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Medical Oncology

Plain Language Summary of Publication

A plain language summary publication of patients' survival with endometrial cancer treated with dostarlimab plus carboplatin-paclitaxel

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Summary

What is the purpose of this PLS-P?

The purpose of this plain language summary of publication is to help you understand recent findings from Part 1 of the RUBY study (full name ENGOT-EN6/GOG3031/RUBY trial).

- Researchers sometimes study new combinations of already approved individual treatments to see if the combinations work well together and if they are safe to prescribe to patients.
- In Part 1 of the RUBY study, the combination of **dostarlimab** with **carboplatin-paclitaxel** was investigated to see how well it worked for patients with primary advanced or recurrent **endometrial** cancer when compared with patients who were given placebo plus **carboplatin-paclitaxel**.
- Patients in the RUBY study were divided into subgroups according to their biomarker status. This allowed researchers to see if biomarker status could help determine how well patients with specific biomarkers would respond to the combination of **dostarlimab** with **carboplatin-paclitaxel**.
- This summary reports the results of the second data cut (the second time investigators looked at all of the data since the start of the study) of the RUBY study. At this time, researchers were looking specifically at how long patients lived and how safe the treatment was in patients who received **dostarlimab** with **carboplatin-paclitaxel** compared with those patients who received placebo plus **carboplatin-paclitaxel**.

How to say...

- **Carboplatin:** KAR-boh-pla-tin
- **Chemotherapy:** KEE-moh-THAYR-uh-pee
- **Dostarlimab:** dos-TAR-lih-mab
- **Endometrial:** EN-doh-MEE-tree-ul
- **JEMPERLI:** gem-PER-lee
- **Paclitaxel:** PA-klih-TAX-sil

Keywords: **dostarlimab**, **endometrial** cancer, immunotherapy, mismatch repair, overall survival

Where can I find the original article on which this summary is based?

You can read the original article published in the journal, *Annals of Oncology*, at https://doi.org/10.1016/j.annonc.2024.05.546

What did this study look at?

The disease

This study looked at primary advanced or recurrent **endometrial** cancer.

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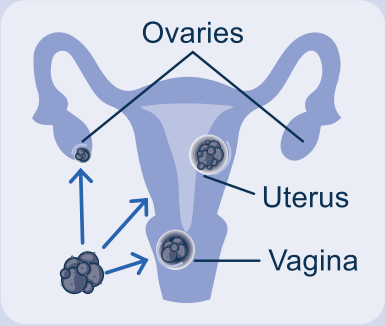
Endometrial cancer

Endometrium
the lining of the uterus

Endometrial cancer is a cancer that starts in the lining of the uterus. This lining of the uterus makes up the endometrium. **Endometrial** cancer is the second most common gynecologic cancer among women worldwide.

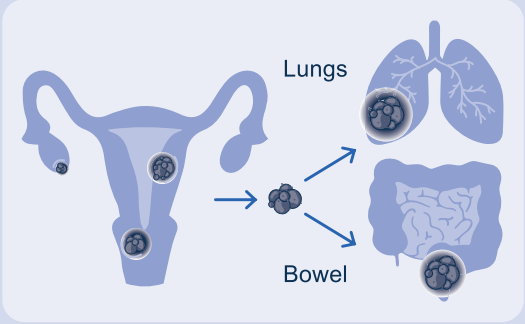
Primary advanced or recurrent **endometrial** *cancer*

Primary advanced **endometrial** cancer means that, at the first diagnosis, the cancer is either stage 3 or stage 4 disease. This means that the cancer has already spread outside of the uterus.



In stage 3 **endometrial** cancer, the cancer has spread to other organs close to the uterus such as the ovaries, vagina, and/or pelvic lymph nodes.

In stage 4 **endometrial** cancer, the cancer has spread to other locations farther from the uterus such as the lungs, bowel, and/or the abdomen.



Recurrent **endometrial** cancer means that the cancer has already been treated and has returned.

Endometrial *cancer biomarkers*

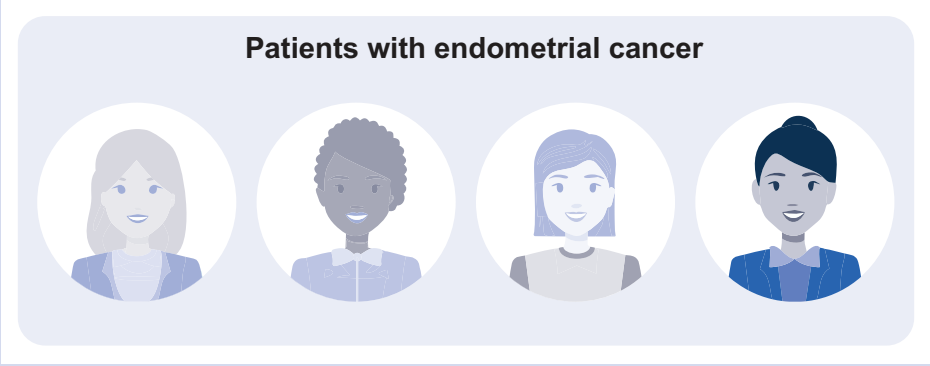
Biomarkers are biological materials (such as genes or proteins) that may be found in cells, tissues, or blood. Biomarkers can provide information about the particular cancer cells in which they are found.

Some patients with **endometrial** cancer have an abnormality in the way that the cancer cells correct mistakes in their DNA. The biomarker that describes this process is called mismatch repair.

Biomarker
a biological material that can provide information about a patient's cancer cells.
Biomarkers may be found in cells, tissues, or in blood.

Cells *with* this specific abnormality have DNA mismatch repair deficiency, or dMMR. In dMMR cells, one of the processes to repair DNA has been damaged and no longer works correctly. About one in four patients with **endometrial** cancer has the dMMR biomarker.

Cells that do *not* have this abnormality are called mismatch repair proficient, or MMRp. This is found in about three in four patients with **endometrial** cancer.



Cells with dMMR can often have changes in the length of DNA regions called microsatellite regions. Microsatellite regions are more likely than other parts of the DNA to have changes in length when mismatch repair is not working correctly, making them a useful biomarker that scientists can look at to gain information about the cancer characteristics. Cells that have many changes to the lengths of these regions are called microsatellite instability-high (MSI-H). The dMMR and MSI-H biomarkers are often spoken of together—tumor cells with these biomarkers are called dMMR/MSI-H.

Cells that do not have the MSI-H abnormality are referred to as microsatellite stable (MSS). This is most often found in cells that are also MMRp, so these biomarkers are usually referred to together as MMRp/MSS.

Biopsy
the removal of parts of a tumor for study by a pathologist

Doctors can test for the mismatch repair or microsatellite status of **endometrial** cancer tumors. These are two types of biomarker tests. When patients have a biopsy performed by their doctor, portions of the tumor sample can be sent for biomarker testing. After the biomarker testing is completed, the results will tell if the patient is dMMR/MSI-H or MMRp/MSS.

Doctors and researchers have found that dMMR/MSI-H tumors may respond well to specific types of cancer treatments. Specifically, in primary advanced or recurrent **endometrial** cancer, previous research has shown that the dMMR/MSI-H biomarker could help predict whether cancer cells will respond to particular types of cancer treatments.

The drug

This study looked at the combination therapy of **dostarlimab** (brand name: **JEMPERLI**) with **carboplatin-paclitaxel** compared with placebo plus **carboplatin-paclitaxel**.

Based on the results of the RUBY study provided in the original manuscript upon which this PLS-P is derived, the combination of **dostarlimab** with **carboplatin-paclitaxel** is approved for the treatment of all patients with primary advanced or recurrent **endometrial** cancer (both those with dMMR/MSI-H and those with MMRp/MSS) in the United States, Europe, and several other countries. In many other countries **dostarlimab** is approved for the treatment of patients with dMMR/MSI-H primary advanced or recurrent **endometrial** cancer.

How does this treatment work?

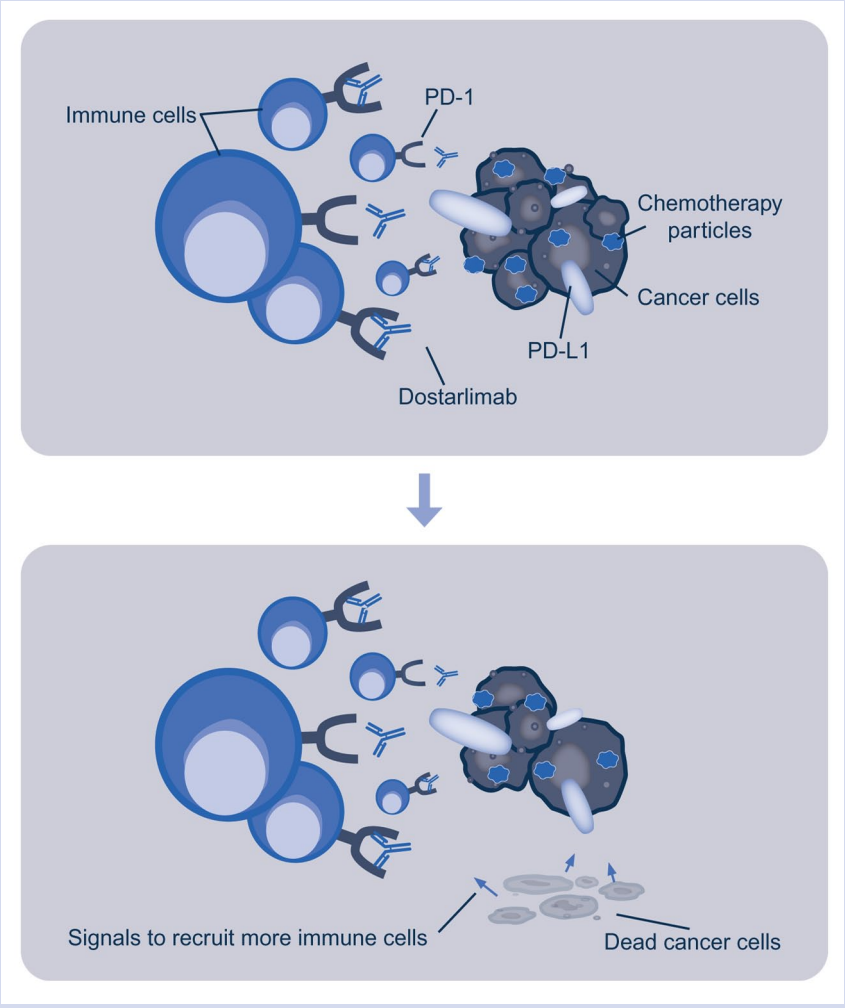
Dostarlimab is a type of treatment known as an immunotherapy. Specifically, **dostarlimab** is a type of immunotherapy known as a programmed cell death inhibitor, or PD-1 inhibitor.

Immunotherapies are a type of cancer treatment that uses the body's immune system to help fight cancer cells.

For many years, patients with primary advanced or recurrent **endometrial** cancer were treated with **chemotherapy** alone. In particular, the recommended treatment in this setting was the combination of two specific **chemotherapy** drugs called **carboplatin** and **paclitaxel**.

Chemotherapy, including the combination of **carboplatin** and **paclitaxel**, acts to kill cancer cells. When **chemotherapy** kills cancer cells, the dying cancer cells release signals that may cause more immune cells to come to the tumor site.

Dostarlimab attaches to a protein, called PD-1, on the surface of immune cells. When **dostarlimab** attaches to the immune cells, it allows the immune cell to recognize that the cancer cells are not healthy cells so that the immune cells can signal to the immune system that the cancer cells should be attacked.



The combination of **dostarlimab** and **chemotherapy** works together to kill cancer cells better than **chemotherapy** alone in patients with **endometrial** cancer. **Dostarlimab** allows the immune cells to recognize the sick cancer cells, and **chemotherapy**, by killing the cancer cells, encourages more immune cells to find the cancer cells and to kill them.

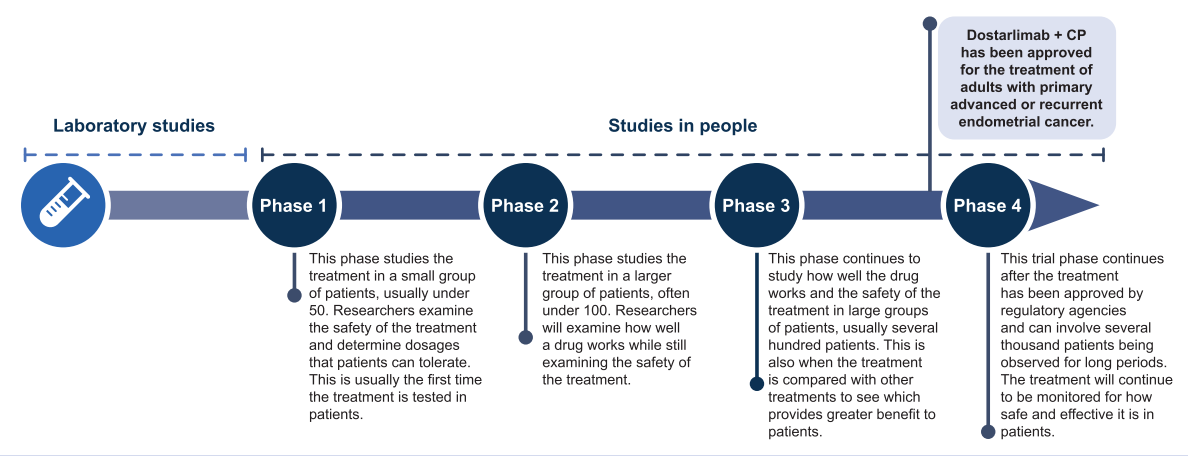
The study

The RUBY study compares how well the combination of **dostarlimab** plus **carboplatin-paclitaxel** works in patients with primary advanced or recurrent **endometrial** cancer compared with patients receiving placebo plus **carboplatin-paclitaxel**. The study also looks at how safe the combination of **dostarlimab** plus **carboplatin-paclitaxel** is for patients who receive it compared with patients who receive placebo plus **carboplatin-paclitaxel**.

The summary

This plain language summary of publication of the RUBY study will describe the results from the RUBY study at the second data cut (the second time investigators looked at all of the data since the start of the study). Here, we will look at results for survival and safety.

Where is this study in the drug development timeline?



Who took part in this study?

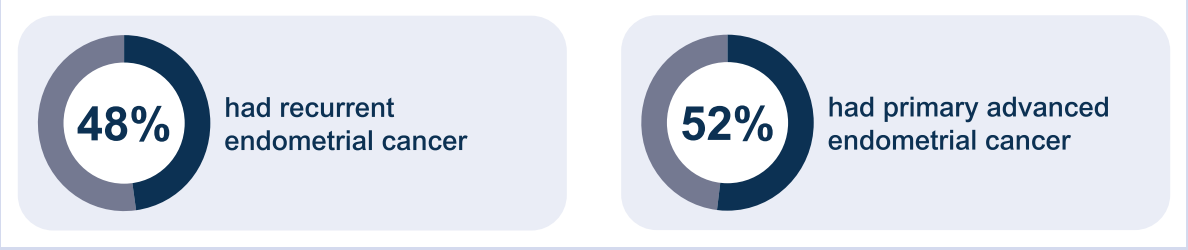
RUBY study patient characteristics

People in this study were women with primary advanced or recurrent **endometrial** cancer. They needed to meet these requirements:

- Have advanced **endometrial** cancer but could not have received **chemotherapy** before entering the study
- Have recurrent **endometrial** cancer and could have received **chemotherapy** once before, but it had to have been at least 6 months since they finished **chemotherapy** treatment
- Had to be tested for their mismatch repair/microsatellite stability biomarker status

Patients from 113 sites in 19 countries were screened and 494 patients were enrolled in the RUBY study:

236 patients (48%) had recurrent **endometrial** cancer and 258 patients (52%) had primary (newly diagnosed) advanced **endometrial** cancer



118 patients (24%) had dMMR/MSI-H tumors and 376 patients (76%) had MMRp/MSS tumors

Patient groups

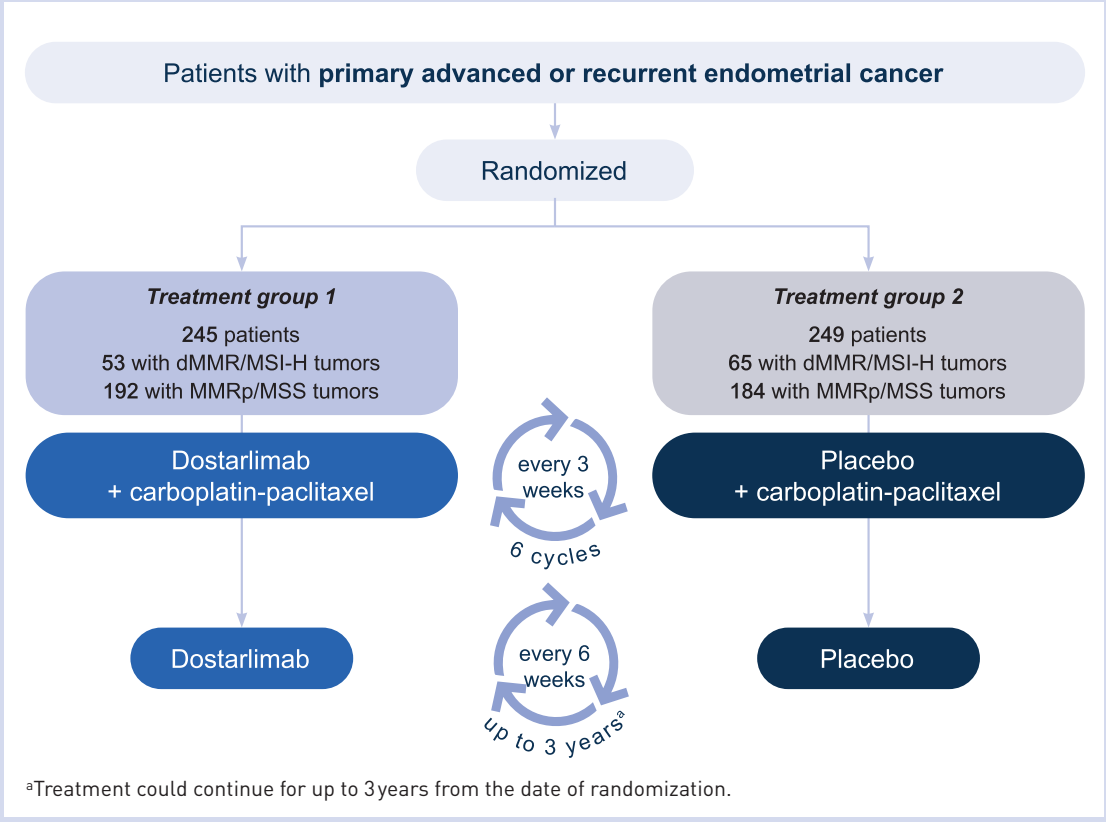
There were two patient groups (also called study arms) who received treatment in the RUBY study.

- In the first group, patients were treated with **chemotherapy** and **dostarlimab**
  - There were 245 patients in this group: 53 patients had **dMMR/MSI-H** tumors, and 192 patients had **MMRp/MSS** tumors
- In the second group, patients were treated with **chemotherapy** and placebo (a treatment that does not have a medicine in it but looks the same as the **dostarlimab** treatment)
  - There were 249 patients in this group: 65 patients had **dMMR/MSI-H** tumors, and 184 patients had **MMRp/MSS** tumors

Placebo
a treatment that does not have a medicine in it but looks the same as the study treatment

Patients were divided into their treatment groups by chance. This process is known as randomization.

The RUBY study was a double-blind study, which means that neither the researchers nor the patients knew which treatment option they were receiving.



[a]Treatment could continue for up to 3 years from the date of randomization.

Treatment

Patients in the first group were given **dostarlimab** with **chemotherapy**, and patients in the second group were given placebo with **chemotherapy**. The patients received their treatments every 3 weeks for a total of 6 times, or 6 cycles over an 18-week period.

After these initial 6 cycles, patients in the first group were given **dostarlimab** alone, and patients in the placebo group were given placebo alone. They received their treatment every 6 weeks. Patients could continue receiving their treatment for up to 3 years from the date of their first treatment cycle in the study.

Patient background characteristics by treatment group

In the **dostarlimab** group, 127 patients (52%) were under 65 years of age, while in the placebo group, 114 patients (46%) were under 65 years of age. Most patients in both groups were White; 189 patients (77%) in the **dostarlimab** group and 191 patients (77%) in the placebo group. Just over 10% of patients in each group were Black or African American; 28 patients (11%) in the **dostarlimab** group and 31 patients (12%) in the placebo group.

What were the results of this study?

The primary endpoint

The primary endpoint is the main question that is investigated in a study. At the first data cut (the first time investigators looked at all the data after the beginning of the RUBY study), researchers looked at both progression-free survival (patients remaining alive without their cancer recurring or getting worse) and overall survival (defined below). Results from that earlier data cut are available in the publications listed under "Where can readers find more information on the RUBY study?" below.

At this second data cut (the second time investigators looked at all of the data since the beginning of the RUBY study), researchers looked at overall survival. Overall survival measures how long patients who were receiving **dostarlimab** plus **chemotherapy** survived compared with patients who were receiving placebo with **chemotherapy**.

Overall survival
A measure of how long patients in the study survived. This is measured from date of randomization to date of death from any cause (this includes all deaths, not just those related to cancer)

Overall survival, as a primary endpoint, was examined in all patients in the RUBY study. However, researchers also examined overall survival in two different populations, or groupings, of patients:

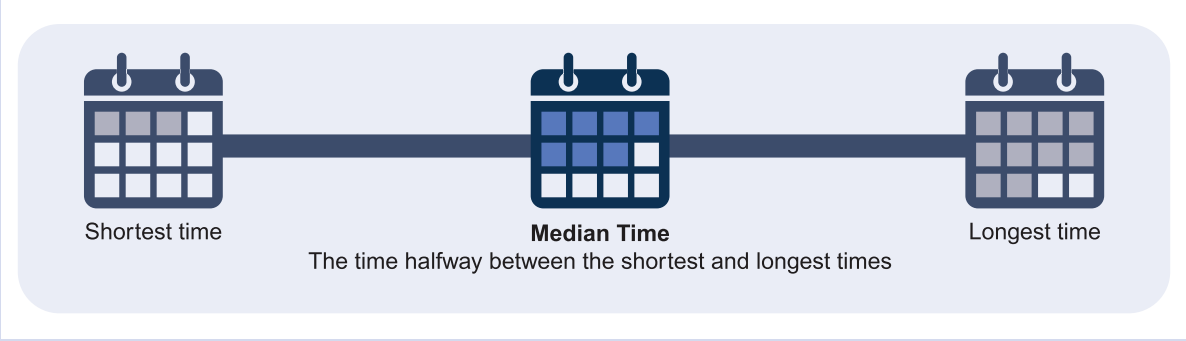
- Only patients with dMMR/MSI-H tumors
- Only patients with MMRp/MSS tumors

Researchers examined these two populations to have a better understanding of how the biomarker status of the patients could impact survival when patients were treated with **dostarlimab** plus **chemotherapy** compared with placebo plus **chemotherapy**.

Here is the breakdown of these results:

In *all patients* in the RUBY study:

- The risk of dying was 31% lower for patients who were in the **dostarlimab** plus **chemotherapy** group than for patients in the placebo plus **chemotherapy** group.
- Patients treated with **dostarlimab** plus **chemotherapy** had an improvement in median survival of 16.4 months compared with patients treated with placebo + **chemotherapy**.
  - The median is the time that is exactly halfway between the shortest length of time that any patient in the study survived and the longest length of time that any patient in the study survived.
  - The median survival of patients treated with **dostarlimab** plus **chemotherapy** was 44.6 months, while the median survival of patients treated with placebo plus **chemotherapy** was 28.2 months.



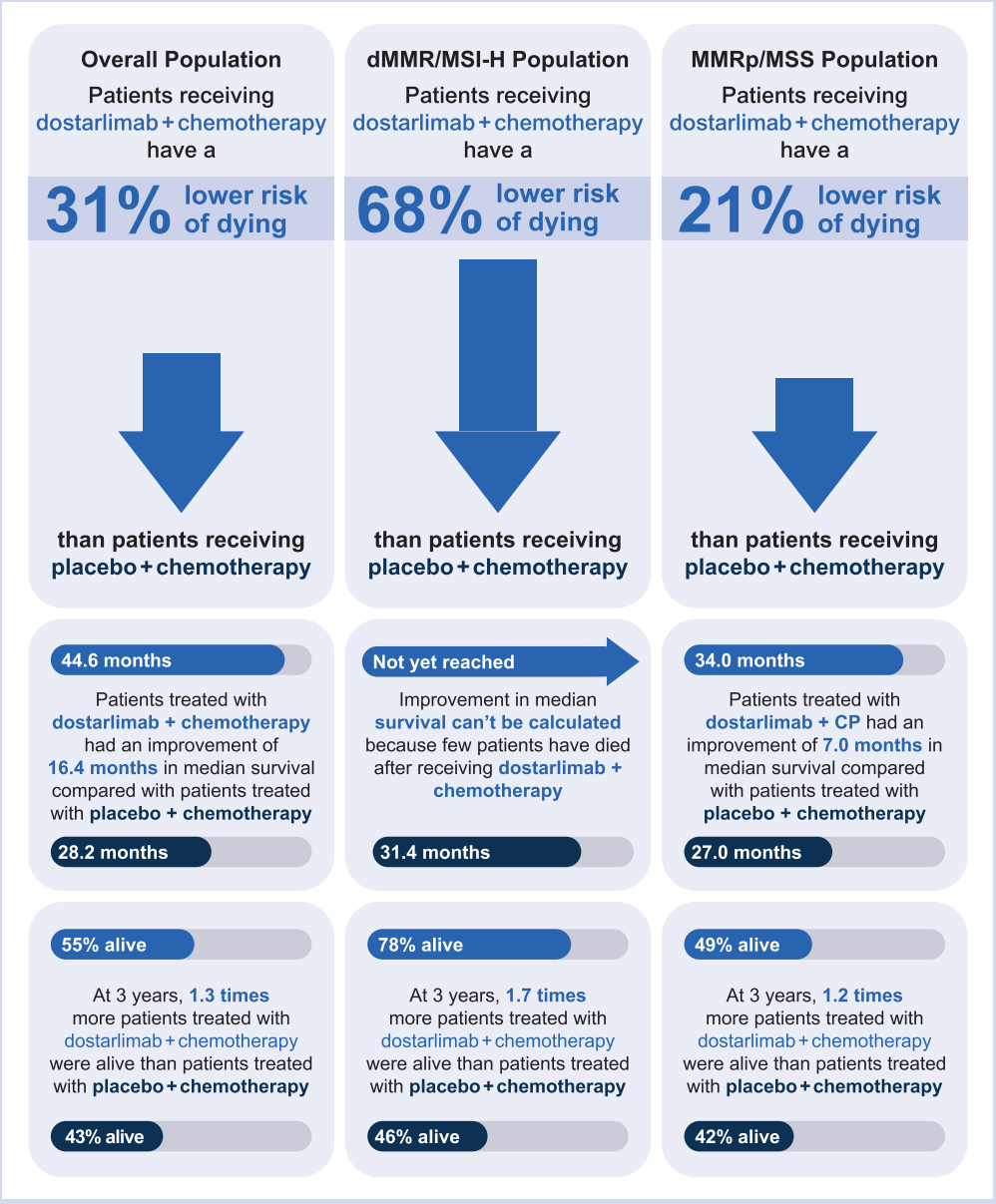
- At the 3-year point in the study, 55% of patients receiving **dostarlimab** plus **chemotherapy** were likely to be alive compared with 43% of patients receiving placebo plus **chemotherapy**. This means that patients receiving **dostarlimab** had about 1.3 times the likelihood of being alive at 3 years.

Patients with dMMR/MSI-H tumors in the RUBY study:

- The risk of dying was 68% lower for patients who were in the **dostarlimab** plus **chemotherapy** group than for patients in the placebo plus **chemotherapy** group.
- Improvement in median survival could not be calculated in this group because few patients in this group who received **dostarlimab** plus **chemotherapy** had died.
  - The median survival of patients treated with placebo plus **chemotherapy** was 31.4 months.
- At the 3-year point in the study, 78% of patients receiving **dostarlimab** plus **chemotherapy** were likely to be alive compared with 46% of patients receiving placebo plus **chemotherapy**. This means that patients receiving **dostarlimab** had about 1.7 times the likelihood of being alive at 3 years.

Patients with MMRp/MSS tumors in the RUBY study:

- The risk of dying was 21% lower for patients who were in the **dostarlimab** plus **chemotherapy** group than for patients in the placebo plus **chemotherapy** group.
- Patients treated with **dostarlimab** plus **chemotherapy** had an improvement in median survival of 7.0 months compared with patients treated with placebo + **chemotherapy**.
  - The median survival of patients treated with **dostarlimab** plus **chemotherapy** was 34.0 months, while the median survival of patients treated with placebo plus **chemotherapy** was 27.0 months.
- At the 3-year point in the study, 49% of patients receiving **dostarlimab** plus **chemotherapy** were likely to be alive compared with 42% of patients receiving placebo plus **chemotherapy**. This means that patients receiving **dostarlimab** had about 1.2 times the likelihood of being alive at 3 years.

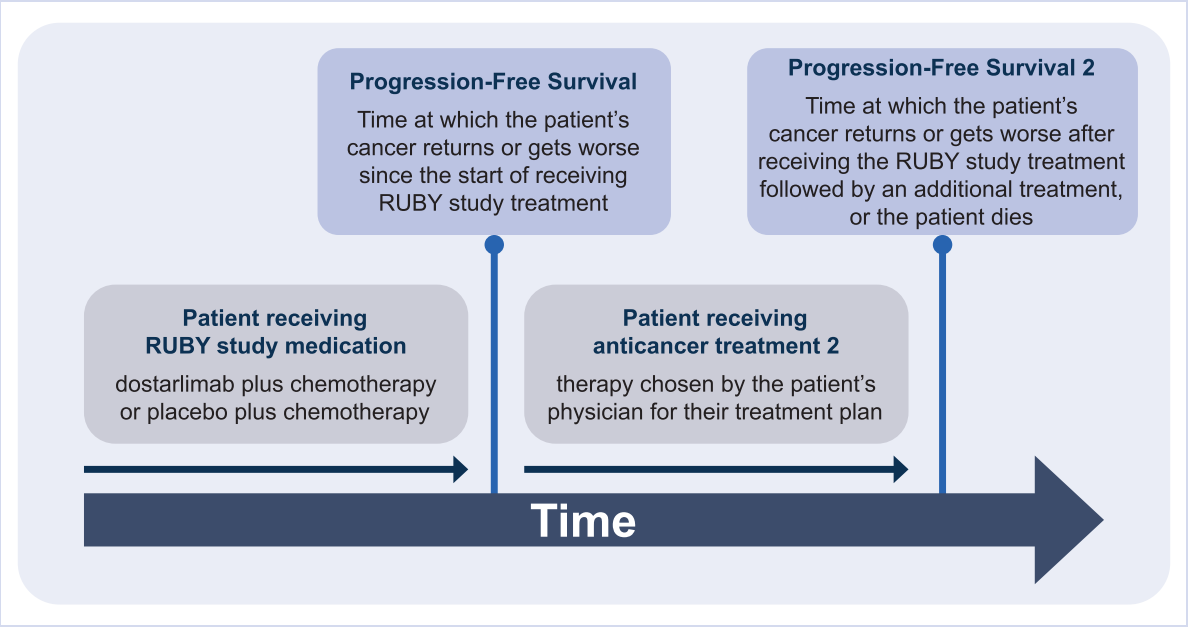


Secondary endpoints

Secondary endpoints are additional questions that researchers are looking at in a study. The researchers were also interested in two additional endpoints at this data cut in the RUBY study:

- Progression-free survival 2
  - Progression-free survival 2 (PFS2) is an endpoint for which researchers look at the time from study entry to the time when patients who had their tumors come back (recur) or get worse (progress) after receiving treatment and then received an additional treatment and have their tumors come back or get worse a second time or died from any cause.

PFS2 allows researchers to see if **dostarlimab** continues to provide benefits to patients if their tumors have come back and they have received a second treatment.



- Side effects and safety
  - Researchers wanted to learn about the side effects that patients may have had while receiving **dostarlimab** plus **chemotherapy**. They also wanted to compare how many and what types of side effects were experienced by patients receiving **dostarlimab** plus **chemotherapy** to those experienced by patients receiving placebo plus **chemotherapy**.

Progression-free survival 2 results

In *all patients* in the RUBY study:

- 47% of patients in the **dostarlimab** plus **chemotherapy** group and 64% of patients in the placebo plus **chemotherapy** group had their tumors come back or get worse after a second treatment or died from any cause.
- For patients in the **dostarlimab** plus **chemotherapy** group who had their tumors come back or get worse after a second treatment or died, the median length of time it took for this to occur was 14 months longer than for patients in the placebo plus **chemotherapy** group.
  - The median is the time halfway between the shortest length of time for any patient in the study whose tumor came back or got worse after a second treatment or who died and the longest length of time for any patient whose tumor came back or got worse after a second treatment or who died.
  - The median PFS2 in patients treated with **dostarlimab** plus **chemotherapy** was 32.3 months, while the median PFS2 in patients treated with placebo plus **chemotherapy** was 18.4 months.

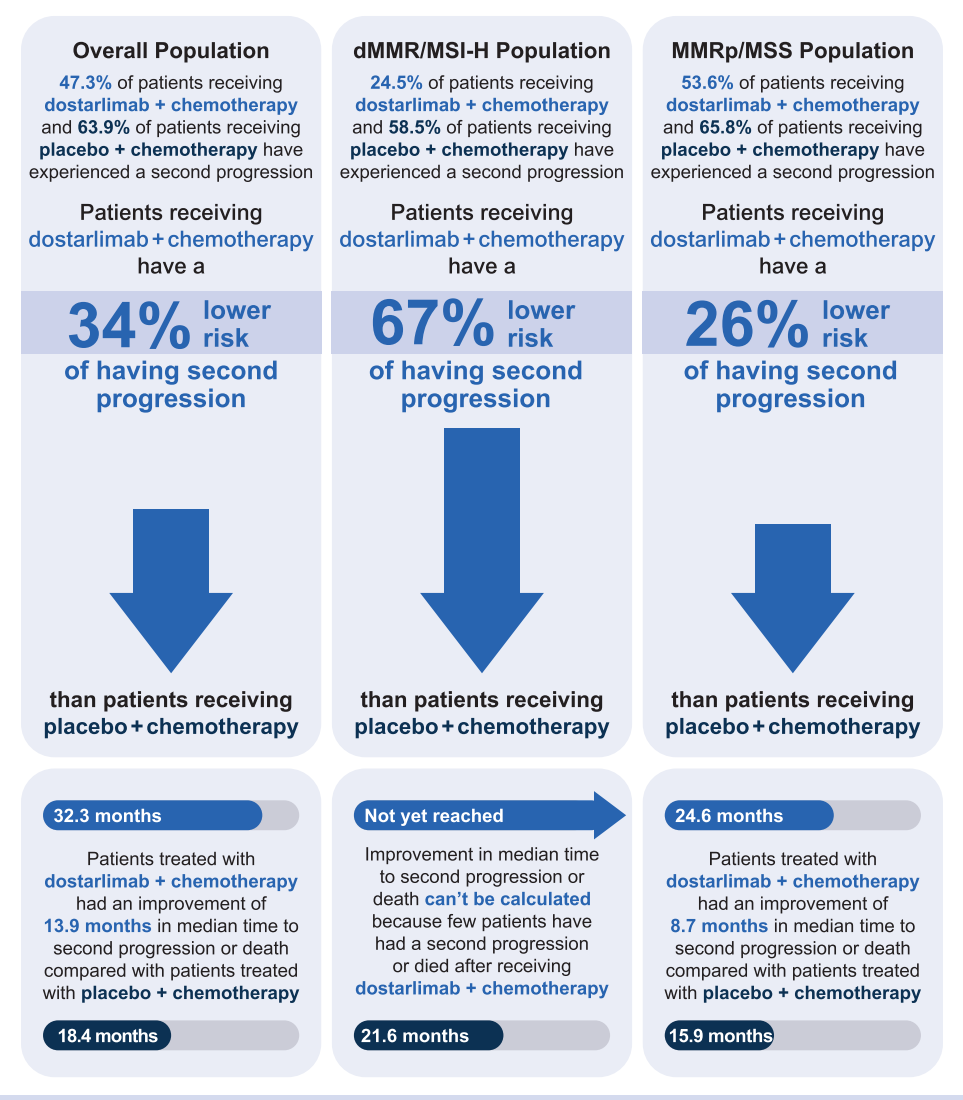
Patients with dMMR/MSI-H tumors in the **RUBY study**

- 25% of patients in the **dostarlimab** plus **chemotherapy** group and 59% of patients in the placebo plus **chemotherapy** group had their tumors come back or get worse after a second treatment or died from any cause.

- For patients in the **dostarlimab** plus **chemotherapy** group who had their tumors come back or get worse after a second treatment or died, no median length of time for this to occur could be determined (this is because few patients with dMMR/MSI-H tumors who received **dostarlimab** plus **chemotherapy** had their tumors come back or get worse after a second treatment or died).
  - The median PFS2 in patients treated with placebo plus **chemotherapy** was 21.6 months.

Patients with MMRp/MSS tumors in the RUBY study:

- 54% of patients in the **dostarlimab** plus **chemotherapy** group and 66% of patients in the placebo plus **chemotherapy** group had their tumors come back or get worse after a second treatment or died from any cause.
- For patients in the **dostarlimab** plus **chemotherapy** group who had their tumors come back or get worse after a second treatment or died, the median length of time it took for this to occur was 9 months longer than for patients in the placebo plus **chemotherapy** group.
  - The median PFS2 in patients treated with **dostarlimab** plus **chemotherapy** was 24.6 months, while the median PFS2 in patients treated with placebo plus **chemotherapy** was 15.9 months.



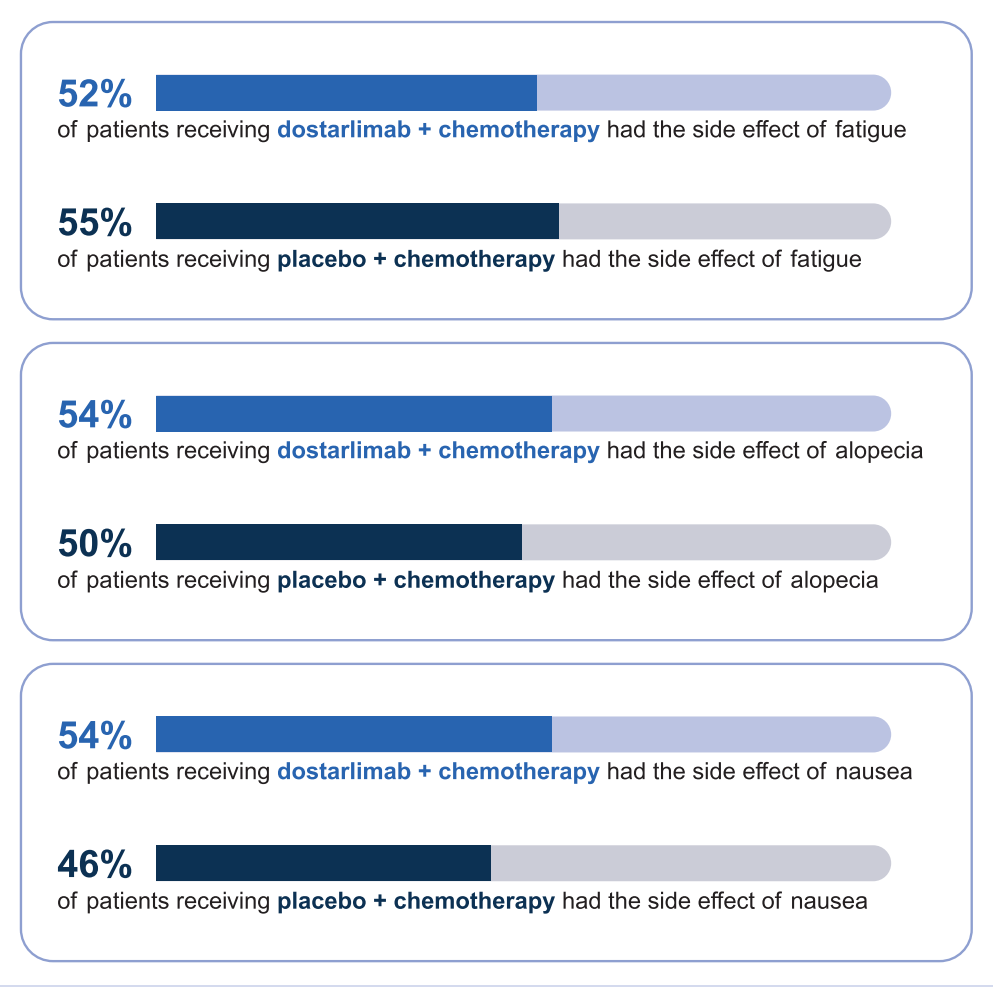
Side effects and safety results

A side effect (also referred to as an adverse event) is an undesired effect that can happen while a patient is receiving treatment or after treatment has finished. Side effects can range in severity from mild to severe or even life-threatening or fatal, and may have life-long effects.

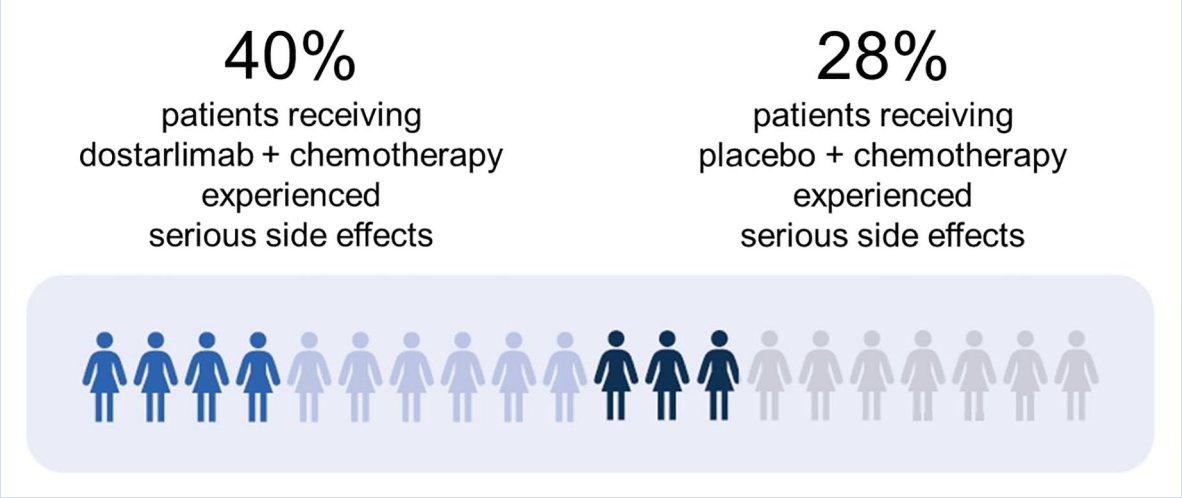
In the RUBY study, the side effects that were experienced by patients were expected by the researchers. This is because the side effects that were experienced are similar to the side effects that patients could have had when being treated with either **dostarlimab** or **chemotherapy** alone and had occurred in previous studies or with other similar medicines.

All patients in the **dostarlimab** plus **chemotherapy** group and in the placebo plus **chemotherapy** group had at least one side effect.

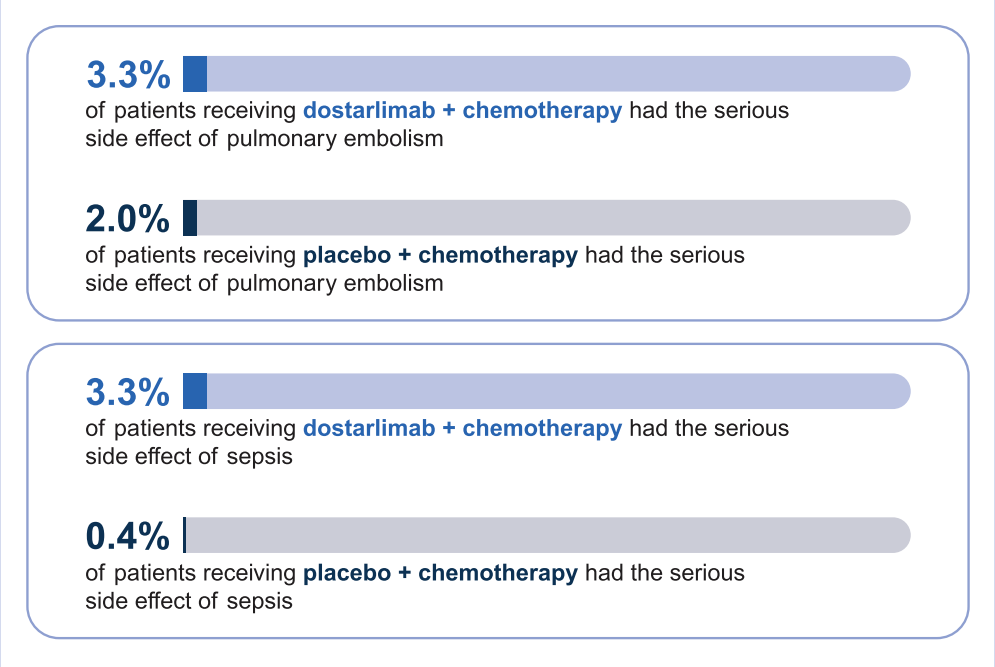
The most common side effects were tiredness (fatigue), hair loss (alopecia), and nausea. These were experienced by similar numbers of patients in both groups.



More patients in the **dostarlimab** plus **chemotherapy** group had side effects that were serious compared with patients in the placebo plus **chemotherapy** group (40% vs 28%). Serious side effects are those that resulted in hospitalization or disability, or were life-threatening or may have led to death.

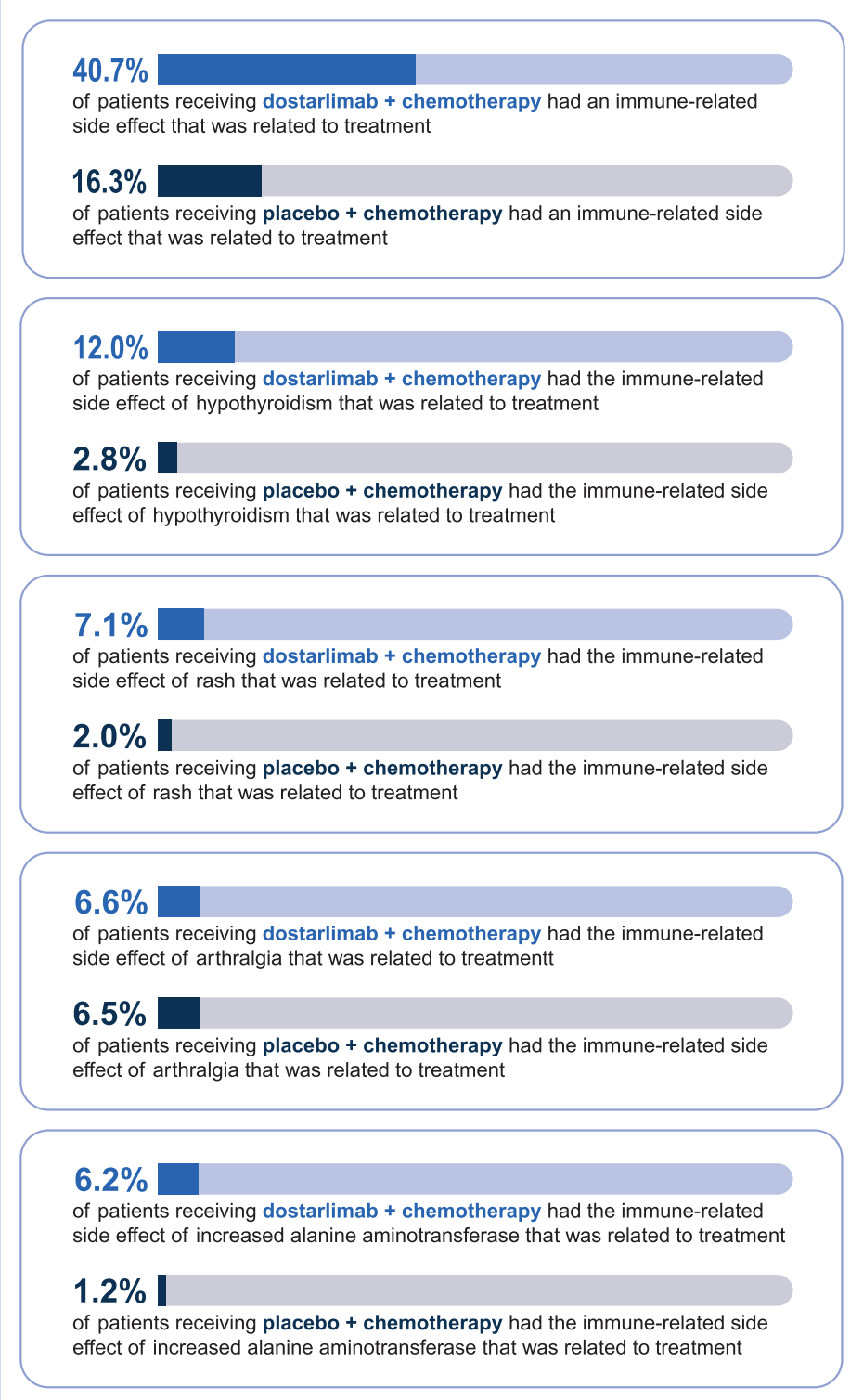


The most common serious side effects in patients in the **dostarlimab** plus **chemotherapy** group were pulmonary embolism (when the blood vessels that bring blood to your lungs are blocked) and sepsis (when the body has an extreme response to infection that can lead to organ failure and death).



Immune-related side effects are a type of side effect that can occur when patients are treated with immunotherapies like **dostarlimab**. Immune-related side effects occur because immunotherapies stimulate the patient's immune system. 41% of patients in the **dostarlimab** plus **chemotherapy** group experienced an immune-related side effect that was related to treatment, while 16% of patients in the placebo plus **chemotherapy** group experienced an immune-related side effect that was related to treatment.

The most common immune-related side effects were hypothyroidism (the thyroid is not producing enough hormones), rash, arthralgia (pain in the joints), and increased alanine aminotransferase (an enzyme produced by the liver). Arthralgia was experienced by similar numbers of patients in both groups.



19% of patients in the **dostarlimab** plus **chemotherapy** group stopped treatment with **dostarlimab** because of a side effect. 8% of patients in the placebo plus **chemotherapy** group stopped treatment with placebo because of a side effect.

When researchers first looked at the RUBY study data (first analysis), five patients in the **dostarlimab** plus **chemotherapy** group had died from a side effect while receiving **dostarlimab** or within 3 months after they stopped receiving **dostarlimab**. Two of these patients died from a side effect considered by researchers to be related to **dostarlimab** treatment. No new deaths because of side effects were observed when researchers looked at the RUBY study data a second time, with about 12 additional months of follow-up. These two deaths were discussed in an earlier published Plain Language Summary of Publication (*A Plain Language Summary of "**Dostarlimab** for primary advanced or recurrent **endometrial** cancer;"* a link has been provided below).

What were the main conclusions found by the researchers in this study?

Patients treated with **dostarlimab** plus **chemotherapy** had a lower risk of dying than patients treated with placebo plus **chemotherapy**.

Compared with patients treated with placebo plus **chemotherapy**, patients treated with **dostarlimab** plus **chemotherapy** had a delay in their time of tumors returning or getting worse for a second time or dying from any cause.

These benefits in both overall survival and PFS2 were seen in the overall population of patients in Part 1 of the RUBY study and in the biomarker-defined subgroups (patients with dMMR/MSI-H tumors and patients with MMRp/MSS tumors).

No new and/or unexpected safety results regarding side effects occurred in patients treated with **dostarlimab** plus **chemotherapy** at this second data-cut of Part 1 of the RUBY study.

Dostarlimab plus **chemotherapy** represents a new treatment for patients with primary advanced or recurrent **endometrial** cancer.

How to use this summary to help patients and doctors talk about this research?

The purpose of this Plain Language Summary of Publication is to help patients and their caregivers understand the results from the original article in nontechnical, accessible language. This helps to enable patients to make informed decisions about their care.

This Plain Language Summary of Publication may be helpful for patients with primary advanced or recurrent **endometrial** cancer, their family members, and/or their caregivers. It may also be helpful for patient advocates and healthcare professionals who treat people with **endometrial** cancer. This Plain Language Summary of Publication is a resource that can help bridge the gap between patients and healthcare providers to allow the discussion of treatment options and research studies in an accessible, mutually understandable way. The Plain Language Summary of Publication can be printed out and brought to the doctor's office to refer to during appointments and discussions.

This Plain Language Summary of Publication is also an educational tool. Patients and caregivers can often hear medical terms at their doctors' offices or read them online but not understand what these terms mean. This summary introduces patients and their caregivers to common medical terms that they may hear, provides an explanation of what these terms mean, and explains how they relate to the patient's disease and their treatment.

In shared decision-making, healthcare providers and their patients work as partners. This Plain Language Summary of Publication can educate patients to better understand their options and to ask relevant questions. The summary can also enable patients to make the best decisions, considering all the available options, for their individual circumstances and, therefore, advocate for themselves and their care.

Are there any plans for further studies?

- The RUBY study is ongoing. This means that patients are still being treated in the RUBY study. Results after a longer period will be published in the future.
- Additional studies of **dostarlimab** are also ongoing, including the DOMENICA study. This study compares **dostarlimab** monotherapy (patients receive **dostarlimab** only) with **chemotherapy** alone (patients receive **chemotherapy** only) in patients with dMMR primary advanced or recurrent **endometrial** cancer. The DOMENICA study is a collaborative study between GSK and ARCAGY-GINECO (an independent, non-profit academic clinical research group specializing in gynecological oncology). More information on the DOMENICA study can be found here: https://clinicaltrials.gov/ct2/show/NCT05201547.

Who sponsored this study?

- The RUBY study was sponsored by GSK.
- The study name is ENGOT-EN6-NSGO/GOG-3031/RUBY.
- The study number is NCT03981796.

Where can readers find more information on the RUBY study?

Original publication citation

- The full title of the original article on which this Plain Language Summary of Publication is based is "Overall survival in patients with **endometrial** cancer treated with **dostarlimab** plus **carboplatin-paclitaxel** in the randomized ENGOT-EN6/GOG-3031/RUBY trial"
  - Powell MA, Bjørge L, Willmott L, et al. Overall survival in patients with **endometrial** cancer treated with **dostarlimab** plus **carboplatin-paclitaxel** in the randomized ENGOT-EN6/GOG-3031/RUBY trial. *Ann Oncol.* 2024;35(8):728–738.
  - You can find the original, free-to-access, article here: https://doi.org/10.1016/j.annonc.2024.05.546
- The full name of the RUBY study is: "A study to evaluate **dostarlimab** with **carboplatin–paclitaxel** versus placebo with **carboplatin–paclitaxel** in participants with recurrent or primary advanced **endometrial** cancer (RUBY)."
  - You can read more about the RUBY study here: https://clinicaltrials.gov/ct2/show/NCT03981796
- Additional papers on the primary endpoints in the RUBY study are also available.
  - Mirza MR, Chase DM, Slomovitz BM, et al. **Dostarlimab** for primary advanced or recurrent **endometrial** cancer. *N Engl J Med.* 2023;388(23):2145–2158.
  - You can find the original, free-to-access, article here: https://doi:10.1056/NEJMoa2216334
  - Mirza MR, Chase DM, Slomovitz BM, et al. A plain language summary of "**Dostarlimab** for primary advanced or recurrent **endometrial** cancer". *Future Oncol.* 2025;21(2):151–168.
  - You can find the original, free-to-access, article here: https://doi:10.2217/fon-2023-0940

Declarations

Ethics approval and consent to participate

The trial adhered to the principles of the Declaration of Helsinki, Good Clinical Practice guidelines, and all local laws under the auspices of an independent data and safety monitoring committee. The trial was approved by the institutional review board at each study site and conducted in accordance with the Declaration of Helsinki and Good Clinical Practice Guidelines of the International Council for Harmonisation. All patients provided written informed consent.

Consent for publication

Not applicable.

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Availability of data and materials

GSK is committed to sharing anonymized subject-level data from interventional trials as per GSK policies and as applicable. Requests for subject-level data should be done via the GSK link: https://www.gsk-studyregister.com/en/.

Glossary of terms

Adverse event: A side effect or an undesired effect that can happen while a patient is receiving treatment

Biomarkers: Biological materials (such as genes or proteins) that can provide information about a patient's cancer cells. Biomarkers may be found in cells, tissues, or blood

Biomarker testing: A laboratory test that uses a biopsy (sample of tissue, blood, or body fluid) to check for genes, proteins, or other molecules that may be a sign of a disease or medical condition

Biopsy: The removal of parts of a tumor for study by a pathologist

Chemotherapy: Medicines (powerful chemicals) that are used in drug treatment for killing fast-growing cells in the body, including cancer cells

- Carboplatin: A chemotherapy drug that is used together with paclitaxel to kill cancer cells. They also work together to make the immune system more effective at killing cancer cells
- Paclitaxel: A chemotherapy drug that is used together with carboplatin to kill cancer cells. They also work together to make the immune system more effective at killing cancer cells

Dostarlimab: A type of treatment known as an immunotherapy. Specifically, dostarlimab is a type of immunotherapy known as a programmed cell death protein 1 inhibitor, or PD-1 inhibitor

- JEMPERLI: The brand name for dostarlimab

Double-blind study: A type of study in which neither the researchers nor the patients know which treatment option the patient is receiving

Endometrial cancer: A type of cancer that starts in the cells that line the uterus

- Primary advanced endometrial cancer: Cancer that is diagnosed as either stage 3 or stage 4 disease. This means that the cancer has already spread outside of the uterus
- Recurrent endometrial cancer: Cancer that has already been treated and has returned

Endometrium: The lining of the uterus

Gynecologic cancer: A cancer found in women's reproductive organs

Immune-related side effects: Side effects that are related to the action of the immunotherapy treatment on the body's immune system

Immunotherapy: A type of cancer treatment that uses the body's immune system to help fight cancer cells

- Programmed cell death protein 1 inhibitor (PD-1 inhibitor): A type of immunotherapy. PD-1 inhibitor attaches to a protein, called PD-1, on the surface of immune cells

Median time: A value halfway between the shortest and longest time

Microsatellite regions: Regions within the DNA that are more likely to vary in length than other regions. Also, a biomarker that can be used for information

- Microsatellite instability-high (MSI-H): Cells that have many changes to the lengths of microsatellite regions
- Microsatellite stable (MSS): Cells that do not have the MSI-H abnormality

Mismatch repair: A process by which cells correct mistakes in their DNA

- Mismatch repair deficiency (dMMR): Cells with an abnormality in the way the cells correct mistakes in their DNA. In dMMR cells, one of the processes to repair DNA has been damaged and no longer works correctly, which can lead to cancer
- Mismatch repair proficient (MMRp): Cells that do not have an abnormality in the way the cells correct mistakes in their DNA

Overall survival: A measure of how long patients in the study survived

Placebo: A treatment that does not have a medicine in it but looks the same as the study treatment

Primary endpoint: The main question that is being investigated in a study

Secondary endpoints: Additional questions that researchers are investigating in a study

Progression-free survival 2 (PFS2): An endpoint for which researchers look at patients who had their tumors come back (recur) or get worse (progress) after receiving treatment, then received an additional treatment (not one of the study treatments) and had their tumors come back or get worse a second time, or the patient died from any cause

Pulmonary embolism: A blockage in the blood vessels that bring blood to the lungs

Randomization: The division of patients into treatment groups by chance

Sepsis: An extreme response by the body to infection that can lead to organ failure and death

Shared decision-making: A collaborative process where healthcare providers and their patients work as partners, allowing for the discussion of treatment options. This enables patients to make the best decisions, considering all the available options, for their individual circumstances and, therefore, advocate for themselves and their care

Standard of care: The treatment that most patients currently receive

Study arm: A patient group that receives a specific treatment

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