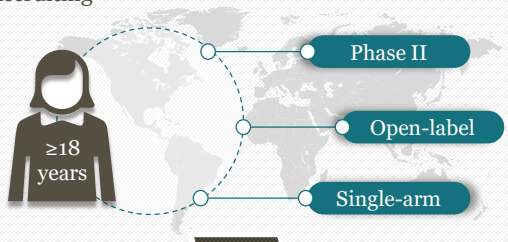
MOONSTONE

Trial in progress

A Phase 2 Study to Evaluate the Efficacy and Safety of the Combination of Niraparib and Dostarlimab in Participants With Platinum Resistant Ovarian Cancer

Background | Study Design

- MOONSTONE (NCT03955471) is evaluating the efficacy and safety of the combination of niraparib and dostarlimab (TSR-042) in patients with advanced, recurrent, high-grade ovarian, fallopian tube, endometrioid, clear cell ovarian or primary peritoneal cancer without known *BRCA* mutation who have platinum-resistant disease and who have also been previously treated with bevacizumab.
- Status: Recruiting



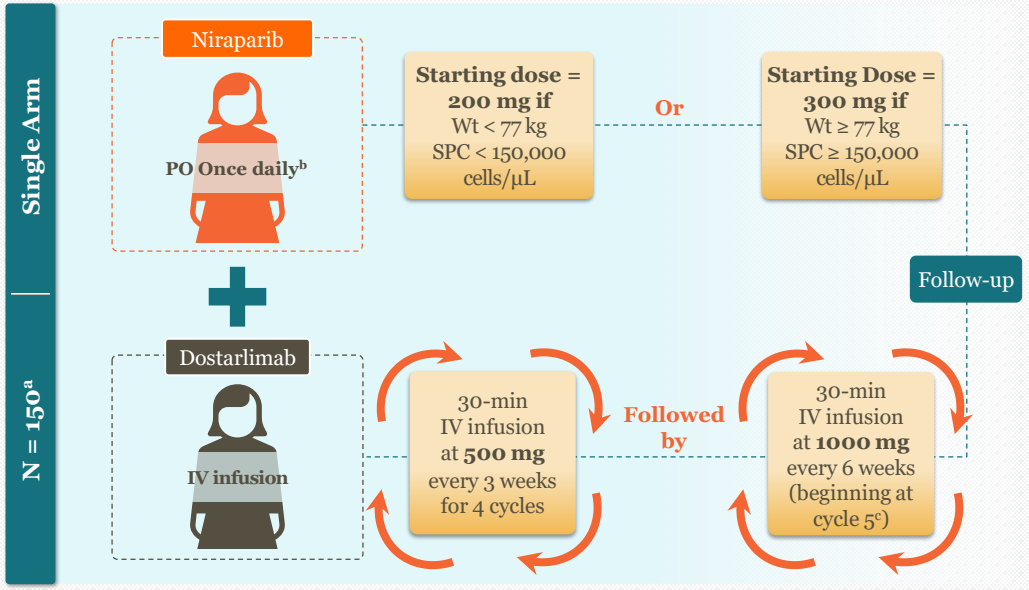
Key Inclusion Criteria

- Recurrent high-grade serous, endometrioid, or clear cell ovarian, fallopian tube, or primary peritoneal cancer
- Resistant to last administered Plt therapy
- Completed at least 1 but no more than 3 prior lines of therapy
- Previously treated with Plt-based regimen, taxane agent(s), and bevacizumab
- Measurable disease (RECIST v1.1)
- ECOG status of 0 or 1

Key Exclusion Criteria

- Disease progression within 3 months of first-line Plt therapy
- Known *BRCA* 1 or 2 mutation
- Prior therapy with an anti-PD-1, anti-PD-L1 or anti-PD-L2 agent, or PARP-1/PARP-2 inhibitor
- Hypersensitivity to study drugs
- History of myelodysplastic syndrome or acute myeloid leukemia
- Not recovered from prior chemotherapy induced adverse events

Dosing



[a]Estimated enrollment; [b]Until PD or toxicity; [c]Until PD or toxicity, for a maximum of 3 years.

Endpoints

Key Primary Endpoint

- Objective response rate using RECIST v.1.1 based on Investigator assessment

Key Secondary Endpoints

- Duration of response
- Progression-free survival
- Overall survival
- Disease control rate

Anti-PD-1: anti-programmed death receptor; anti-PD-L1: anti-PD-1-ligand-1; anti-PD-L2 agent: anti PD-1-ligand-2; *BRCA*: breast cancer susceptibility gene; ECOG: Eastern Cooperative Oncology Group; IV: intravenous; PARP: poly (ADP-ribose) polymerase; PD: progressive disease; PFS: progression free survival; Plt: platinum; PO: per os; RECIST: response evaluation criteria in solid tumors; SPC: screening platelet count; Wt: weight

Reference: ClinicalTrials.gov identifier NCT03955471.

For full medical information letter, click here or scan the QR code.

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.

For the digital copy, scan the QR code.

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