of an investigational agent

Dosing and Endpoints



[a]Due to data from the SOLO-1 and PRIMA studies, Arm 1 has been closed. 1L: first line; BICR: blinded independent central review; CCo: complete cytoreduction score 0; FIGO: International Federation of Gynecology and Obstetrics; HRQoL: health-related quality of life; HRR: homologous recombinant repair; ir: immune-related; NACT: neoadjuvant chemotherapy; OC: ovarian cancer; ORR: objective response rate; OS: overall survival; PARP: poly(ADP-ribose) polymerase; PD-1: programmed death 1; PD-L1: programmed death-ligand 1; PDS: primary debulking surgery; PFS: progression-free survival; PFS2: progression-free survival 2; PK: pharmacokinetics; RECIST: response evaluation criteria in solid tumors; SoC: standard of care TFST: time to first subsequent treatment; TSST: time to second subsequent treatment;

References: Hardy-Bessard AC, et al. Presented at ASCO; May 29-31, 2020. Chicago, Illinois. Poster #272; Berek JS, et al. Ann Oncol. 2018; 29:1784-1792. 2. DOI: https://doi.org/10.1093/annonc/mdy181; ClinicalTrials.gov identifier NCT03602859.

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Some information contained in this response is outside the approved local label for niraparib. This product is not approved for the use described.

Dostarlimab (TSR-042) is an investigational humanized anti-programmed death-1 (PD- 1) antibody under development for the treatment of advanced solid tumors in an ongoing Phase 1 dose escalation and cohort expansion study (GARNET). Dostarlimab is not approved for use anywhere in the world.

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