**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, anti-PD-L1, or anti-PD-L2 agent
- Concomitant malignancies within the last 3 years
- Uncontrolled metastases
- Immunocompromised/autoimmune disease

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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

**Enrolling Sites**

- Patients can be enrolled from the following countries

**Trial Design**

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

<table>
<thead>
<tr>
<th>Treatment Arm</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dostarlimab</td>
<td>1000 mg IV once every 3 weeks</td>
</tr>
<tr>
<td>Carboplatin+Paclitaxel</td>
<td>500 mg/m² carboplatin + 175 mg/m² paclitaxel</td>
</tr>
</tbody>
</table>

**Primary Endpoint**

- Compare investigator-assessed PFS per RECIST v1.1

**Secondary Endpoints**

- PFS by blinded independent central review
- Overall survival

**Safety Assessment**

- All adverse events will be assessed for intensity according to CTCAE v4.03

**Key Inclusion Criteria**

- Uncontrolled CNS metastases
- Concomitant malignancies within the last 3 years
- >1 disease recurrence
- Patients with disease recurrence <6 months after completing chemotherapy
- Patients with recurrent or primary advanced EC compared with carboplatin–paclitaxel alone

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**Authors**

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**View plain text summary:**

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

- **Purpose:** The purpose of this study is to evaluate the efficacy and safety of dostarlimab + carboplatin–paclitaxel versus placebo + carboplatin–paclitaxel in patients with recurrent or primary advanced endometrial cancer
- **Methods:** Patients will be randomized 1:1 to treatment arms
- **Primary Endpoint:** Investigator-assessed PFS per RECIST v1.1
- **Secondary Endpoints:** PFS by blinded independent central review and overall survival
- **Safety Assessment:** All adverse events will be assessed for intensity according to CTCAE v4.03

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**View E-Course:**

**CNS:** central nervous system; **EC:** endometrial cancer; **ECOG:** Eastern Cooperative Oncology Group; **FIGO:** International Federation of Gynecology and Obstetrics; **MMR:** DNA mismatch repair; **PD:** programmed death; **PD-1:** programmed death-1; **PD-L1:** programmed death ligand 1; **PD-L2:** programmed death ligand 2; **RECIST:** Response Evaluation Criteria in Solid Tumors; **AUC:** area under the curve; **CTCAE:** Common Terminology Criteria for Adverse Events; **MMR:** DNA mismatch repair; **PFS:** progression-free survival; **RECIST:** Response Evaluation Criteria in Solid Tumors; **TSR:** tesarlimab; **PD-1L:** programmed death ligand 1; **PD-1R:** programmed death receptor.