### General Information about the study

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 type:** Randomized, Double-Blind, Multicenter Study of Dostarlimab + Carboplatin-Paclitaxel Versus Placebo + Carboplatin-Paclitaxel in Recurrent or Primary Advanced Endometrial Cancer  

**Study sponsor:** GlaxoSmithKline  

**Writing and editorial support:** Ashfield Healthcare Communications

### Why is this study being done?

The RUBY study is a randomized, double-blind, placebo-controlled, phase 3 trial designed to evaluate the efficacy and safety of dostarlimab plus carboplatin-paclitaxel compared to placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced endometrial cancer. This study will help to determine if the addition of dostarlimab to chemotherapy improves outcomes for patients with this type of cancer.

### What medicine is being tested?

**Dostarlimab**

Dostarlimab is a monoclonal antibody (mAb) that targets programmed death receptor-1 (PD-1), a receptor expressed on immune cells. By binding to PD-1, dostarlimab inhibits the interaction between PD-1 and its ligand PD-L1, which is expressed on cancer cells. This interruption of the PD-1/PD-L1 interaction helps to re-activate the immune system against cancer.

**Carboplatin**

Carboplatin is a chemotherapy drug that works by interfering with DNA synthesis by blocking the activity of DNA polymerase. This leads to cell death in rapidly growing cells, which can include cancer cells.

**Paclitaxel**

Paclitaxel is a chemotherapy drug that works by binding to microtubules in cancer cells, preventing them from forming cell structures needed for cell division and causing cell death.

### What will patients receive?

Patients will be randomly assigned to receive either dostarlimab plus carboplatin-paclitaxel or placebo plus carboplatin-paclitaxel.

### Recurrent or primary advanced endometrial cancer

- **Recurrent endometrial cancer** means that the cancer has come back after treatment.
- **Primary advanced endometrial cancer** means that the cancer has spread beyond the uterus.

### Phase 3 trial design

- **Randomized 1:1**
- **Double-blind**

### Treatment arm 1

<table>
<thead>
<tr>
<th>Arm</th>
<th>Treatment</th>
<th>Dose</th>
<th>Administration</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>RUBY</td>
<td>Placebo + carboplatin-paclitaxel</td>
<td></td>
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<tr>
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### Treatment arm 2

<table>
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<td>Dostarlimab + carboplatin-paclitaxel</td>
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<tr>
<td>RUBY</td>
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### How will the trial be conducted?

- **PD-L1**
  - PD-L1 is a protein that is expressed on the surface of cancer cells. It helps cancer cells avoid being attacked by the immune system.
  - Dostarlimab binds to PD-L1 and prevents the cancer cells from signaling to other immune cells that they should not be killed.

### Analysis of results

- **Stage 1**
  - The cancer has spread only to the ovaries or vagina.
  - The cancer is localized to the body and has not spread outside of the grandmother.

- **Stage 2**
  - The cancer has spread to other areas of the body, such as the bladder, bowel, or other areas of the body.

- **Stage 3**
  - The cancer has spread to the lymph nodes or other internal organs.

- **Stage 4**
  - The cancer has spread to distant parts of the body, such as the lungs, liver, or bone.

### Where can I find more information?

[https://clinicaltrials.gov/ct2/show/NCT03981796](https://clinicaltrials.gov/ct2/show/NCT03981796)