

Plain Language Summary of 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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i General information about this study

Full scientific title:
A Study of Dostarlimab (TSR-042) Plus Carboplatin-Paclitaxel Versus Placebo Plus Carboplatin-Paclitaxel in Patients With Recurrent or Primary Advanced Endometrial Cancer (RUBY)

Study number: NCT03981796 **Study name:** RUBY **Sponsored by:** GlaxoSmithKline

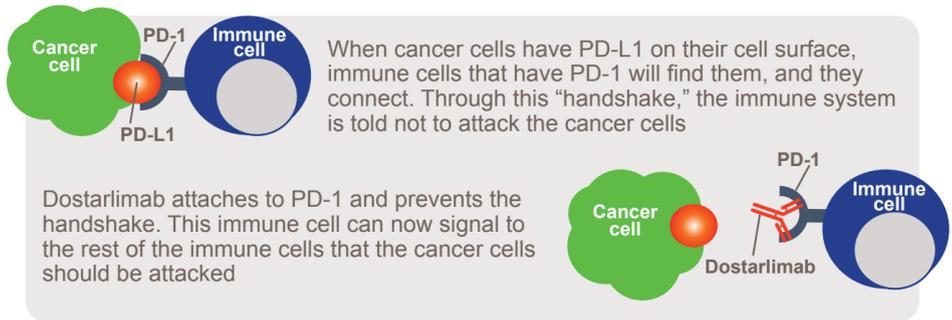
Collaborators:
European Network of Gynaecological Oncological Trial Groups (ENGOT) and Gynecologic Oncology Group (GOG)
Writing and editorial support for this report was provided by Ashfield Healthcare Communications and funded by GlaxoSmithKline

? Why is this study being done?

The RUBY study is being done to see if treatment with dostarlimab plus chemotherapy followed by dostarlimab alone is useful in treating endometrial cancer

🧪 What medicine is being tested?

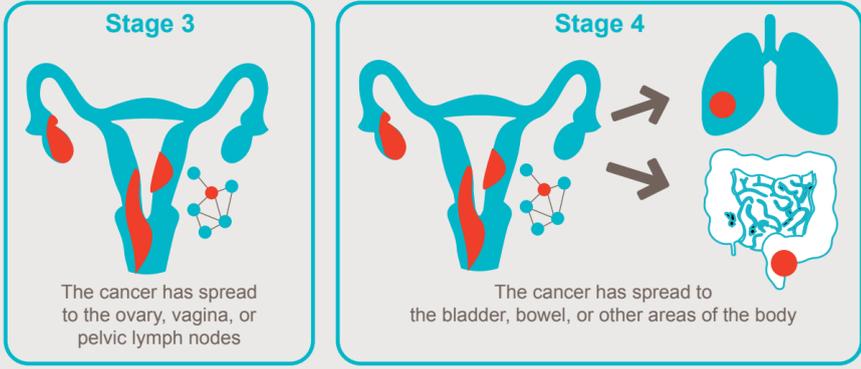
Dostarlimab is a medicine being tested that is part of a category called **programmed cell death inhibitors** (or “PD-1 inhibitors”). These drugs help your immune system to find and **attack cancer cells**



👤 Which patients can enroll?

Patients must have endometrial cancer that is advanced or recurrent

Advanced endometrial cancer means it is **stage 3 or 4 disease** when the cancer is first diagnosed

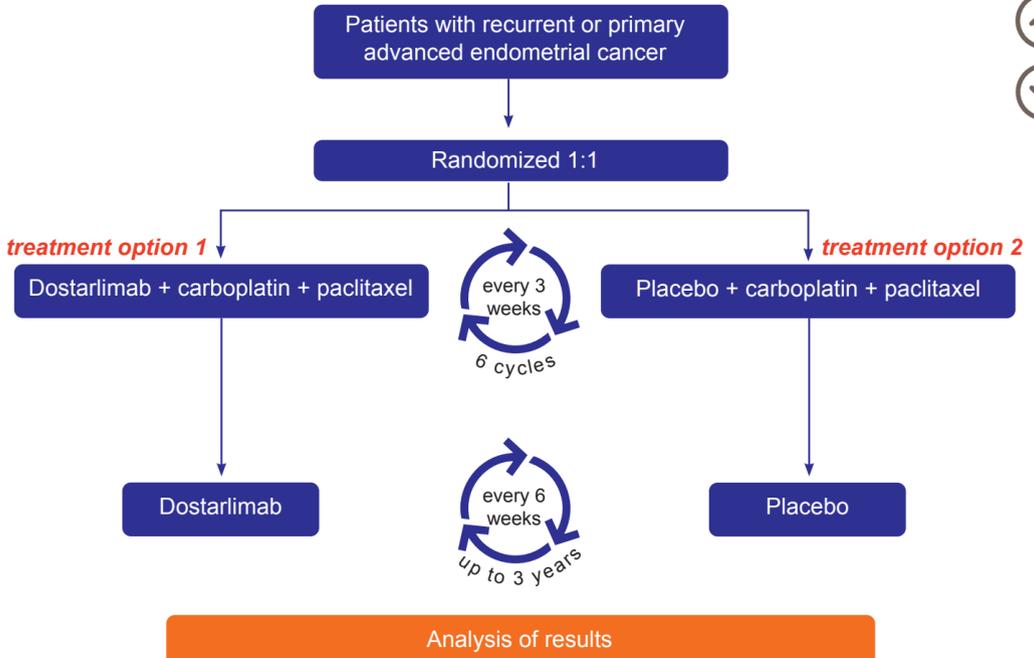


Recurrent endometrial cancer means it was treated and has **returned**

Patients must be in good enough condition to take care of themselves on their own. For example, they must be able to walk or do light housework or office work

Not all patients who meet the criteria shown here will be eligible. More detailed information on who is eligible to participate is available at <https://clinicaltrials.gov/ct2/show/NCT03981796>

🗨️ How will the trial be conducted?



RUBY is a randomized, double-blind, phase 3 trial. This means that there are **2 treatment options**

- 1. Dostarlimab plus chemotherapy (the treatment being tested)**
- 2. Standard chemotherapy (the control)**

- ✓ **Chemotherapy** is a drug treatment that uses powerful chemicals to kill cancer cells in your body
- ✓ There are **two chemotherapy drugs** that are used together in this trial: one is called **carboplatin**, and the other is called **paclitaxel**

- ✓ Patients will be **placed into the arms randomly** (this is what is meant by “**randomized**”)
- ✓ In the **control arm**, patients will receive a **placebo** (inactive treatment that looks the same as the dostarlimab treatment) so that neither the patient nor the oncologist know which treatment option the patient is getting (this is what is meant by “**double-blind**”)
- ✓ **Phase 3 trials** compare a new potential treatment against the current standard of care to see if the new treatment is **better than the current standard of care**
- ✓ More details on clinical trial phases can be found [here](#)
- ✓ **The trial is enrolling at sites in several countries**

ENGOT

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

📁 Where can I find more information?

<https://clinicaltrials.gov/ct2/show/NCT03981796>