

# 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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### 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

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### 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**

When cancer cells have PD-L1 on their cell surface, immune cells that have PD-1 will find them, and they connect. Through this “handshake,” the immune system is told not to attack the cancer cells

Dostarlimab attaches to PD-1 and prevents the handshake. This immune cell can now signal to the rest of the immune cells that the cancer cells should be attacked

### 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

**Stage 3**

The cancer has spread to the ovary, vagina, or pelvic lymph nodes

**Stage 4**

The cancer has spread to the bladder, bowel, or other areas of the body

**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)**

- ✓ **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**

**2. Standard chemotherapy (the control)**

- ✓ 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**

- Belarus

Belgium

Canada

Czech Republic

Denmark

Finland

Germany
- Greece

Hungary

Israel

Italy

Netherlands

Norway

Poland
- Sweden

Turkey

Ukraine

United Kingdom

United States

### Where can I find more information?

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