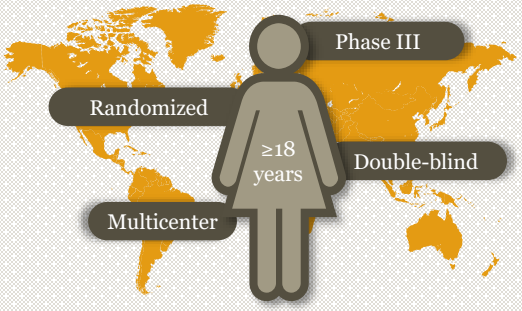
RUBY
Trial in progress

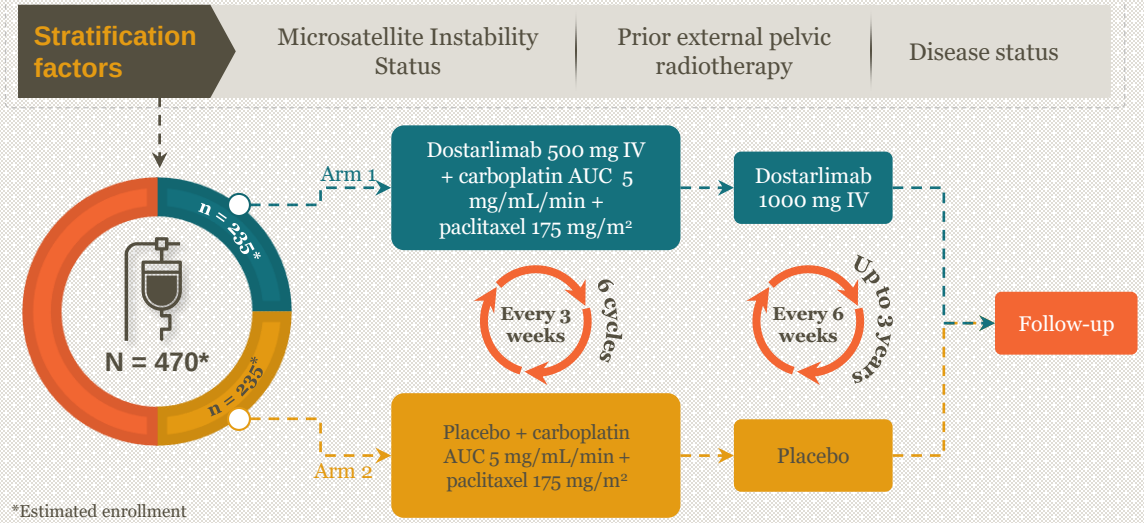
Study Evaluating the Efficacy and Safety of Dostarlimab plus Carboplatin-Paclitaxel versus Placebo plus Carboplatin-Paclitaxel in Patients with Recurrent or Primary Advanced Endometrial Cancer

Background | Study design

- The purpose of the RUBY study (NCT03981796) is to evaluate the efficacy and safety of dostarlimab plus carboplatin-paclitaxel versus placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced (Stage III or IV) endometrial cancer.
- Dostarlimab has not been approved by any regulatory authority for any use outside of a clinical trial.



Dosing



*Estimated enrollment

Key Inclusion Criteria

- Histologically or cytologically proven endometrial cancer with recurrent or advanced disease
- Primary Stage III or Stage IV disease or first recurrent endometrial cancer with a low potential for cure by radiation therapy or surgery alone or in combination
- ECOG performance status of 0 or 1

Key Exclusion Criteria

- Received neo-adjuvant/ adjuvant systemic chemotherapy for primary Stage III or IV disease and:
  - Has not had a recurrence or PD prior to entering the study OR
  - Has had a recurrence or PD within 6 months of completing chemotherapy treatment prior to entering the study
- > 1 recurrence of endometrial cancer
- Prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent

Primary Endpoints

- Progression-free survival as assessed by the Investigator per RECIST v.1.1 in:
  - All patients with recurrent or primary advanced endometrial cancer
  - Patients with microsatellite instability-high recurrent or primary advanced endometrial cancer

Secondary Endpoints

- PFS based on BICR
- Overall survival
- Objective response rate
- Duration of response
- Disease control rate
- Patient-reported outcomes
- Number and percentage of participants experiencing TEAEs
- Number and percentage of participants with drug-related AEs
- Number and percentage of participants discontinuing study drug due to an AE

AE: adverse event; Anti-PD-1: anti-programmed death receptor; anti-PD-L1: anti-PD-1-ligand-1; anti-PD-L2 agent: anti PD-1-ligand-2; AUC: area under the plasma or serum concentration-time curve; BICR: blinded independent central review; ECOG: Eastern Cooperative Oncology Group; IV: intravenous; PD: progressive disease; PFS: progression free survival; RECIST: response evaluation criteria in solid tumors; TEAE: treatment-emergent adverse event

Reference: ClinicalTrials.gov identifier NCT03981796.

Dostarlimab is investigational and is not approved anywhere in the world.

For the digital copy, scan the QR code.

MED--ALL-5960 | April-2020