Taylor & Francis
Taylor & Francis Group

Future Oncology

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/ifon20

A Plain Language Summary of "Dostarlimab for primary advanced or recurrent endometrial cancer"

Mansoor R Mirza, Dana M Chase, Brian M Slomovitz, René dePont Christensen, Zoltán Novák, Destin Black, Lucy Gilbert, Sudarshan Sharma, Giorgio Valabrega, Lisa M Landrum, Lars C Hanker, Ashley Stuckey, Ingrid Boere, Michael A Gold, Annika Auranen, Bhavana Pothuri, David Cibula, Carolyn McCourt, Francesco Raspagliesi, Mark S Shahin, Sarah E Gill, Bradley J Monk, Joseph Buscema, Thomas J Herzog, Larry J Copeland, Min Tian, Zangdong He, Shadi Stevens, Eleftherios Zografos, Robert L Coleman & Matthew A Powell

To cite this article: Mansoor R Mirza, Dana M Chase, Brian M Slomovitz, René dePont Christensen, Zoltán Novák, Destin Black, Lucy Gilbert, Sudarshan Sharma, Giorgio Valabrega, Lisa M Landrum, Lars C Hanker, Ashley Stuckey, Ingrid Boere, Michael A Gold, Annika Auranen, Bhavana Pothuri, David Cibula, Carolyn McCourt, Francesco Raspagliesi, Mark S Shahin, Sarah E Gill, Bradley J Monk, Joseph Buscema, Thomas J Herzog, Larry J Copeland, Min Tian, Zangdong He, Shadi Stevens, Eleftherios Zografos, Robert L Coleman & Matthew A Powell (11 Jul 2024): A Plain Language Summary of "Dostarlimab for primary advanced or recurrent endometrial cancer", Future Oncology, DOI: 10.2217/fon-2023-0940

To link to this article: https://doi.org/10.2217/fon-2023-0940

Published online: 11 Jul 2024.

Plain Language Summary of Publication

Future ONCOLOGY

A plain language summary of dostarlimab for primary advanced or recurrent endometrial cancer

Mansoor R Mirza[1], Dana M Chase[2], Brian M Slomovitz[3], René dePont Christensen[4], Zoltán Novák[5], Destin Black[6], Lucy Gilbert[7], Sudarshan Sharma[8], Giorgio Valabrega[9], Lisa M Landrum[10], Lars C Hanker[11], Ashley Stuckey[12], Ingrid Boere[13], Michael A Gold[14], Annika Auranen[15], Bhavana Pothuri[16], David Cibula[17], Carolyn McCourt[18], Francesco Raspagliesi[19], Mark S Shahin[20], Sarah E Gill[21], Bradley J Monk[22], Joseph Buscema[23], Thomas J Herzog[24], Larry J Copeland[25], Min Tian[26], Zangdong He[26], Shadi Stevens[27], Eleftherios Zografos[27], Robert L Coleman[28] and Matthew A Powell[29]

First draft submitted: 3 November 2023; Accepted for publication: 16 February 2024

Summary

What is this summary about?
Dostarlimab, also known by the brand name JEMPERLI, is a medicine that uses a patient's own immune system to treat **endometrial cancer**. Dostarlimab is a type of medicine called an immunotherapy. Immunotherapies help the immune system find and attack cancer cells. Dostarlimab stops cancer cells from being able to hide from the immune system, which allows the patient to have a boosted immune response against their cancer.

How to say (double click sound icon to play sound)...

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

The RUBY study is a phase 3 clinical study of primary advanced (cancer that has spread outside the uterus) or recurrent (cancer that has come back) endometrial cancer. A phase 3 clinical study looks at how well a new treatment works compared to the standard, or usual, treatment in a large patient population. The RUBY study is testing how well dostarlimab given with **chemotherapy**, followed by dostarlimab alone, works at delaying primary advanced or recurrent endometrial cancer from getting worse and preventing patients from dying, compared to chemotherapy given alone (the current standard treatment for primary advanced or recurrent endometrial cancer).

What were the results?
When dostarlimab was given with chemotherapy, this combination was found to delay primary advanced or recurrent endometrial cancer from getting worse and to prevent patients from dying, compared with chemotherapy given alone (without dostarlimab). Patients in the study who received dostarlimab with chemotherapy had a 36% lower risk of dying or having their cancer get worse.

What do the results mean?
The results from this study contributed to the approval of dostarlimab with chemotherapy as a new treatment option for patients with mismatch repair deficient/microsatellite instability-high primary advanced or recurrent endometrial cancer. As of the publication of this plain language summary of publication (PLSP), this combination of dostarlimab with chemotherapy has been approved in the United States of America, the United Kingdom, the European Union and Hong Kong.

Endometrial cancer: A type of cancer that begins in the lining cells of the uterus.
Chemotherapy: Medicines that are used to kill rapidly growing cells in the body, including cancer cells.

Taylor & Francis
Taylor & Francis Group

What is the purpose of this PLSP?

The purpose of this PLSP is to help you to understand the findings from recent research. Jemperli (dostarlimab) is approved to treat the condition under study that is discussed in this summary. Approval varies by country; please check with your local provider for more details.

The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence, not on the results of a single study.

This summary reports the results of a planned interim analysis of the study, which means that the study has not yet been completed. The study described is still ongoing; therefore, the final outcomes of this study may differ from the outcomes described in this summary.

Who should read this PLSP?

This summary may be helpful for patients with primary advanced or recurrent endometrial cancer and their family members, patient advocates, health care professionals and caregivers.

Sponsor: a sponsor is a company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information that was generated during the study.

Who sponsored the study?

This study was **sponsored** by GSK (Waltham, MA, USA).

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

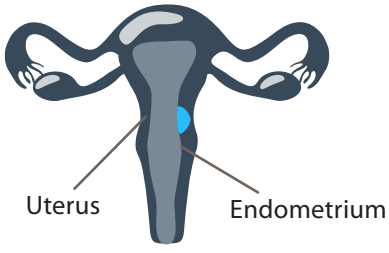
The free-to-access and free-to-read original article, 'Dostarlimab for advanced or recurrent endometrial cancer', can be found at:
https://www.nejm.org/doi/full/10.1056/NEJMoa2216334

Why is this study being done?

The RUBY study is being done to see if treatment with a combination of dostarlimab and chemotherapy for 18 weeks followed by dostarlimab alone for up to 3 years works better at treating patients with primary advanced or recurrent endometrial cancer than placebo and chemotherapy for 18 weeks followed by placebo alone for up to 3 years.

Placebo: A placebo is a substance given to the participant that looks the same as the drug but does not contain any medicine. It is used to check the real effect of new drugs as some participants may see an improvement in their disease when given a placebo, though it contains no active drug/treatment (this is known as the placebo effect).

What is endometrial cancer?



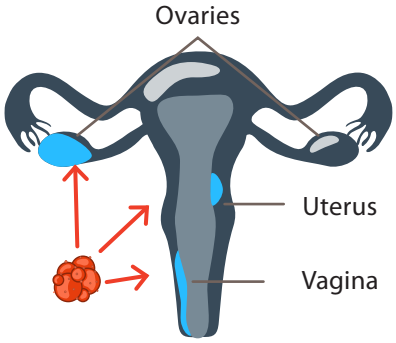
Endometrial cancer is a type of cancer that starts in the cells that create the lining of the uterus. The lining of the uterus is known as the endometrium. The endometrium is the portion of the uterus that builds up, or thickens, during the menstrual cycle and is lost during menstruation.

It is the 6th most common cancer among women worldwide.

- Primary advanced endometrial cancer means it is stage 3 or 4 disease when the cancer is first diagnosed, meaning the cancer has spread outside of the uterus.
- Recurrent endometrial cancer means the cancer was previously treated and has returned.

Stage 3

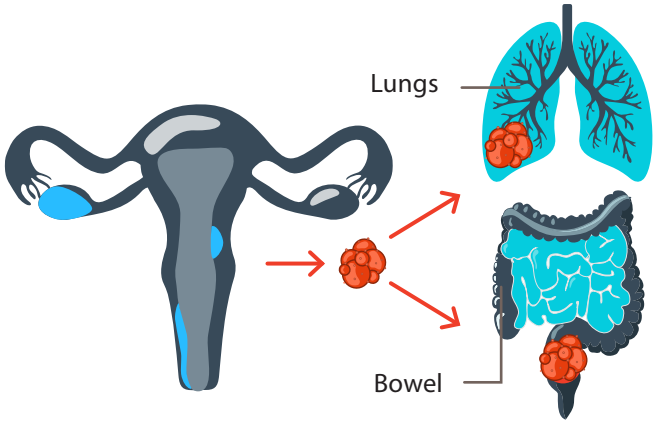
In stage 3 cancer, the cancer may be larger and may have spread to nearby organs.



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

Stage 4

In stage 4 cancer, the cancer has spread to more distant areas of the body.



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

Lymph nodes: Small glands that filter fluid from areas of the body. They contain cells from the immune system to help defend the body from threats.

- Over half of all patients who have primary advanced or recurrent endometrial cancer live less than 3 years.

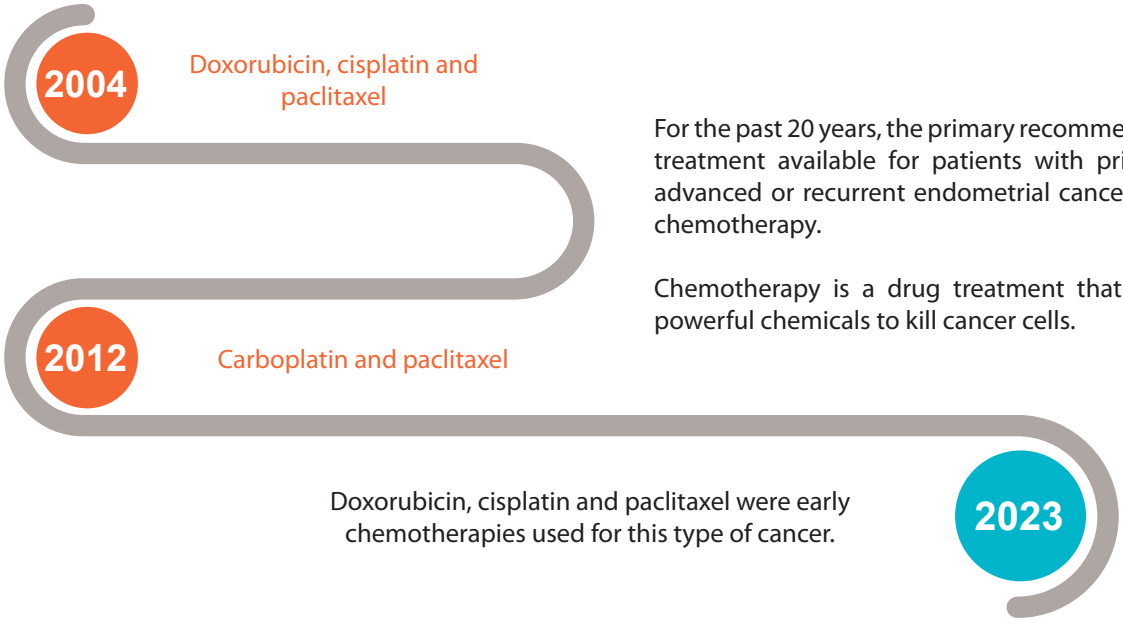
Biomarkers in endometrial cancer

About 1 in 4 patients with endometrial cancer have an abnormality in the way the cancer cells correct mistakes in their DNA. This is called DNA mismatch repair deficiency, or dMMR. DNA repair happens in all human cells, but in cells with dMMR, one of the processes to repair damaged DNA no longer works correctly, which can lead to cancer. Cells *without* dMMR are called mismatch repair proficient (pMMR).

In addition, having dMMR can lead to changes in the length of certain DNA regions, which is called microsatellite instability-high (MSI-H), which is another abnormality in some endometrial cancer cells. Cells *without* the MSI-H abnormality are referred to as microsatellite stable (MSS).

- Doctors can test the dMMR/MSI-H or pMMR/MSS status of the tumors. These are called biomarkers. These tests help to classify the type of endometrial cancer that is present. The classifications are either dMMR/MSI-H or pMMR/MSS.
  - In endometrial cancer that has worsened after previous chemotherapy, dMMR/MSI-H is a biomarker that has been found to help predict if the cancer cells will respond to immunotherapies like dostarlimab. This means that a patient with dMMR/MSI-H tumors was more likely to benefit from dostarlimab, when given alone, than a patient with a pMMR/MSS tumor.

Endometrial cancer treatments



For the past 20 years, the primary recommended treatment available for patients with primary advanced or recurrent endometrial cancer was chemotherapy.

Chemotherapy is a drug treatment that uses powerful chemicals to kill cancer cells.

Doxorubicin, cisplatin and paclitaxel were early chemotherapies used for this type of cancer.

In time, the combination of two specific chemotherapy drugs, carboplatin and paclitaxel, became standard of care for primary advanced or recurrent endometrial cancer. No new treatments had been approved until 2023, when dostarlimab plus chemotherapy was approved.

Despite being effective in many patients, with chemotherapy alone half of all patients with primary advanced or recurrent endometrial cancer die within 3 years of their diagnosis.

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

Treating cancer with multiple types of medications that work in different ways may be more effective than using only one type of treatment.

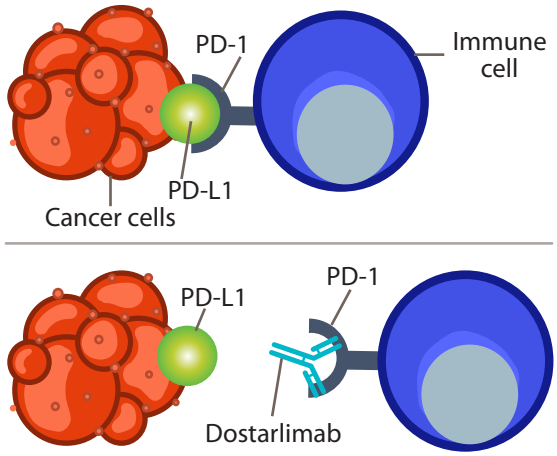
- For example, chemotherapy drugs may be used together with a different type of medicine mentioned earlier, called **immunotherapy**.
- Combining chemotherapy and immunotherapy may help more patients benefit from treatment (including patients with pMMR/MSS cancer).

What medicine was tested in the RUBY study?

The RUBY study tested a combination of the medicines dostarlimab and chemotherapy.

Dostarlimab is part of a group of immunotherapy medicines called programmed cell death inhibitors, or PD-1 inhibitors. These drugs help the immune system find and attack cancer cells.

- PD-1 is a protein on the surface of cells in the immune system (immune cells). PD-1 attaches to another protein called programmed death ligand 1 (PD-L1) that is found on the surface of other cells. This attachment acts like a 'handshake' that tells the immune cell not to attack the cell with PD-L1.

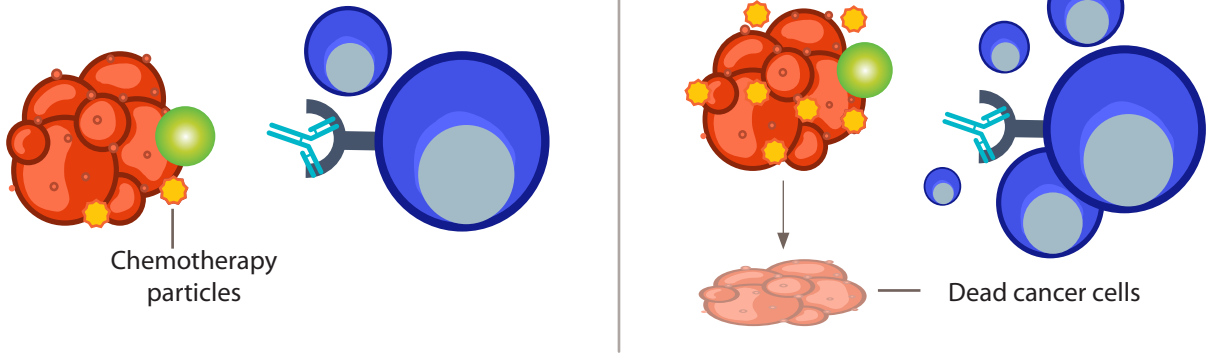


When cancer cells have PD-L1 on their cell surface, immune cells that have PD-1 will find them, and they connect. Through this handshake, the immune system is told not to attack the cancer cells.

Dostarlimab attaches to PD-1 and prevents the handshake. The immune cell can now recognize that the cancer cell is not healthy and can signal to the rest of the immune cells that the cancer cells should be attacked.

Figure reused from Oaknin A *et al.* A plain language summary of results from the GARNET study of dostarlimab in patients with endometrial cancer. *Future Oncol.* 19(25), 1709–1714 (2023).

The chemotherapy given in the RUBY study was a combination of carboplatin and paclitaxel. Carboplatin and paclitaxel act together to kill cancer cells, but they also act to allow the immune system to work better to kill cancer cells. When the cancer cells are killed by carboplatin and paclitaxel, the cells release signals that can cause more immune cells to come to the tumor site. This increase in the number of immune cells at the tumor site increases the potential of finding and killing more cancer cells.



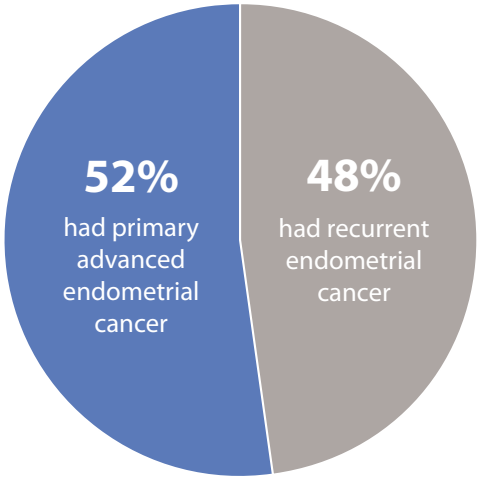
The combination of dostarlimab and chemotherapy, when given together, could potentially work together to kill cancer cells better than chemotherapy alone. Dostarlimab would prevent the cancer cells from hiding from the immune cells. At the same time, chemotherapy – by killing the cancer cells – may encourage more and more immune cells to find the cancer cells and kill them.

Who took part in the RUBY study?

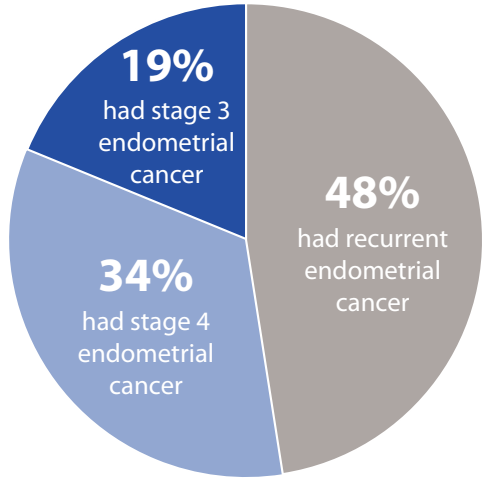
To participate in the RUBY study, patients had to have primary advanced or recurrent endometrial cancer. Patients with advanced endometrial cancer could not have received chemotherapy before entering into the study. For patients who had recurrent endometrial cancer, they could have received chemotherapy once before, as long as it had been at least 6 months since they finished the chemotherapy treatment.

In order to join the study, patients had to be tested for dMMR/MSI-H (mismatch repair deficient/microsatellite instability-high) or pMMR/MSS (mismatch repair proficient/microsatellite stable) biomarkers to identify what type of endometrial cancer they had. To test for these biomarkers, the patient's doctor took tumor samples and sent them to a laboratory. Both patients with dMMR/MSI-H tumors and patients with pMMR/MSS tumors were allowed to join the study.

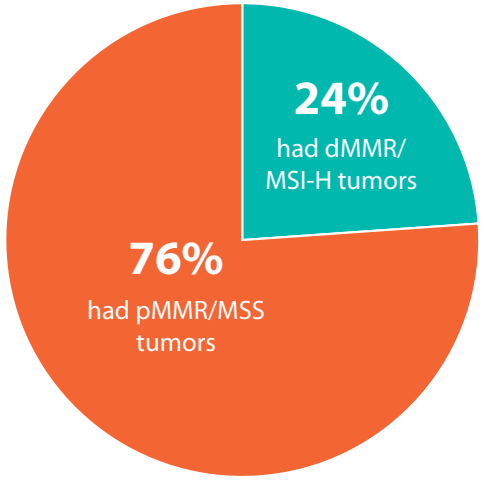
A total of 494 patients were included in the RUBY study; 236 (48%) had recurrent endometrial cancer, and 258 (52%) had primary advanced endometrial cancer.



Of the 494 patients, 92 (19%) had stage 3 disease, 166 (34%) had stage 4 disease, and 236 (48%) had recurrent endometrial cancer.



Of the 494 patients, 118 (24%) had dMMR/MSI-H tumors, and 376 (76%) had pMMR/MSS tumors. This is similar to the percentage of patients with dMMR/MSI-H tumors and the percentage of patients with pMMR/MSS tumors found in all patients diagnosed with primary advanced or recurrent endometrial cancer.



How was the study carried out?

The RUBY study is a phase 3 study. A phase 3 study compares a new potential treatment against the standard of care (what most patients currently receive) to see if the new treatment is better.

- In the RUBY study, dostarlimab given with chemotherapy is the new potential treatment, and chemotherapy given alone is the standard of care.

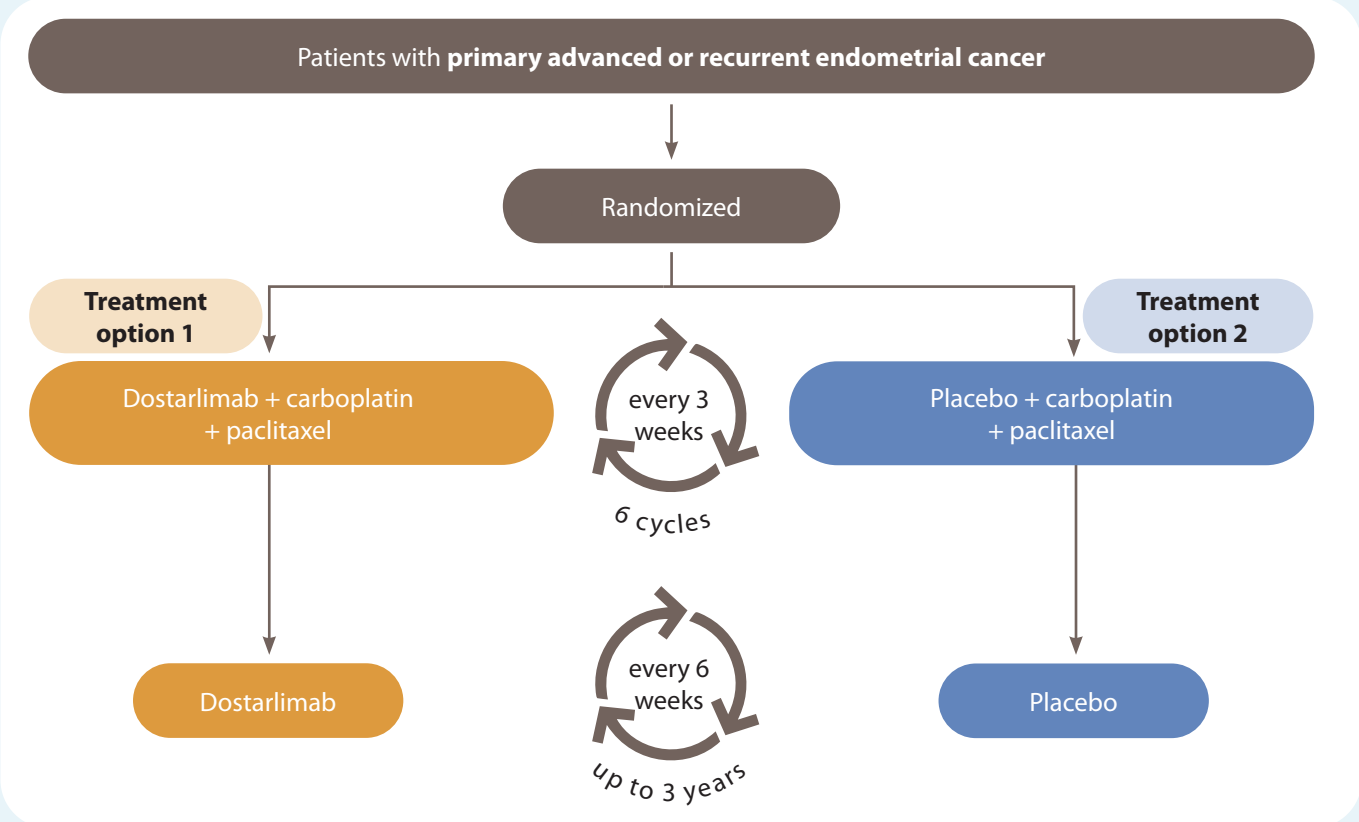
The RUBY study is a randomized study. In a randomized study, patients are divided into treatment groups by chance (this is what is meant by randomized). In the RUBY study, all patients were treated with chemotherapy (carboplatin and paclitaxel), but one half of the patients also received dostarlimab, while the other half of the patients also received placebo (a treatment that does not have a medicine in it but looks the same as the dostarlimab treatment).

- Patients in treatment group 1 were treated with chemotherapy and dostarlimab.
- Patients in treatment group 2 were treated with chemotherapy and placebo.

The RUBY study is a double-blind study. In a double-blind study, neither the patients nor the researchers knew which treatment option the patients were receiving. Double-blind studies improve the reliability of the final results since they help to minimize bias influencing the results. An example of bias that could influence the study results is that if the patients or researchers know which treatment they are receiving, then they may have a more favorable view of the experimental treatment, which might affect how they report any results. However, a double-blind study reduces these types of biases, resulting in more reliable results.

Patients were given dostarlimab with chemotherapy or placebo with chemotherapy every 3 weeks a total of 6 times, or for 6 cycles.

- 6 cycles of chemotherapy is a common treatment approach for patients with primary advanced or recurrent endometrial cancer.
- After those 6 cycles, patients were given dostarlimab alone or placebo alone every 6 weeks for up to 3 years.



Patients' tumors were scanned every 6 weeks using **computed tomography** (CT) or **magnetic resonance imaging** (MRI) for the first 6 months of the study. After that, patients continued to have CT or MRI scans, but the scans did not occur as often.

Computed tomography: This type of scan is a series of many x-rays that are combined together to create very detailed images of the inside of the body.
Magnetic resonance imaging: This type of imaging uses magnetic fields and radio waves to create detailed images of the organs of the body.

The researchers were looking to find out how long patients lived without their tumors getting worse (progressing) or coming back (recurring) or dying (from any cause). This length of time is called progression-free survival.

The researchers also wanted to find out how long patients in this study survived. This length of time is called overall survival.

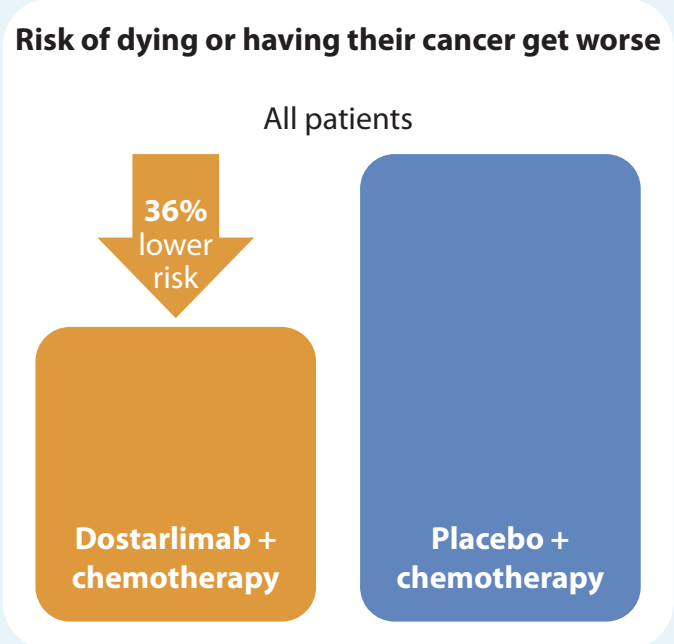
Finally, the researchers wanted to see if patients had adverse events occur from the different treatments. An adverse event is an undesired effect that happens while a patient is receiving treatment.

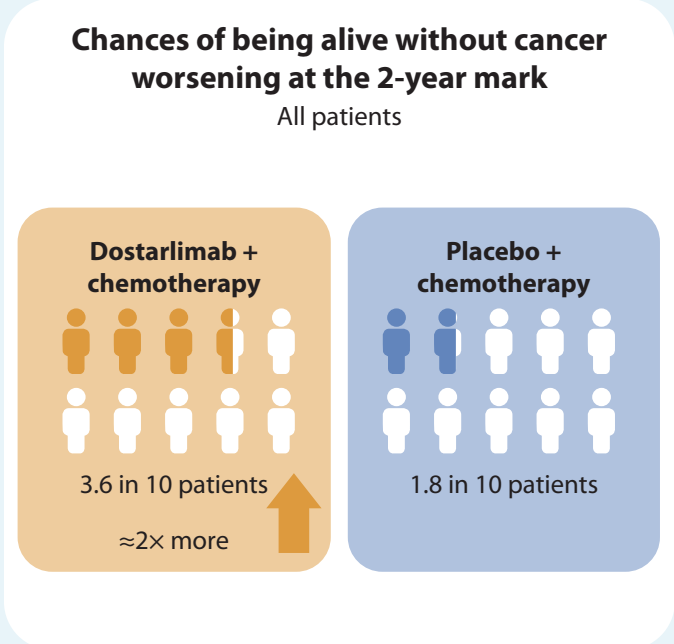
What were the results of the study?

Progression-free survival results: patients who received dostarlimab with chemotherapy were less likely to die or have their cancer come back/get worse than patients who received placebo with chemotherapy.

All patients

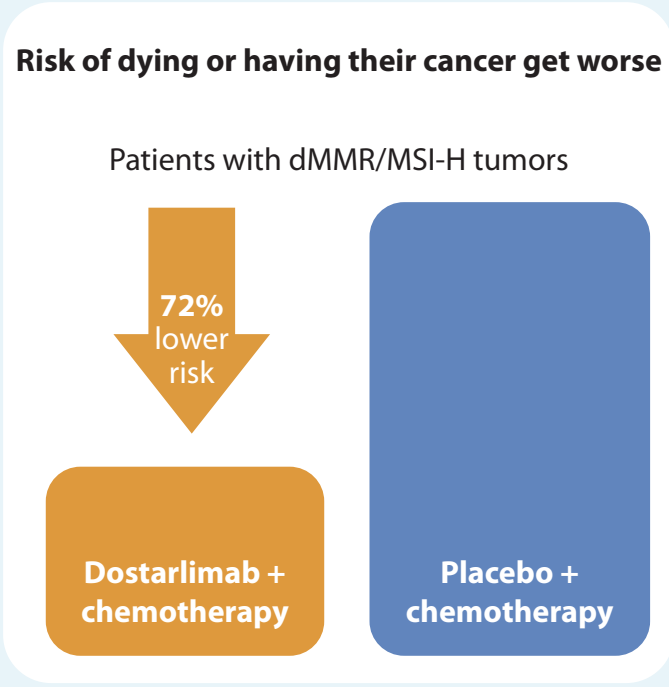
- For all the patients in the RUBY study, the risk of dying or of having their cancer get worse was 36% lower for patients in the dostarlimab group than for patients in the placebo group.
- At 2 years in the study, all patients receiving dostarlimab had about 2 times the likelihood of being alive and having their cancer not get worse: 36% of patients (about 4 in 10 people) from the dostarlimab group versus 18% of patients (about 2 in 10 people) from the placebo group.

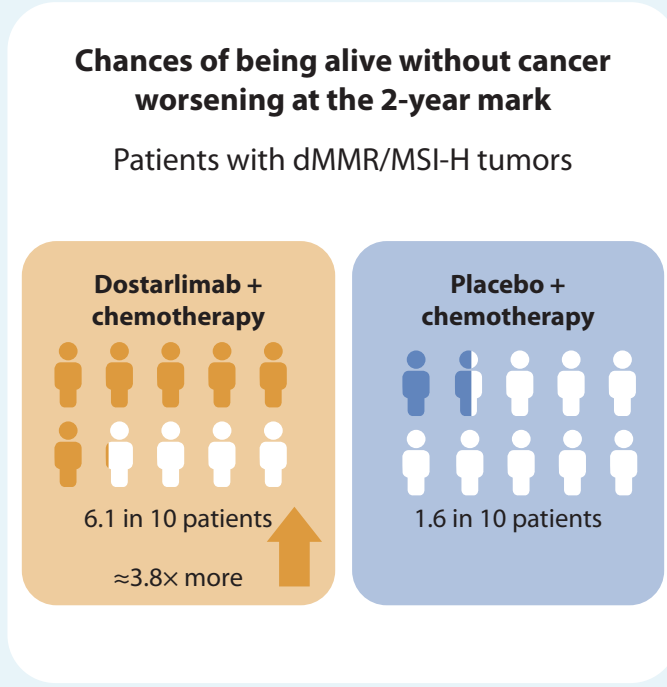




Patients with mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) tumors

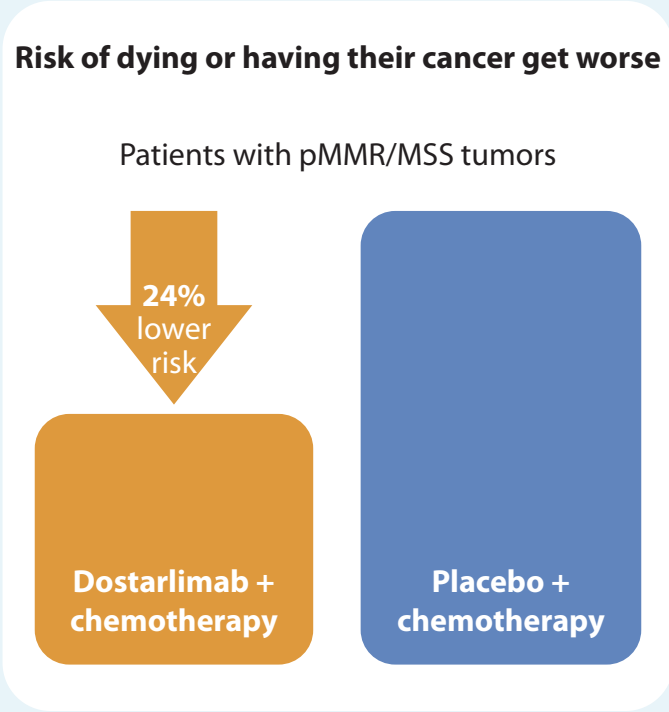
- For patients with dMMR/MSI-H endometrial cancer, the risk of dying or of having their cancer get worse was 72% lower for those patients in the dostarlimab group than for those patients in the placebo group.
- At 2 years in the study, patients with dMMR/MSI-H tumors receiving dostarlimab had about 3.8-times the likelihood of being alive and having their cancer not get worse: 61% of patients (about 6 in 10 people) from the dostarlimab group and 16% of patients (about 2 in 10 people) from the placebo group.

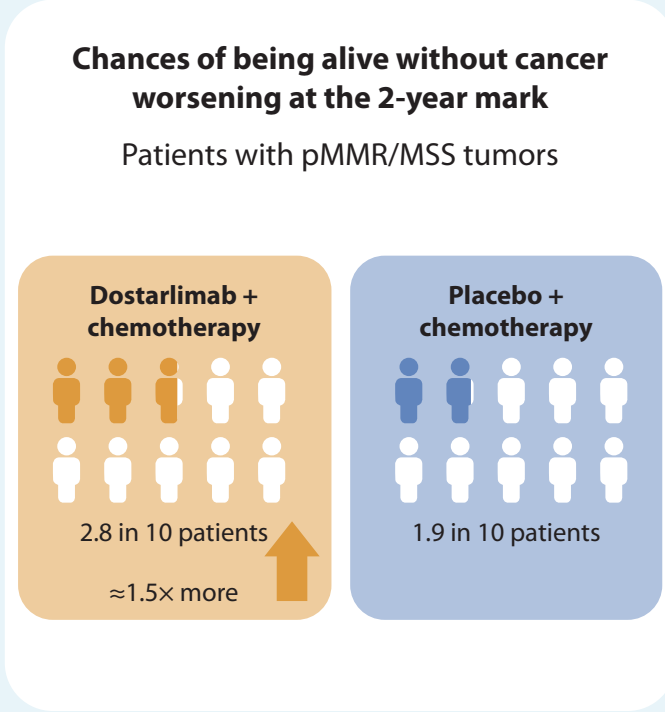




Patients with mismatch repair proficient/microsatellite stable (pMMR/MSS) tumors

- For patients with pMMR/MSS endometrial cancer, the risk of dying or of having their cancer get worse was 24% lower for those patients in the dostarlimab group than for those patients in the placebo group.
- At 2 years in the study, patients with pMMR/MSS tumors receiving dostarlimab had about 1.5 times the likelihood of being alive and having their cancer not get worse: 28% of patients (about 3 in 10 people) from the dostarlimab group and 19% of patients (about 2 in 10 people) from the placebo group.

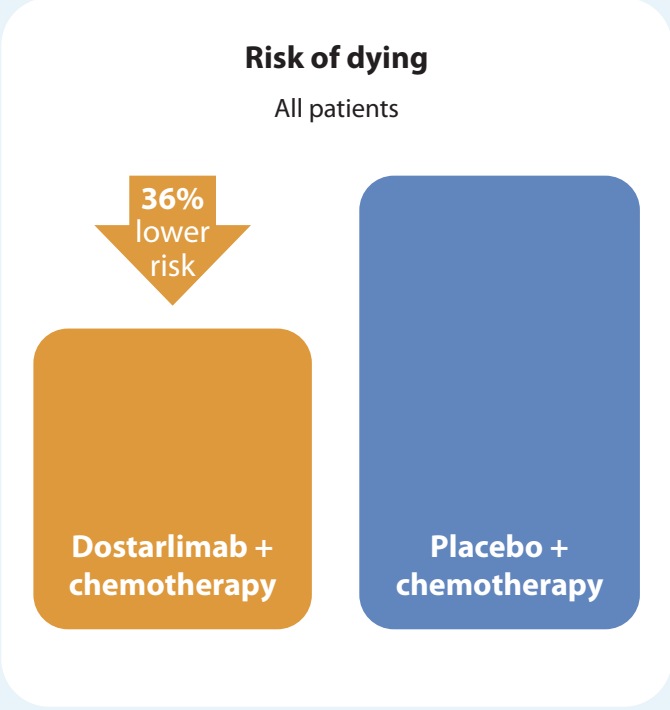


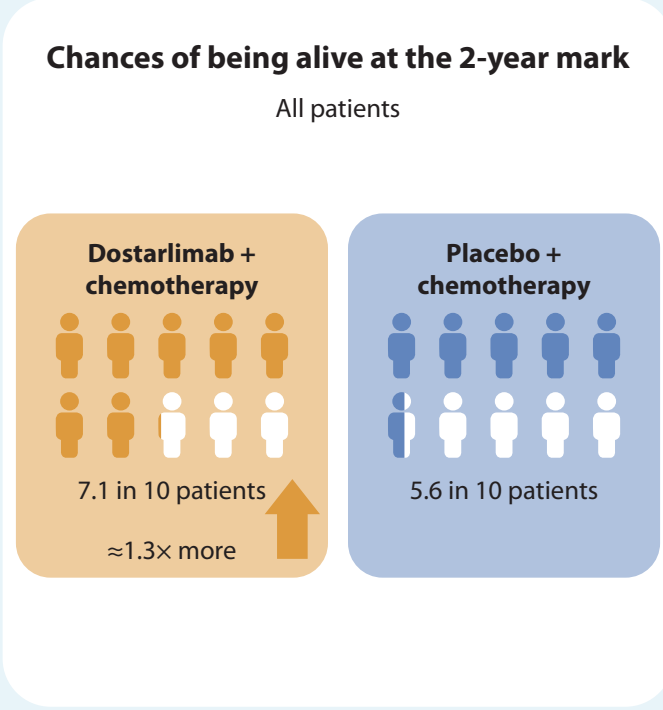


Overall survival results: researchers looked at how long patients lived when they receive dostarlimab in combination with chemotherapy compared to when patients receive chemotherapy alone. The final results will come at a later date, but some early information on how long patients lived showed that patients who received dostarlimab with chemotherapy may survive longer than patients who received placebo with chemotherapy.

All patients

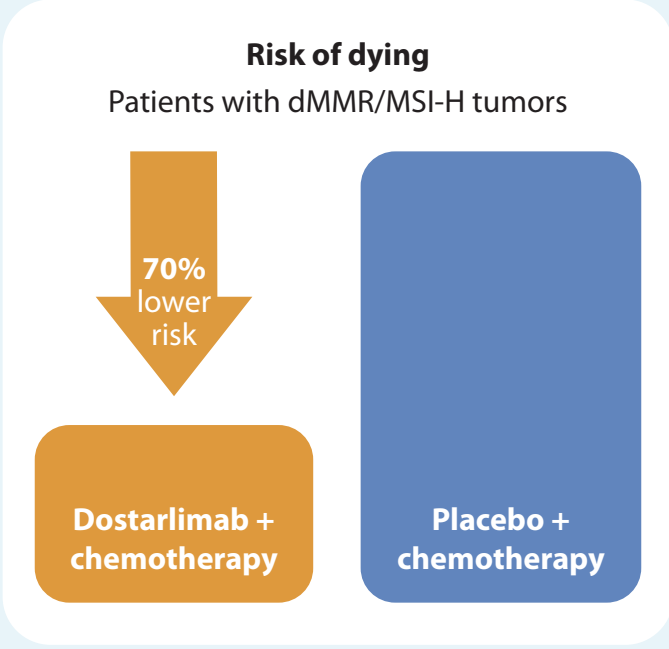
- For all the patients in the RUBY study, the overall risk of dying was 36% lower for patients in the dostarlimab group than for patients in the placebo group.
- At 2 years in the study, all patients receiving dostarlimab had about 1.3 times the likelihood of being alive: 71% of patients (about 7 in 10 people) from the dostarlimab group and 56% of patients (about 6 in 10 people) from the placebo group were expected to be alive.

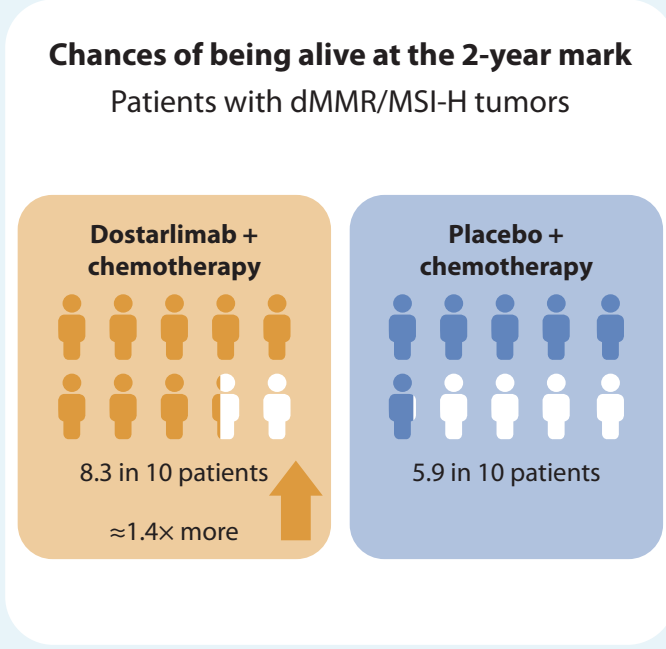




Patients with mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) tumors

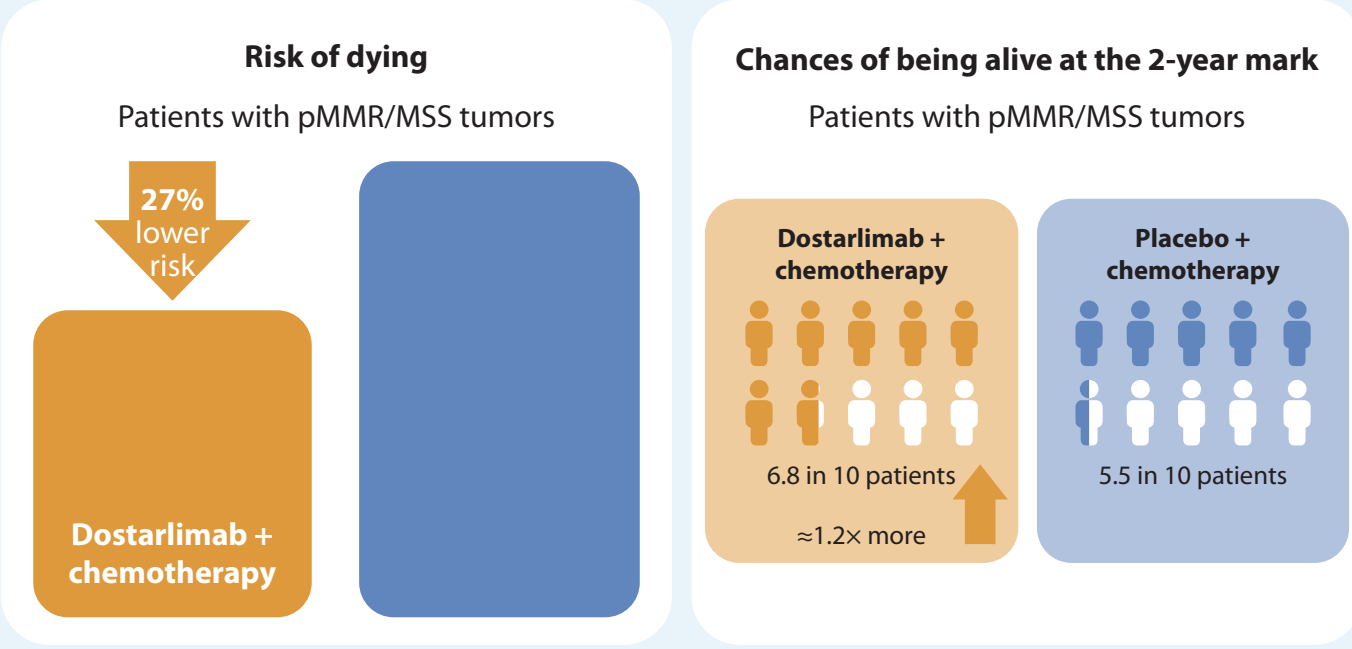
- For patients with dMMR/MSI-H endometrial cancer, the overall risk of dying was 70% lower for patients in the dostarlimab group than for patients in the placebo group.
- At 2 years in the study, patients with dMMR/MSI-H tumors receiving dostarlimab had about 1.4 times the likelihood of being alive: 83% of patients (about 8 in 10 people) from the dostarlimab group and 59% of patients (about 6 in 10 people) from the placebo group were expected to be alive.





Patients with mismatch repair proficient/microsatellite stable (pMMR/MSS) tumors

- For patients with pMMR/MSS endometrial cancer, the overall risk of dying was 27% lower for patients in the dostarlimab group than for patients in the placebo group.
- At 2 years in the study, patients with pMMR/MSS tumors receiving dostarlimab had about 1.2 times the likelihood of being alive: 68% of patients (about 7 in 10 people) from the dostarlimab group and 55% of patients (about 6 in 10 people) from the placebo group were expected to be alive or have tumors that had not gotten worse.



These results show that dostarlimab + chemotherapy was beneficial for all patient populations. It was most beneficial for patients with dMMR/MSI-H endometrial cancer.

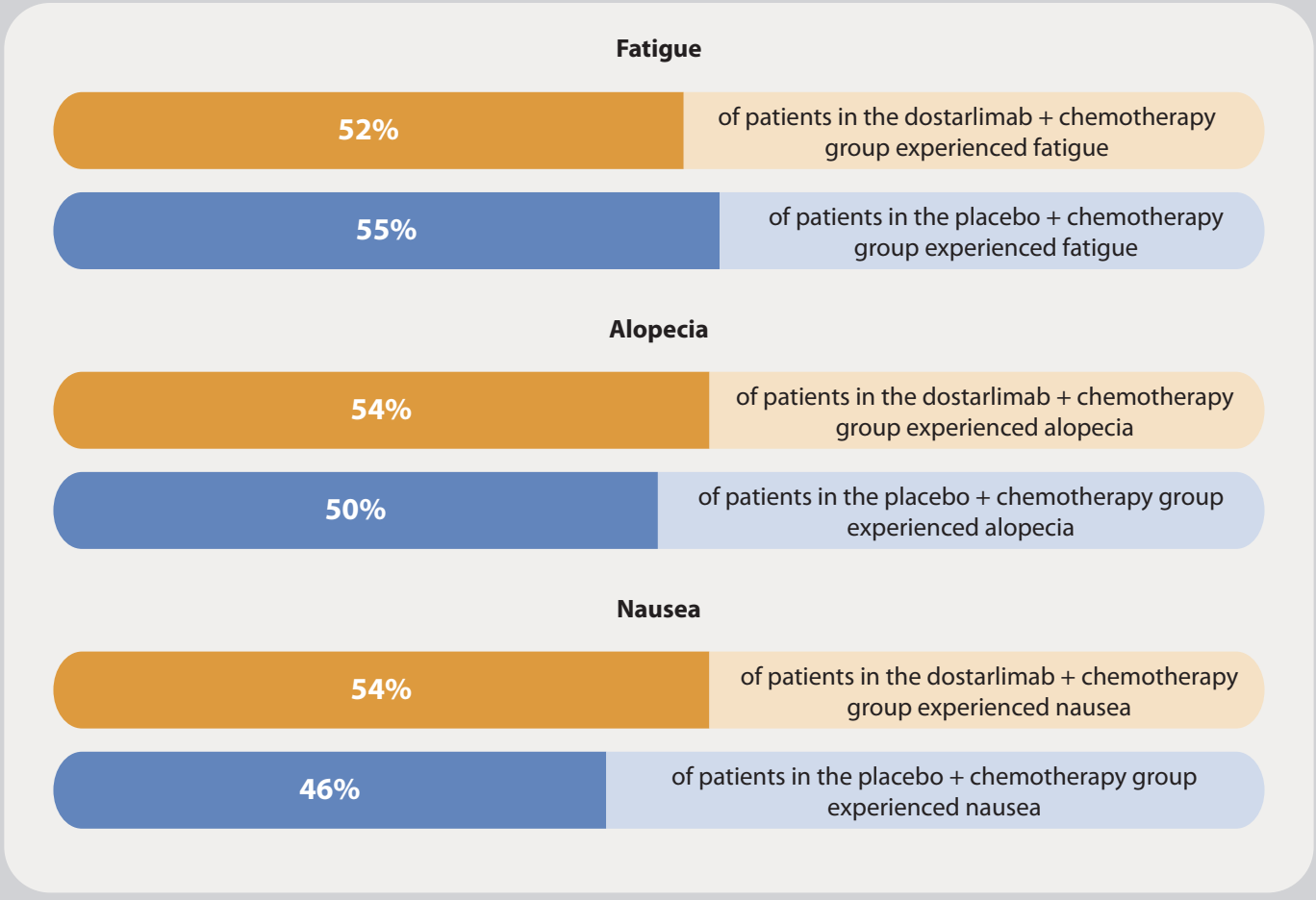
What were the adverse events?

In any clinical study, some patients will experience **adverse events** while being treated. Some adverse events may be directly related to any of the medications patients are receiving during the study, while others are not directly related to the medications but occur at random during the treatment cycles.

The adverse events experienced by patients in the RUBY study safety population were similar to what researchers expected. This is because researchers already knew what adverse events patients could experience when treated with either dostarlimab or chemotherapy alone.

No matter which treatment they received, 100% of patients, or every patient in the RUBY study safety population, experienced at least one adverse event. The most common adverse events that patients experienced while in the RUBY study were fatigue (tiredness), alopecia (hair loss) and nausea.

Adverse event: an undesired effect that happens while receiving treatment. Adverse events can range from mild to severe or even life-threatening (which could potentially lead to death).

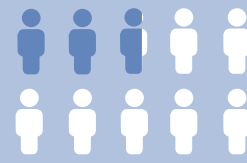


Taylor & Francis
Taylor & Francis Group

More patients receiving dostarlimab plus chemotherapy, as compared to those receiving placebo plus chemotherapy, had adverse events that were serious. This includes adverse events that were life threatening or may have led to death.

38% of patients in the dostarlimab group experienced a serious adverse event

28% of patients in the placebo group experienced a serious adverse event



The 2 types of serious adverse events that occurred most often were pulmonary embolism (a blockage of the blood vessels that send blood to your lungs) and sepsis (an extreme response by the body to an infection that can lead to organ failure or death).

Sepsis

3.3% of patients in the dostarlimab + chemotherapy group experienced serious sepsis

0.4% of patients in the placebo + chemotherapy group experienced serious sepsis

Pulmonary embolism

2.5% of patients in the dostarlimab + chemotherapy group experienced serious pulmonary embolism

2.0% of patients in the placebo + chemotherapy group experienced serious pulmonary embolism

Most patients were able to keep receiving the study medications even if they had an adverse event.

17% of patients in the dostarlimab group stopped treatment with dostarlimab because of an adverse event

9% of patients in the placebo group stopped treatment with placebo because of an adverse event

5 patients who received dostarlimab with chemotherapy died of an adverse event during the treatment-emergent period.
- In 2 of these patients, the adverse event was considered by the researcher to be related to dostarlimab.
  - One patient died of myelosuppression (a decrease in the production of red and white blood cells and platelets) while they were receiving both dostarlimab and chemotherapy. This adverse event was considered by the researcher treating the patient to be related to dostarlimab, carboplatin and paclitaxel.
  - One patient died of hypovolemic shock (severe blood or fluid loss), which was considered to be related to dostarlimab only.
- The other 3 patients had adverse events that were not considered to be related to dostarlimab or chemotherapy (opiate overdose, COVID-19 and general loss of health).

During the chemotherapy treatment period (when patients were receiving dostarlimab plus chemotherapy or placebo plus chemotherapy), patients in both the dostarlimab group and the placebo group reported similar quality of life.

How do these results help patients and physicians?

Dostarlimab given with chemotherapy is an important new treatment option for patients with primary advanced or recurrent endometrial cancer.
- This new treatment option is important because patients with this type of cancer currently do not have many treatment options available.

Patients receiving dostarlimab with chemotherapy had a longer time of being alive without their cancer getting worse or coming back.

In addition, early results of the study showed that patients receiving dostarlimab plus chemotherapy tended to survive longer than those patients receiving chemotherapy alone.
- These results were more obvious in patients with dMMR/MSI-H tumors. However, the combination of dostarlimab with chemotherapy helped more patients stay alive and not have their cancer worsen or return in the overall population, which includes patients with dMMR/MSI-H or pMMR/MSS tumors.

Although all patients in the study had adverse events, they were generally manageable (treatable with medicine and/or study treatment dose interruption or discontinuation), and most patients were able to keep taking study treatments. The adverse events that occurred were expected by researchers for patients taking immunotherapy or chemotherapy.

Patients are still being treated in the RUBY study. Results after a longer treatment period will give physicians and patients additional information on the survival of patients in the study.

Where can I find more information about this study?

The original article described in this summary, 'Dostarlimab for primary advanced or recurrent endometrial cancer', was published in *The New England Journal of Medicine* in 2023.

Mirza MR, Chase DM, Slomovitz BM *et al.* Dostarlimab for primary advanced or recurrent endometrial cancer. *N. Engl. J. Med.* 388(23), 2145–2158 (2023).
- You can read the original, free-to-access, article: https://www.nejm.org/doi/full/10.1056/NEJMoa2216334

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

A recent paper on overall survival in the RUBY trial is also available. Powell MA, Bjorge 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. Onc.* (2024).

- You can read the original, free-to-access, article: https://doi.org/10.1016/j.annonc.2024.05.546

A similar study called GARNET was done to research dostarlimab alone in patients with solid tumors, including advanced or recurrent endometrial cancer.

- You can read more about the GARNET study: https://clinicaltrials.gov/ct2/show/NCT02715284
- A PLSP on the GARNET study is available: https://doi.org/10.2217/fon-2022-1157

Educational resources

Learn more about endometrial cancer at these websites:

- The American Cancer Society: https://www.cancer.org/cancer/types/endometrial-cancer.html
- The European Society for Medical Oncology: https://www.esmo.org/for-patients/patient-guides/endometrial-cancer

General information about this study

The RUBY study is ongoing.

- Study number: NCT03981796
- Study name: ENGOT-EN6-NSGO/GOG-3031/RUBY
- Study sponsor: GSK

Affiliations

[1]Department of Oncology, Rigshospitalet, Copenhagen University Hospital, and Nordic Society of Gynaecological Oncology – Clinical Trial Unit, Copenhagen, Denmark; [2]David Geffen School of Medicine at UCLA, Los Angeles, CA, USA; [3]Department of Gynecologic Oncology, Mount Sinai Medical Center, and the Department of Obstetrics and Gynecology, Florida International University, Miami Beach, FL, USA; [4]Research Unit for General Practice, University of Southern Denmark, Institute of Public Health, Odense, Denmark; [5]Department of Gynecology, Hungarian National Institute of Oncology, Budapest, Hungary; [6]Department of Obstetrics and Gynecology, LSU Health Shreveport, and Willis-Knighton Physician Network, Shreveport, LA, USA; [7]Division of Gynecologic Oncology, McGill University Health Centre, Montreal, Quebec, Canada; [8]Department of Obstetrics/Gynecology, AMITA Adventist Hinsdale Hospital, Hinsdale, IL, USA; [9]University of Torino, AO Ordine Mauriziano, Torino, Italy; [10]Indiana University Health and Simon Cancer Center, Indianapolis, IN, USA; [11]Department of Gynecology and Obstetrics, University Hospital Schleswig-Holstein, Campus Lübeck, Lübeck, Germany; [12]Women and Infants Hospital, Providence, RI, USA; [13]Department of Medical Oncology, Erasmus MC Cancer Centre, Rotterdam, The Netherlands; [14]Oklahoma Cancer Specialists and Research Institute, Tulsa, OK, USA; [15]Tays Cancer Centre and FICAN Mid, Tampere University and Tampere University Hospital, Tampere, Finland; [16]NYU Langone Health, New York, NY, USA; [17]Department of Obstetrics and Gynecology, General University Hospital in Prague, First Faculty of Medicine, Charles University, Prague, Czech Republic; [18]Division of Gynecologic Oncology, Washington University School of Medicine, Washington University in St Louis, St Louis, MO, USA; [19]Gynecological Oncology Unit, Fondazione IRCCS Istituto Nazionale dei Tumori di Milano, University of Milan, Milan, Italy; [20]Hanjani Institute for Gynecologic Oncology, Abington Hospital–Jefferson Health, Asplundh Cancer Pavilion, Sidney Kimmel Medical College of Thomas Jefferson University, Willow Grove, PA, USA; [21]Division of Gynecologic Oncology, Nancy N and JC Lewis Cancer and Research Pavilion, Savannah, GA, USA; [22]HonorHealth Research Institute, University of Arizona College of Medicine, and Creighton University School of Medicine, Phoenix, AZ, USA; [23]Department of Gynecologic Oncology, Arizona Oncology, Tucson, AZ, USA; [24]Department of Obstetrics & Gynecology, University of Cincinnati Cancer Center, Paul and Carolyn Flory, Cincinnati, OH, USA; [25]The Ohio State University Comprehensive Cancer Center, Hillard, OH, USA; [26]GSK, Collegeville, PA, USA; [27]GSK, London, UK; [28]US Oncology Research, The Woodlands, TX, USA; [29]National Cancer Institute sponsored NRG Oncology, Washington University School of Medicine, St Louis, MO, USA

Financial disclosure

All disclosures can be found in the original article. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Competing interests disclosure

Dr Mirza reports consulting or advisory role at AstraZeneca, Biocad, GSK, Karyopharm, Merck, Roche, and Zailab; speakers' bureau fees from AstraZeneca and GSK; research funding (to institution) from Apexigen, AstraZeneca, Deciphera (trial chair), GSK, and Ultimovacs; and personal financial interest in Karyopharm (stocks/shares, member of Board of Directors). Dr Chase reports speakers' bureau fees and/or advisory roles from AstraZeneca, Clovis, Genentech/Roche, and GSK and consulting fees from AstraZeneca, Clovis, Genentech/Roche, and GSK. Dr Slomovitz reports advisory fees from AstraZeneca, Clovis, Eisai, EQRX, Genentech, GOG Foundation, GSK, Incyte, Jazz Pharma, Merck, Myriad, Onconova, Nuvation Bio, and Regeneron; and participation on the Board of Directors for GOG Foundation and HOW: Hearing Ovarian Cancer Whispers. Dr dePont Christensen reports direct consulting payment from Nordic Society of Gynecological Oncology for the RUBY P1 primary manuscript; consulting fees from Karyopharm; payment for advisory board DMC participation from the Swiss GO Trial Group (MATAO trial); and stock options from Y-mAbs Therapeutics. Dr Novak reports honoraria from AstraZeneca, MSD, and Sofmedica; support for attending meetings from PregLem and Sofmedica; participation on a data safety monitoring board or advisory board for AstraZeneca and Richter Gedeon; leadership role as the president of Hungarian Society of Gynecologic Oncology; stock options from Richter Gedeon; and receipt of equipment, materials, drugs, medical writing, gifts, or other services from AstraZeneca. Dr Black reports institutional grant fees from GSK; fees for being a member of GOG Partners Investigational Council; and medical director/owner of Trials365, LLC. Dr Gilbert reports institutional grants from Alkermes, AstraZeneca, Clovis, Esperas, ImmunoGen, IMV, Karyopharm, Merck Sharp & Dohme, Mersana, Novocure GmbH, OncoQuest Pharmaceuticals, Pfizer, Roche, and Tesaro; and consulting fees from Merck; honoraria from Alkermes, AstraZeneca, Eisai, Eisai-Merck, and GSK. Dr Sharma has nothing to disclose. Dr Valabrega reports consulting/advisory fees from Amgen, AstraZeneca, Clovis Oncology, GSK, PharmaMar, Roche, and Tesaro. Dr Landrum has nothing to disclose. Dr Hanker reports consulting/advisory fees from Amgen, AstraZeneca, Clovis, Eisai, GSK, Intuitive Surgery, Janssen, MSD, Novartis, Pfizer, PharmaMar, Roche, and Tesaro. Dr Stuckey reports royalties as an UpToDate reviewer. Dr Boere reports institutional research grant from GSK and institutional advisory board meeting fees from AstraZeneca and GSK. Dr Gold has nothing to disclose. Dr Auranen reports consulting/advisory board fees from GSK and MSD. Dr Pothuri reports institutional grant support from AstraZeneca, Celsion, Clovis Oncology, Eisai, Genentech/Roche, GSK, I-Mab, Incyte, Karyopharm, Merck, Mersana, Sutro, and Toray; consulting fees from AstraZeneca, GSK, Merck, and Seagen; support for attending meetings from GOG Partners; and advisory board fees from Arquer Diagnostics, Atossa, Deciphera, Eisai, Elevar Therapeutics, GOG Foundation, I-Mab, Lily, Merck, Mersana, Sutro Biopharma, Tesaro/GSK, Toray, and VBL Therapeutic. Dr Cibula has nothing to declare. Dr McCourt reports personal royalties <$200 annually from UpToDate and personal honoraria of $200 from the Washington University OB/Gyn annual symposium. Dr Raspagliesi reports institutional grants or contracts from AstraZeneca; honoraria from GSK and MSD; travel support from GSK; and advisory board fees from PharmaMar. Dr Shahin reports institutional grants from AstraZeneca, GSK, and Merck; honoraria from AstraZeneca, GSK, Merck, and Seagen; expert testimony fees from Robinson & Havens PSC (Lexington, KY); advisory board fees from Seagen; and board membership for Unite for Her. Dr Gill has nothing to disclose. Dr Monk reports consulting fees from Agenus, Akeso Bio, Amgen, Aravive, Bayer, Elevar, EMD Merck, Genmab/Seagen, GOG Foundation, Gradalis, ImmunoGen, Iovance, Karyopharm, Macrogenics, Mersana, Myriad, Novartis, Novocure, Pfizer, Puma, Regeneron, Sorrento, US Oncology Research, and VBL and speaker's bureau honoraria from AstraZeneca, Clovis, Eisai, Merck, Roche/Genentech, and Tesaro/GSK. Dr Buscema has nothing to disclose. Dr Herzog reports personal consulting fees from AstraZeneca, Caris, Clovis, Eisai, Epsilogen, Genentech, GSK, Immunogen, J&J, Merck, Mersana, and Seagen; participation on a data safety monitoring board or advisory board from Corcept; and leadership role on the GOG Foundation board. Dr Copeland reports institutional research funding from AbbVie, Advaxis, Agenus, Ajinomoto, Arcus Biosciences, Array BioPharma, AstraZeneca, BeiGene USA, BMS, Cerulean Pharma, Clovis Oncology, Deciphera Pharma, Eisai, EMD Serano, ERGOMED Clinical Research, Exelixis, Genentech/Roche, Genmab, GSK, Hoffman-LaRoche, Immunogen, Incyte Corp, Iovance Biotherapeutics, InVentiv Health Clinical, Jansen R&D, Karyopharm, Leap Therapeutics, Ludwig Institute of Pharmaceuticals, Merck, Mersana Therapeutics, Novocure, OncoQuest, OvaGene, Pfizer, PharmaMar USA, PRA International, Precision Therapeutics, Regeneron, Sanofi, Seattle Genetics, Serono, Stemcentrx, Sumitomo Dainippon Pharma Oncology, Sutro Biopharma, Tesaro (GSK), TRACON Pharmaceuticals, and Verastem; personal advisory board fees from A28 Therapeutics, Celsion Corporation, Corcept Therapeutics, Elevar Therapeutics, GSK, Immunogen, InxMed, Luzsana Biotechnology, Myriad Genetics, Onconova, Rubius Therapeutics, Sorrento Therapeutics, Toray Industries, and VBL Therapeutics; and member of the DMCC for Corcept Therapeutics. Drs. Tian, He, Stevens, and Zografos are employees of GSK. Dr Coleman reports grants or contracts from AstraZeneca, Clovis, Genelux, Genmab, Immunogen, Merck, and Roche/Genentech; consulting fees from AbbVie, Agenus, Alkermes, AstraZeneca, Clovis, Deciphera, Genelux, Genmab, GSK, Immunogen, Merck, Novocure, OncoQuest, OncXerna, Regeneron, and Roche/Genentech; honoraria from AstraZeneca, Clovis, Merck, and Roche/Genentech; and participation on a data safety monitoring board or advisory board from Eisai/BMS and VBL Therapeutics. Dr Powell reports consulting fees from AstraZeneca, Clovis Oncology, Eisai, GSK, Merck, Seagen, and Tesaro. The authors have no other competing interests or relevant affiliations with any organization or entity with the subject matter or materials discussed in the manuscript apart from those disclosed.

Writing support

Writing and editorial support for this plain language summary was provided by Shannon Morgan-Pelosi, PhD, CMPP, and Jennifer Robertson, PhD, CMPP, of Ashfield MedComms, an Inizio company, and funded by GSK.

Open access