# ENGOT-EN6/GOG-3031/NSGO-RUBY: A Phase 3, Randomized, Double-Blind, Multicenter Study of Dostarlimab + Carboplatin–Paclitaxel Versus Placebo + Carboplatin–Paclitaxel in Recurrent or Primary Advanced Endometrial Cancer


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## Mechanism of action

- Dostarlimab (TSR-042) is an anti–programmed cell death (PD)-1 humanized monoclonal antibody that binds to PD-1 and effectively blocks the interaction with the PD-1 ligands 1 and 2 (PD-L1 and PD-L2)
- Dostarlimab has demonstrated antitumor activity, with an objective response rate of 42%, as well as an acceptable safety profile in patients with recurrent or advanced DNA mismatch repair deficient (dMMR) endometrial cancer (EC) in the GARNET trial

## The RUBY trial

- RUBY is a registrational trial designed to evaluate the efficacy and safety of dostarlimab in combination with carboplatin–paclitaxel in recurrent or primary advanced EC compared with carboplatin–paclitaxel alone
  - Clinical Trial Number: NCT03981796
- This trial is part of an international collaboration of ENGOT and the GOG Foundation
- Enrollment is ongoing
  - 139 patients have been randomized as of May 1, 2020
- Expected primary readout is late 2021

## Patients

- Patients with recurrent or primary advanced EC are eligible
  - All histologies (including carcinosarcoma) are eligible

### Key Inclusion Criteria

- Female
- Aged ≥18 years
- Histologically or cytologically proven EC that is first recurrent or primary advanced (FIGO stage III or IV at diagnosis)
- Patient is able to provide a tumor sample for MMR status test
- ECOG score of 0 or 1
- Adequate organ function

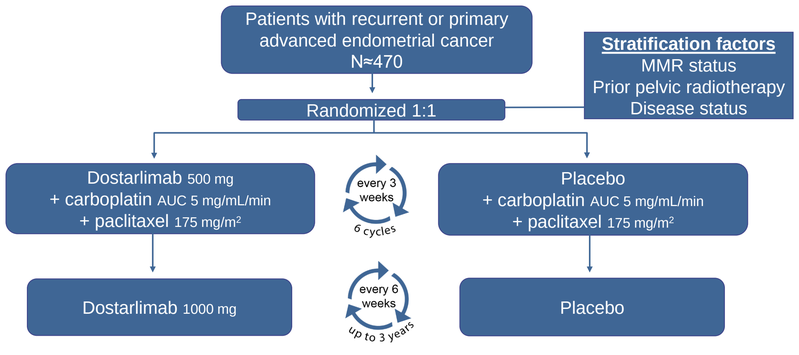
### Key Exclusion Criteria

- Patients with primary advanced disease must not have received prior adjuvant or neoadjuvant chemotherapy
- Patients with disease recurrence <6 months after completing chemotherapy
- >1 disease recurrence
- Prior therapy with an anti–PD-1, anti–PD-L1, or anti–PD-L2 agent
- Concomitant malignancies within the last 3 years
- Uncontrolled CNS metastases
- Immunocompromised/autoimmune disease

CNS=central nervous system; EC=endometrial cancer; ECOG=Eastern Cooperative Oncology Group; FIGO=International Federation of Gynecology and Obstetrics; MMR=DNA mismatch repair; PD-1=programmed cell death-1; PD-L1=programmed death ligand 1; PD-L2=programmed death ligand 2.

## Trial design

- Enrolled patients will be randomized 1:1 to treatment arms




AUC=area under the curve; dMMR=DNA mismatch repair; MMR=mismatch repair; Q3W=every 3 weeks; Q6W=every 6 weeks.

### Primary Endpoint

- Compare investigator-assessed progression-free survival (PFS) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
  - Testing will be performed in
    - All randomized patients (intent-to-treat [ITT])
    - Patients with dMMR recurrent or primary advanced EC

### Secondary Endpoints

- PFS by blinded independent central review
- OS

### Safety Assessment

- All adverse events (AEs) will be assessed for intensity according to Common Terminology Criteria for Adverse Events (CTCAE) v4.03

## Enrolling sites

- Patients can be enrolled from the following countries

**ENGOT**

- Belarus (CEEGOG)
- Belgium (BGOG)
- Czech Republic (CEEGOG)
- Denmark (NSGO)
- Finland (NSGO)
- Germany (AGO)
- Greece (HeGOG)
- Hungary (CEEGOG)
- Israel (ISGO)
- Italy (MITO)
- Netherlands (DGOG)
- Norway (NSGO)
- Poland (PGOG)
- Sweden (NSGO)
- Turkey (TRSGO)
- Ukraine (CEEGOG)
- United Kingdom (NCRI)

- Canada
- United States (GOG Foundation)

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