ENGOT-EN/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

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 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.

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

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

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])

Secondary Endpoints
- PFS by blinded independent central review
- OS

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
- Immunosuppressed/autimmune disease

Adequate organ function

Adequate organ function

Enrolling sites

Belarus (CEEGOG)
Belgium (NSGO)
Czech Republic (CEEGOG)
Denmark (NSGO)
Finland (NSGO)
Cyprus (Europe) (CEEGOG)
Greece (NSGO)
Italy (MITO)
Netherlands (NSGO)
Norway (NSGO)
Poland (NSGO)
Sweden (NSGO)
Ukraine (CEEGOG)
United Kingdom (NCRI)
Turkey (MITO)
United States (GOG Foundation)

References

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Department of Surgery, The Netherlands Cancer Institute, Amsterdam, The Netherlands

Universidade de São Paulo, Brazil

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Corporate-supported research

Dostarlimab

Mechanism of action
- Dostarlimab (TSR-042) is an anti–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)
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For patients with primary advanced disease, this trial is part of an international collaboration of ENGOT and the GOG Foundation

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Secondary Endpoints
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- OS

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

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N=470

Randomized 1:1

Endpoint Assessment

AUC 5 mg/mL/min

Dostarlimab 500 mg + carboplatin AUC 5 mg/mL/min + paclitaxel 175 mg/m²

Dostarlimab 1000 mg + carboplatin AUC 5 mg/mL/min + paclitaxel 175 mg/m²

Placebo + carboplatin AUC 5 mg/mL/min + paclitaxel 175 mg/m²

Placebo