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Plain Language Summary of Publication

Future ONCOLOGY

# Plain language summary of results from the DUO-E study: durvalumab given with or without olaparib in patients with advanced endometrial cancer

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Author affiliations can be found at the end of this article.

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

This summary is based on the article 'Durvalumab plus carboplatin/paclitaxel followed by maintenance durvalumab with or without olaparib as first-line treatment for advanced endometrial cancer: the phase III DUO-E trial' which can be read for free at: https://ascopubs.org/doi/10.1200/JCO.23.02132

## Summary

**How to say** (download PDF and double click sound icon to play sound)...

- **Carboplatin:** CAR-bo-PLA-tin
- **Durvalumab:** dur-VAL-yoo-mab
- **Olaparib:** oh-LA-puh-rib
- **Paclitaxel:** pac-lih-TAX-uhl

### What is this summary about?

There are only a few current treatment options for people with newly diagnosed advanced or recurrent endometrial cancer (cancer that has returned). The DUO-E study is testing an immunotherapy, durvalumab, and a targeted therapy, olaparib, in people with newly diagnosed advanced endometrial cancer or recurrent endometrial cancer. Durvalumab blocks the activity of a protein called PD-L1 (programmed death-ligand 1). This makes cancer cells more susceptible to being killed by immune cells. Olaparib inhibits a protein called PARP (poly [ADP-ribose] polymerase), thereby stopping cancer cells from being able to repair their DNA. This can cause cancer cells to die or make them more visible to the immune system.

Mismatch repair (MMR) is a DNA repair mechanism, and patients with endometrial cancer can be defined as having tumors that are able to carry out mismatch repair (mismatch repair proficient [pMMR]) or are not able to carry out mismatch repair (mismatch repair deficient [dMMR]). DUO-E enrolled people with either mismatch repair proficient (pMMR) or mismatch repair deficient (dMMR) tumors. DUO-E investigated whether chemotherapy + durvalumab followed by either durvalumab or durvalumab + olaparib can improve outcomes compared with chemotherapy alone.

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**What are the key takeaways?**
For all the people in DUO-E, the risk of disease progression (the cancer growing, spreading, or getting worse) or death was reduced with chemotherapy + durvalumab followed by either durvalumab or durvalumab + olaparib, compared with chemotherapy alone. In terms of reducing the risk of disease progression or death, the greatest benefit for chemotherapy + durvalumab compared with chemotherapy alone was seen in people with tumors that were mismatch repair deficient (dMMR); for people with tumors that were mismatch repair proficient (pMMR), the addition of olaparib further enhanced the benefit seen with durvalumab. Side effects of the treatments were manageable and generally consistent with the known side effects of the drugs when used alone.

**What were the main conclusions reported by the researchers?**
Chemotherapy + durvalumab followed by either durvalumab or durvalumab + olaparib represent new treatment options for people with newly diagnosed advanced or recurrent endometrial cancer.

## What is the purpose of this plain language summary?

The purpose of this plain language summary is to help you to understand the findings from recent research. IMFINZI® (durvalumab) and LYNPARZA® (olaparib) are used 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.

**Approval:** Approval of a medicine means that health authorities (such as the Food and Drug Administration in the USA and the European Medicines Agency in Europe) have checked and confirmed that a medicine is well tolerated by people treated with it and works well for its intended use.

## Who is this article for?

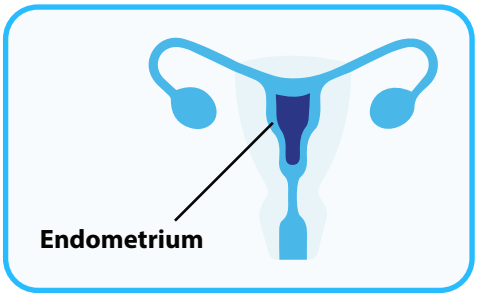
This summary may be helpful for people with endometrial cancer and their families, as well as patient advocates, caregivers, healthcare professionals, or anyone who wants to learn more about new treatments for endometrial cancer.

## Who sponsored this study?

This study was **sponsored** by AstraZeneca.

**Sponsor:** A company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information from the study.

## What is endometrial cancer?




Endometrial cancer is one of the most common cancers among women worldwide.

Endometrial cancer occurs when cells grow and multiply too much in the lining of the womb (known as the endometrium), causing a growth called a malignant tumor.

Most people are diagnosed with early-stage disease, but some people are diagnosed with advanced disease (cancer that has spread beyond the endometrium).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## How is endometrial cancer treated?

Early-stage endometrial cancer is initially treated by hysterectomy (surgical removal of the uterus) to try and remove all trace of the tumor.

For more advanced disease, chemotherapy (with or without surgery) and radiotherapy have been the standard treatments for a long time.

Chemotherapy is a treatment that targets and kills rapidly dividing cells, such as cancer cells. The recommended standard chemotherapy treatment for people with endometrial cancer is carboplatin and paclitaxel.

Despite receiving chemotherapy, cancer can worsen after treatment.

New treatment options are emerging, and immunotherapies (such as durvalumab) that stimulate the body's immune system to fight cancer cells are being introduced in combination with chemotherapy for some advanced endometrial cancers. However, treatment options remain limited.

## Which drugs were tested in this study?

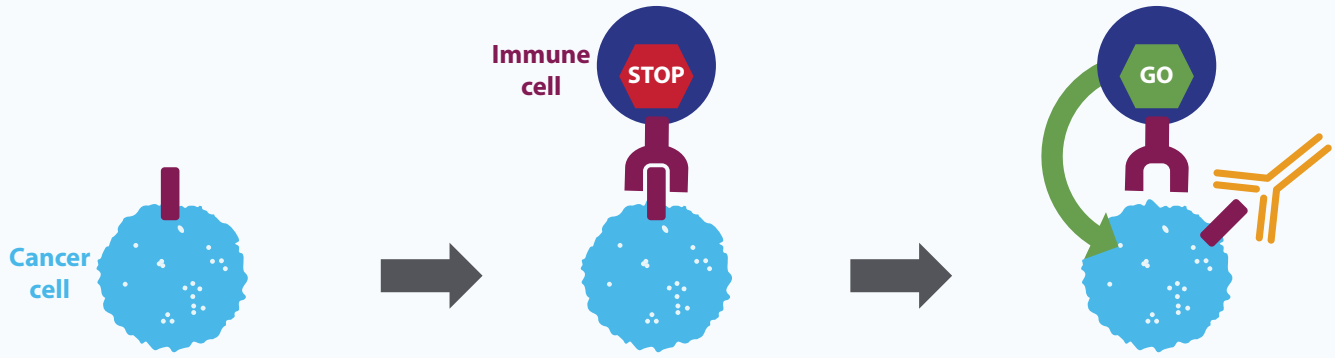
The DUO-E clinical study tested the addition of durvalumab (an immunotherapy) to chemotherapy followed by durvalumab either with or without olaparib (a targeted therapy).

Durvalumab works by blocking the activity of a protein called PD-L1 (programmed death-ligand 1). PD-L1 makes immune cells (cells that circulate around the body to fight infections and cancers) less active. Therefore, blocking PD-L1 makes them more active and helps them to kill cancer cells.

Olaparib works by inhibiting PARP (poly[ADP-ribose] polymerase) protein activity.

Inhibiting PARP stops cancer cells from being able to efficiently repair single-strand DNA breaks. This leads to an increase in damaged DNA, which can result in cancer cell death, or an immune response against cancer cells. This approach works particularly well in tumors with mutations or defects in DNA repair mechanisms (e.g., breast cancer [BRCA] genes or homologous recombination repair).

**How does durvalumab (an immunotherapy) work?**




**PD-L1 (programmed death-ligand 1)** is a protein present on the surface of some cancer cells

Immune cells circulate around the body to fight infections and cancers

**PD-L1** makes immune cells less active, so they are less likely to attack cancer cells

**Durvalumab** blocks **PD-L1** which makes cancer cells more susceptible to being killed by immune cells

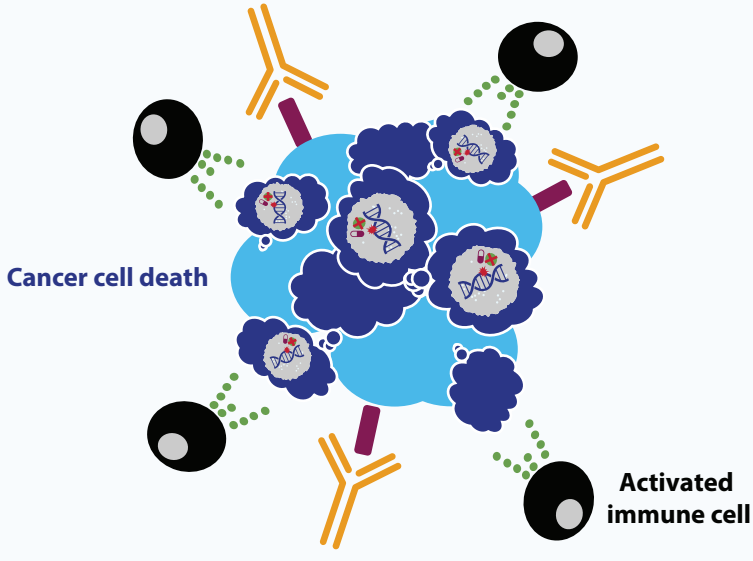
**How does olaparib (a targeted therapy) work?**


DNA is damaged in some cancer cells

**PARP (poly[ADP-ribose] polymerase)** helps to repair damaged DNA in cancer cells so they can survive

**Olaparib** prevents **PARP** from repairing DNA damage, which can cause cancer cells to die, or promote immune responses against cancer cells

**How do durvalumab and olaparib work together?**




**Durvalumab** makes cancer cells more likely to be killed by immune cells

**Olaparib** stops cancer cells repairing DNA damage, resulting in direct cancer cell death and/or the promotion of immune responses against cancer cells

Both effects increase the amount of cancer cell death

**Durvalumab** and **olaparib** can also work together, with **olaparib** promoting an immune response against cancer cells and **durvalumab** preventing that immune response from being shut down by **PD-L1**

## What did the DUO-E study investigate?

DUO-E, a phase III, three-arm randomized study, tested the effectiveness and safety of chemotherapy + durvalumab followed by either durvalumab or durvalumab + olaparib compared with chemotherapy alone followed by **placebo** in people with advanced or recurrent endometrial cancer.

**Placebo:** A placebo is an inactive substance that looks the same and is given in the same way as the active treatment being tested.

Patients were randomized to 3 treatment groups for comparison:

- Chemotherapy alone.
- Chemotherapy + durvalumab, followed by durvalumab (immunotherapy).
- Chemotherapy + durvalumab, followed by durvalumab (immunotherapy) + olaparib (targeted therapy).

DUO-E looked at how well these combinations work at reducing the risk of disease progression (the cancer growing, spreading, or getting worse) or death. This is studied by using an outcome called progression-free survival (PFS), which is a measure of how long women lived without their cancer growing, spreading or getting worse. Any side effects that may occur were also studied.

## Who took part in the DUO-E study?

To take part in DUO-E, people had to have:

- Newly diagnosed advanced endometrial cancer or recurrent endometrial cancer (cancer that has returned) that could be measured at the start of the study and was either stage III (cancer that has spread to nearby tissues) or stage IV (cancer that has spread to other parts of the body).
- No prior treatment with a PARP inhibitor (targeted therapy) or immunotherapy.
- Known mismatch repair (MMR) status (tested in a tumor sample taken during surgery or a biopsy).

## MMR status as a biomarker in the DUO-E study for endometrial cancer

A biomarker is a measurable feature that can provide information about a disease, for example, how it will develop, or how likely it will be to respond to therapy.

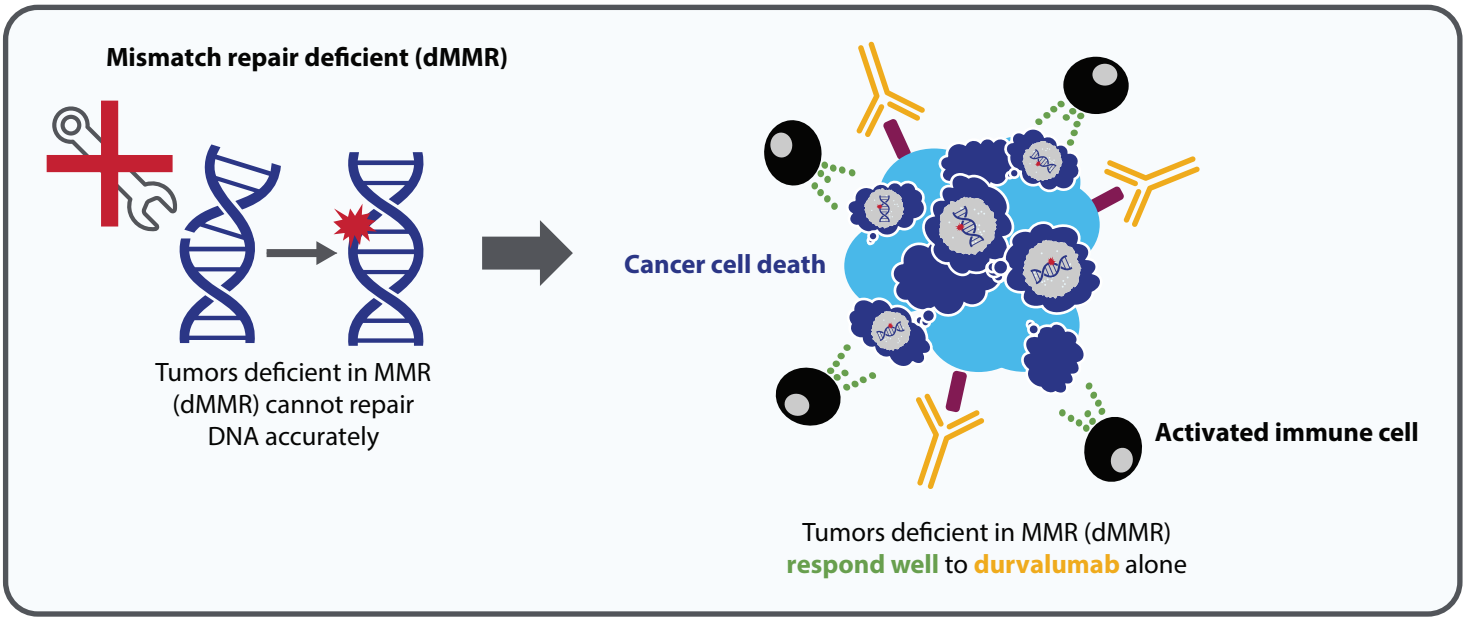
### MMR

Mismatch repair, or MMR, is a DNA repair mechanism. In endometrial cancer, MMR status can identify to what extent patients respond to immunotherapy. MMR status also suggests how likely it is that the cancer will get worse or return. MMR status can be determined from a tumor sample during surgery or a biopsy.

### dMMR

About 1 out of 4 people with endometrial cancer have tumors that are deficient in MMR (dMMR).

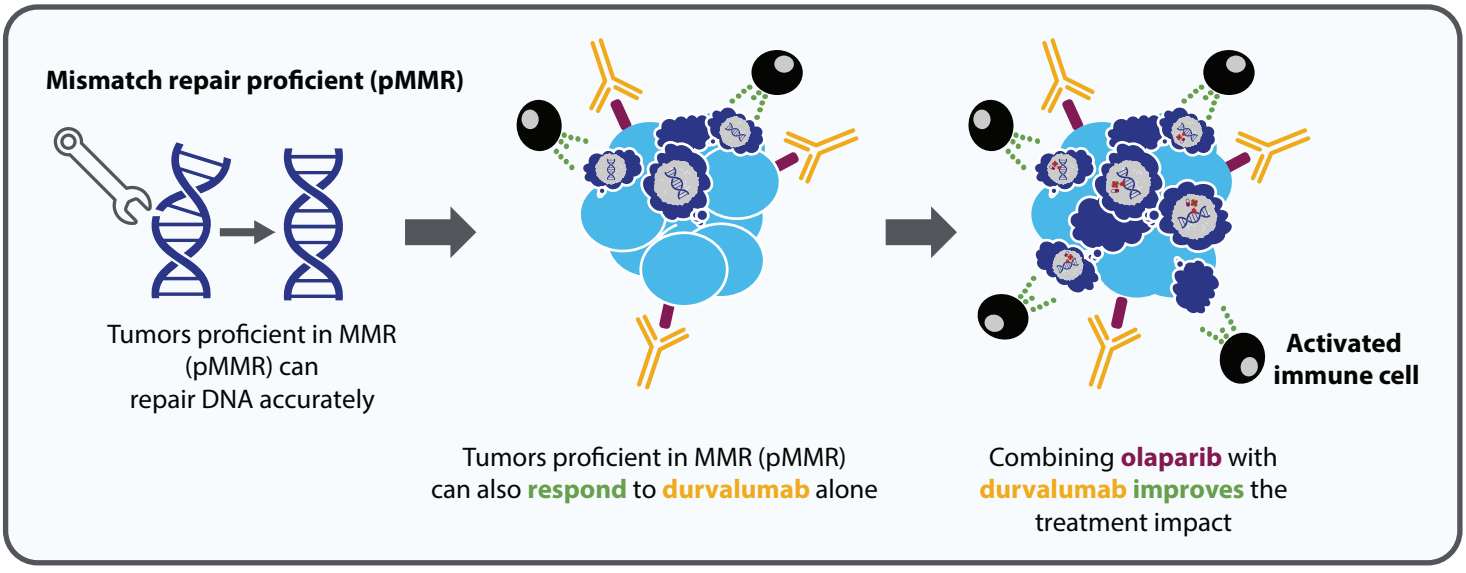
Tumors that are deficient in MMR (dMMR) cannot repair errors that appear in DNA effectively, resulting in the accumulation of mistakes. These mistakes in DNA make the tumor more visible to the immune system and easier to target. dMMR tumors in endometrial cancer generally have better responses to immunotherapies such as durvalumab.




**pMMR**

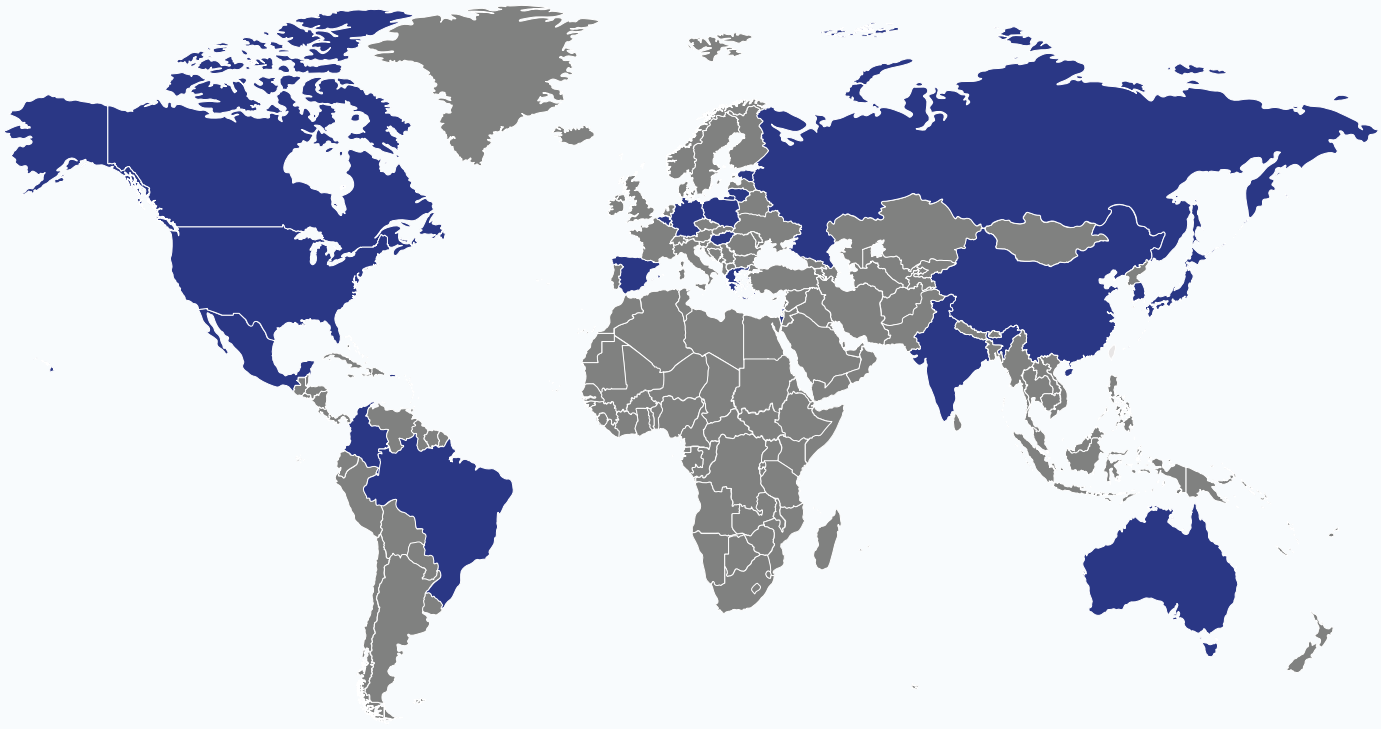
About 3 out of 4 people with endometrial cancer have tumors proficient in MMR (pMMR). Available treatments are not as effective in people with tumors proficient in MMR (pMMR) compared with people with tumors deficient in MMR (dMMR). Therefore, there is a need for new treatment options.

Tumors that are proficient in MMR (pMMR) can repair DNA accurately, which makes them look more like healthy cells, and therefore they are more likely to be ignored by the immune system. They also have a more diverse set of biological features, which makes them harder to treat with only one therapy. Combining olaparib with durvalumab improves the treatment impact.



The DUO-E study included 718 people from 22 countries worldwide.

These 718 people were randomly assigned to one of three treatment arms. Neither the participant nor their doctor knew which treatment they were taking.



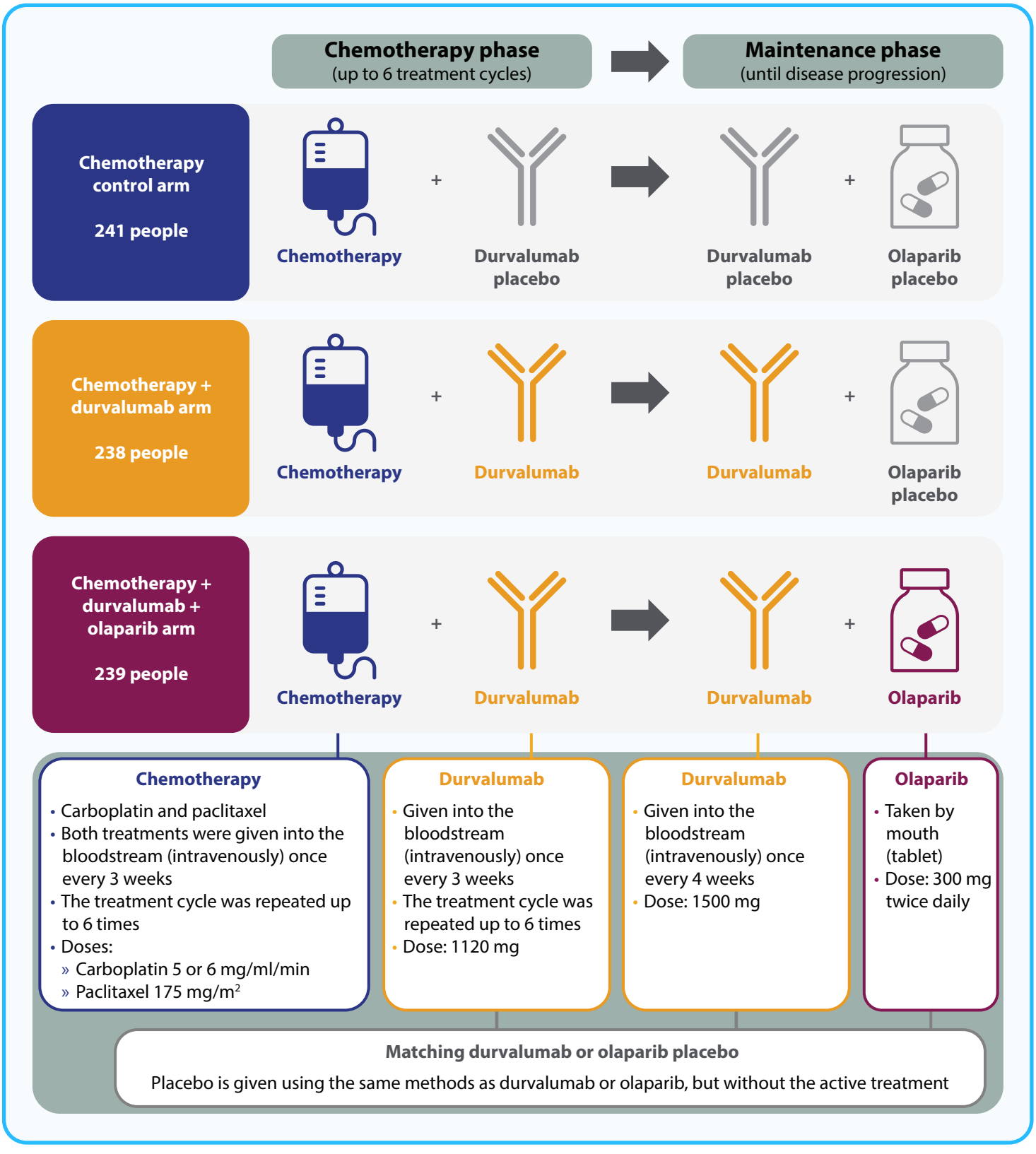
Countries with study sites: Australia, Belgium, Brazil, Canada, China, Colombia, Estonia, Germany, Greece, Hong Kong, Hungary, India, Israel, Japan, Lithuania, Mexico, Poland, Republic of Korea, Russia, Singapore, Spain and the United States of America

## How were the treatments given in DUO-E?

DUO-E had two phases of treatment and three treatment arms:

- The chemotherapy phase. During this, people received initial (first-line) chemotherapy with placebo (control) or durvalumab.
- The maintenance phase. This is the period after the chemotherapy phase had finished, when treatment continued to help prevent the cancer from coming back or worsening. During this, people continued to receive placebo (control) or durvalumab either with or without olaparib added as a maintenance therapy.

Treatment continued until the cancer grew, spread, or got worse (disease progression), or until people experienced unmanageable side effects.


Chemotherapy phase
(up to 6 treatment cycles)
Maintenance phase
(until disease progression)
Chemotherapy control arm
241 people
Chemotherapy
Durvalumab placebo
Durvalumab placebo
Olaparib placebo
Chemotherapy + durvalumab arm
238 people
Chemotherapy
Durvalumab
Durvalumab
Olaparib placebo
Chemotherapy + durvalumab + olaparib arm
239 people
Chemotherapy
Durvalumab
Durvalumab
Olaparib
Chemotherapy
• Carboplatin and paclitaxel
• Both treatments were given into the bloodstream (intravenously) once every 3 weeks
• The treatment cycle was repeated up to 6 times
• Doses:
» Carboplatin 5 or 6 mg/ml/min
» Paclitaxel 175 mg/m²
Durvalumab
• Given into the bloodstream (intravenously) once every 3 weeks
• The treatment cycle was repeated up to 6 times
• Dose: 1120 mg
Durvalumab
• Given into the bloodstream (intravenously) once every 4 weeks
• Dose: 1500 mg
Olaparib
• Taken by mouth (tablet)
• Dose: 300 mg twice daily
Matching durvalumab or olaparib placebo
Placebo is given using the same methods as durvalumab or olaparib, but without the active treatment

## What were the characteristics of the people in the DUO-E study?

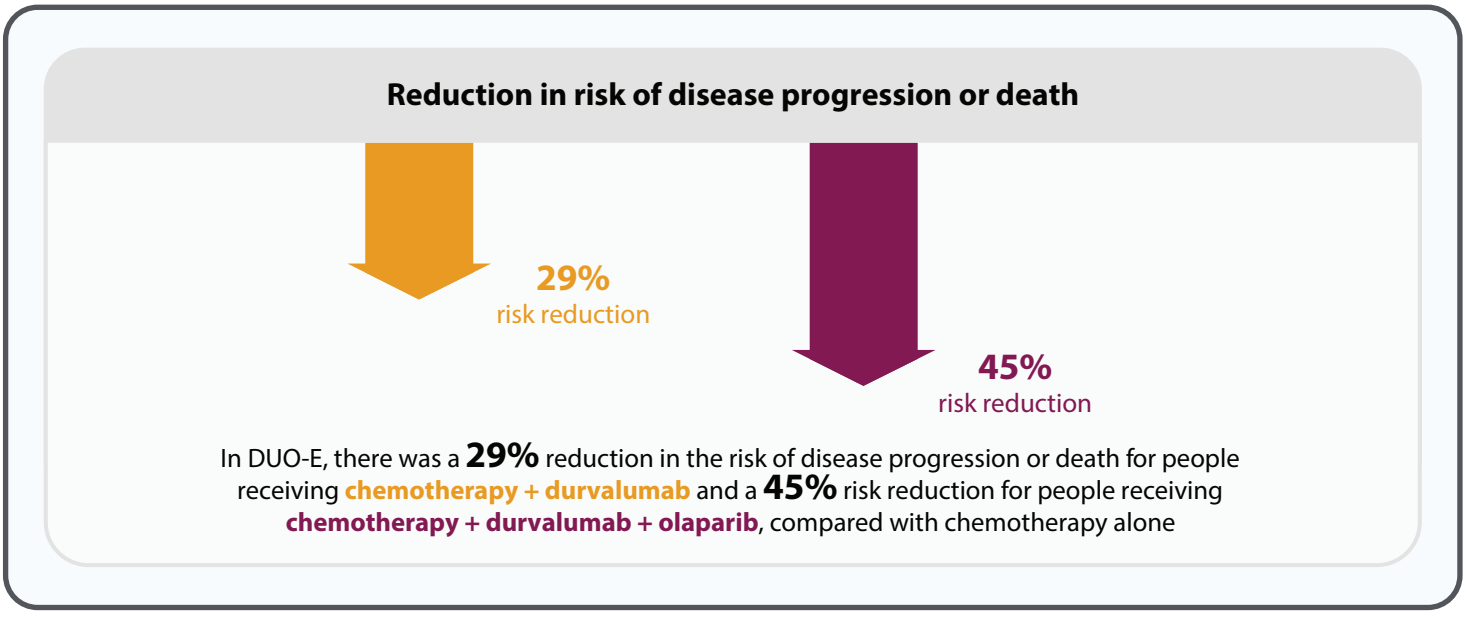
The characteristics of people who took part in DUO-E were similar between the treatment arms. This is important to allow comparison of treatment outcomes between the different arms.

| | Chemotherapy control<br>241 people | Chemotherapy + durvalumab<br>238 people | Chemotherapy + durvalumab + olaparib<br>239 people | |
|---|---|---|---|---|
| Average age (range) | 64 (31–85) | 64 (22–84) | 63 (27–86) | The average age was 64 years Participants were aged 22–86 years old |
| Asia region | 28% | 29% | 28% | Approximately one third of people lived in Asia |
| Newly diagnosed | 48% | 47% | 48% | Approximately half of people were newly diagnosed |
| Newly diagnosed<br>• Stage III disease<br>• Stage IV disease | 5%<br>42% | 7%<br>40% | 5%<br>41% | A small proportion of patients had stage III disease |
| • MMR proficient<br>• MMR deficient | 80%<br>20% | 81%<br>19% | 80%<br>20% | Most people had tumors proficient in MMR |

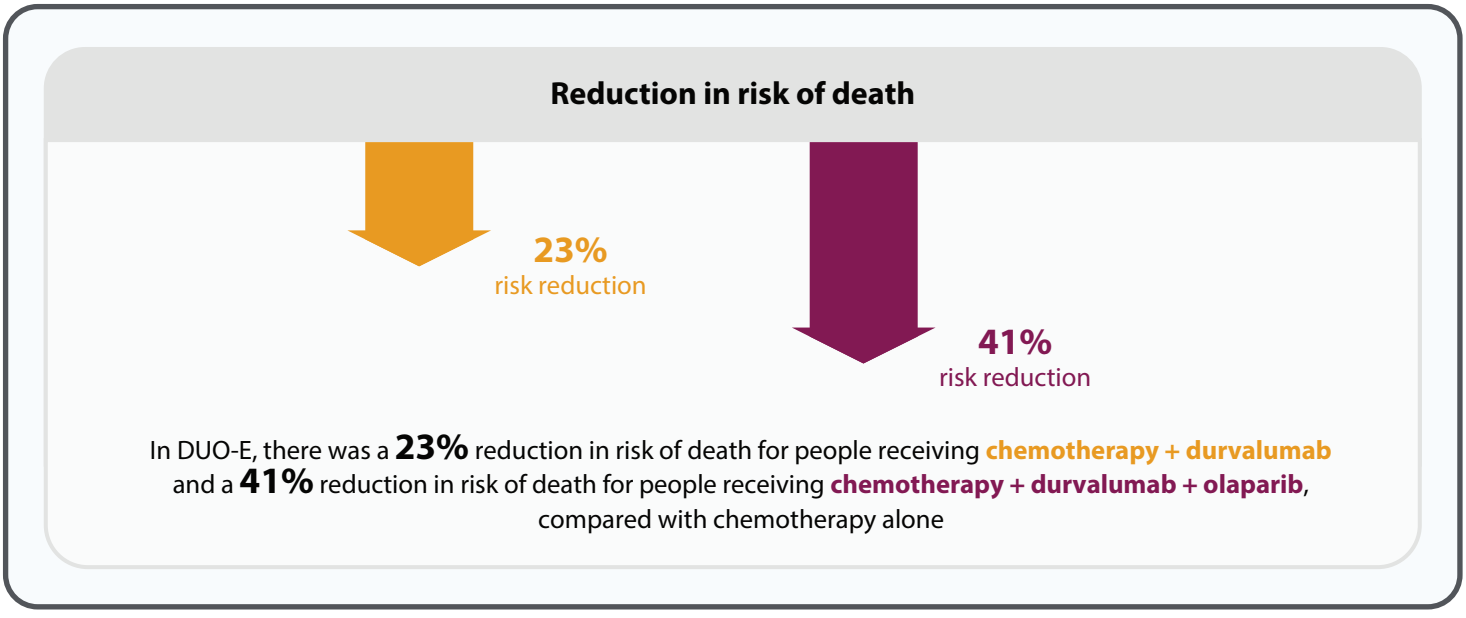
## How effective were the treatments in the DUO-E study?

**What were the overall effectiveness results of the study?**

Overall, the risk of disease progression (the cancer growing, spreading, or getting worse) or death was reduced with both chemotherapy + durvalumab followed by durvalumab, and chemotherapy + durvalumab followed by durvalumab + olaparib, compared with chemotherapy alone.

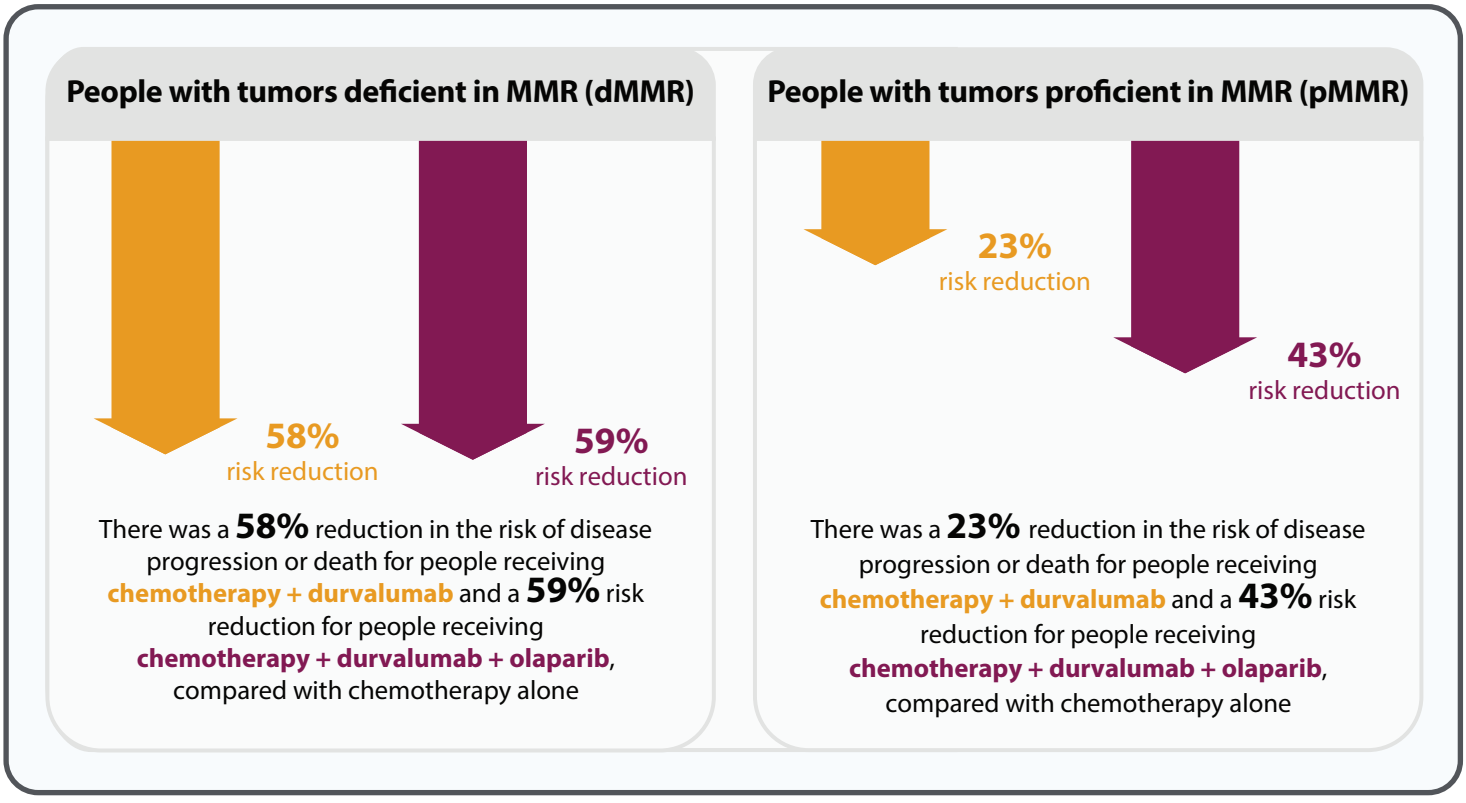



Overall survival (the length of time people were alive after starting treatment) was also tested at this time. Results suggest that the risk of death was reduced with both chemotherapy + durvalumab followed by durvalumab, and chemotherapy + durvalumab followed by durvalumab + olaparib, compared with chemotherapy alone.



**What were the effectiveness results by MMR status?**

For people with tumors deficient in MMR (dMMR), chemotherapy + durvalumab followed by durvalumab and chemotherapy + durvalumab followed by durvalumab + olaparib reduced the risk of disease progression or death by a similar amount compared with chemotherapy alone. For people with tumors that were mismatch repair proficient (pMMR), the benefit of chemotherapy + durvalumab followed by durvalumab was further enhanced with the addition of olaparib.



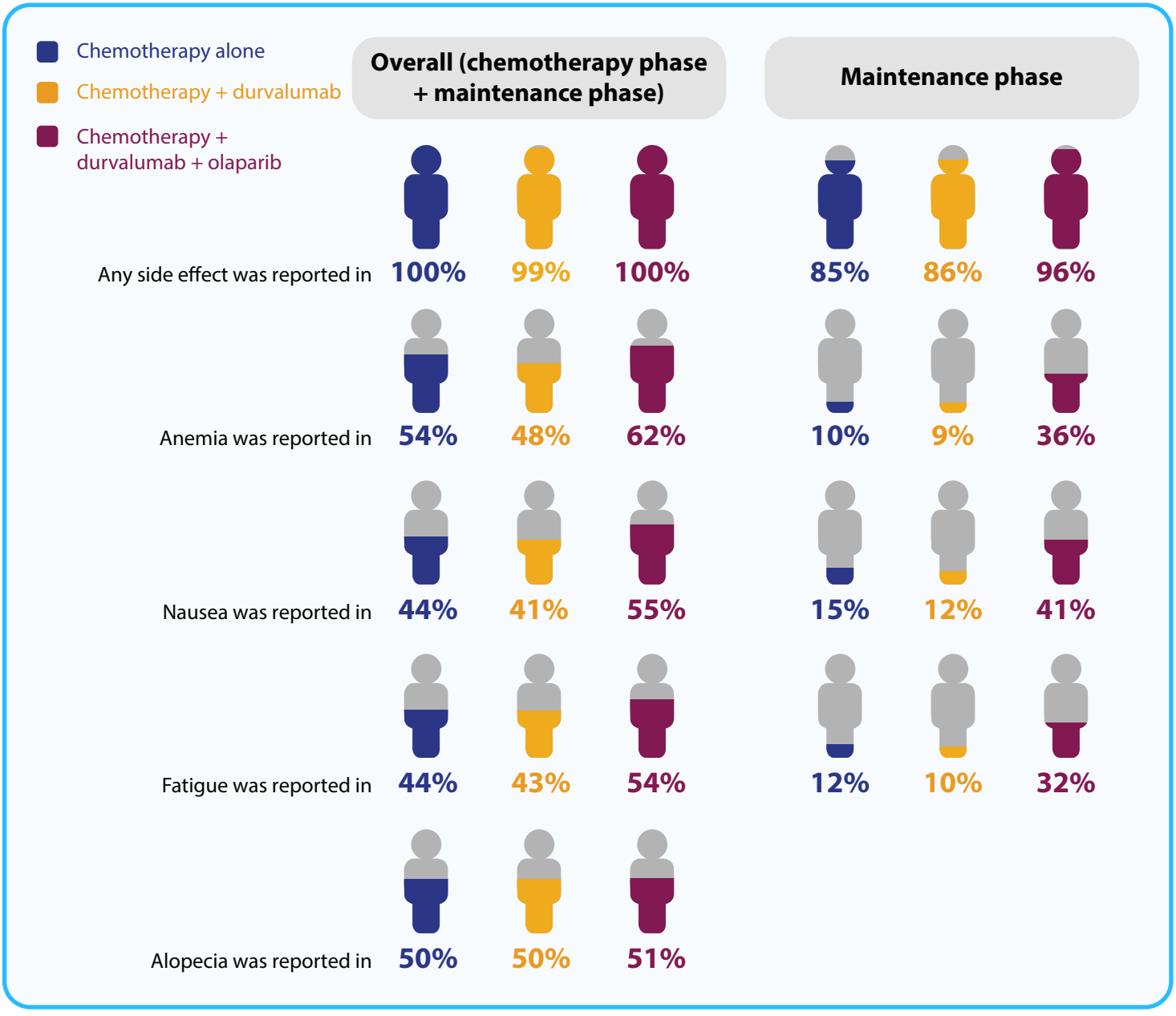

## Which side effects were reported in the DUO-E study?

During the study, side effects that develop after people start treatment are monitored. Side effects may or may not be directly related to the drugs received as part of the study. Side effects can be mild, moderate, severe, or even life-threatening, and may require treatment to manage.

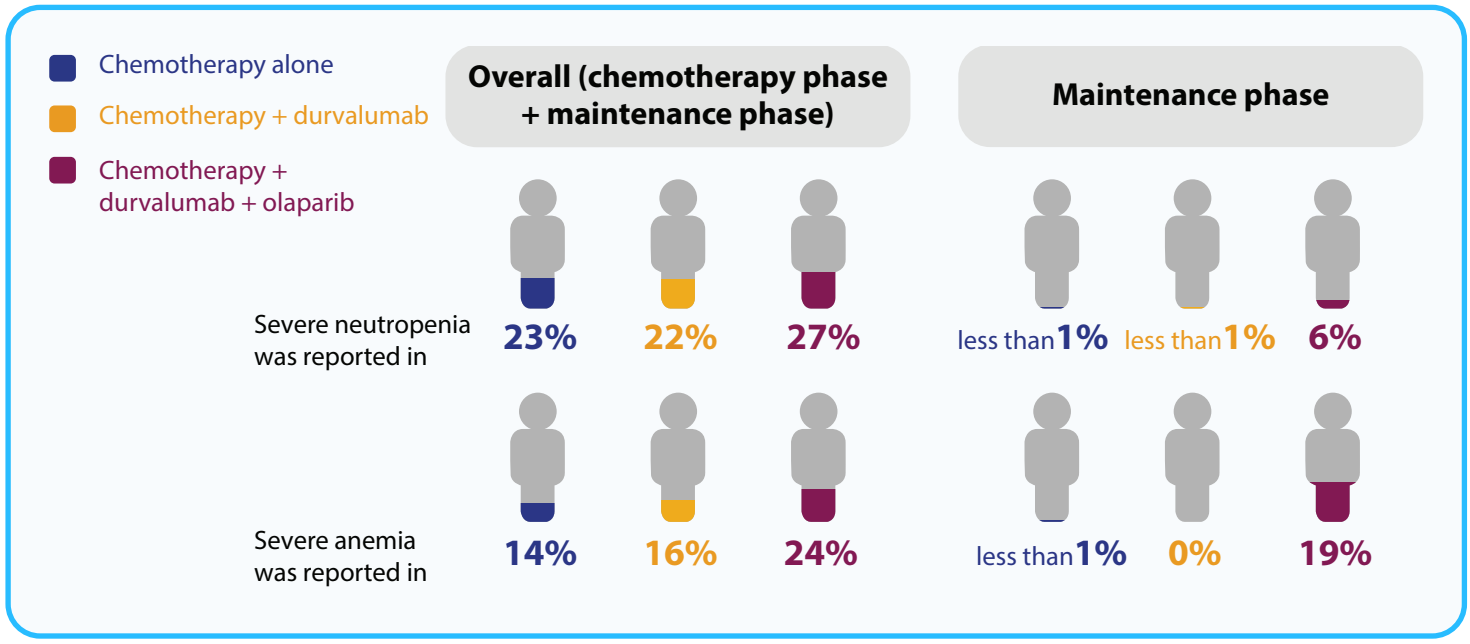
An example of a side effect is a headache (sore head), which can cause discomfort.

Side effects of the treatments were manageable and mostly consistent with the known side effects of the treatments when used alone. Few people stopped their treatments because of side effects.

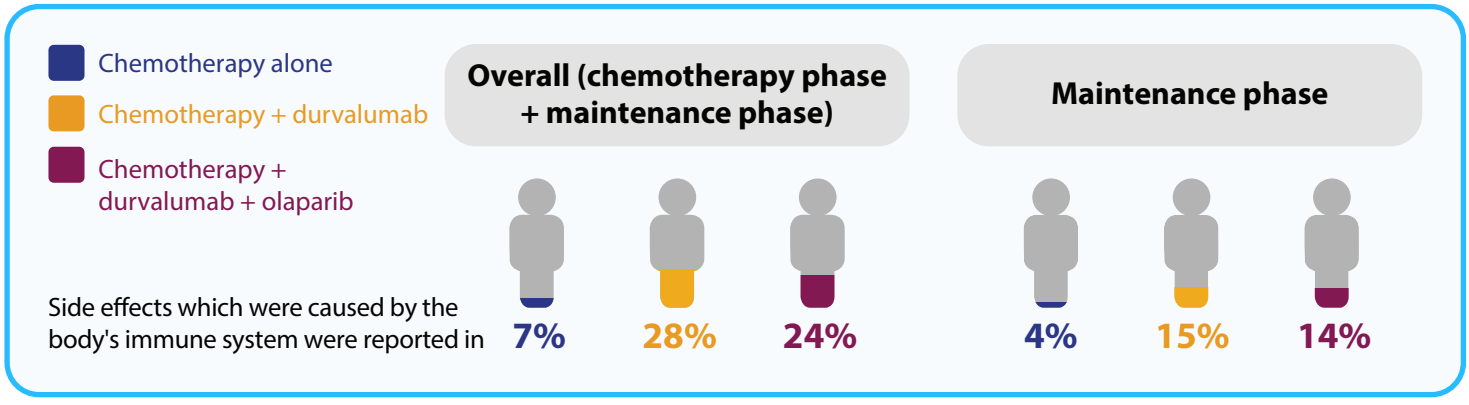
Across the treatment arms the most common side effects overall (during the chemotherapy phase and the maintenance phase) were anemia (abnormally low number of red blood cells, which can cause tiredness), nausea, fatigue (tiredness), and alopecia (hair loss). During the maintenance phase, most side effects were mild. The most common side effects during the maintenance phase were nausea, anemia, and fatigue.



The most common severe side effect (a side effect that caused meaningful harm) was neutropenia, followed by anemia. Neutropenia is abnormally low levels of white blood cells called neutrophils. Neutropenia can make it harder to fight off infection.




Immunotherapies, such as durvalumab, could result in the immune system becoming overactive, causing side effects. As expected with immunotherapies, the proportion of people who experienced a side effect caused by the body's immune system was higher in the chemotherapy + durvalumab and chemotherapy + durvalumab + olaparib treatment arms, compared with chemotherapy alone.




A small number of people who received chemotherapy + durvalumab followed by durvalumab + olaparib had the following severe side effects:

- Three people (1.6%) had pure red cell aplasia (PRCA), which is the failure to produce red blood cells.
- Two people (less than 1%) had autoimmune hemolytic anemia (AIHA), which is the excessive breakdown of red blood cells.

AIHA was also reported in one person (less than 1%) who received chemotherapy + durvalumab followed by durvalumab.

PRCA and AIHA can be associated with symptoms of shortness of breath, fatigue, pale skin, or fast heartbeat.

## Conclusions and key messages

- For all the people in DUO-E, chemotherapy + durvalumab, followed by either durvalumab or durvalumab + olaparib, improved outcomes (reduced the risk of disease progression or death) compared with chemotherapy alone.
- The greatest benefit for chemotherapy + durvalumab compared with chemotherapy alone was seen in people with tumors that were mismatch repair deficient (dMMR); for people with tumors that were mismatch repair proficient (pMMR) the addition of olaparib further enhanced the benefit.
- The study was limited by a small proportion of patients in the study who had stage III disease, which was likely due to the requirement for measurable disease.
- Chemotherapy + durvalumab, followed by durvalumab, is a new treatment option for endometrial cancer, including people with tumors deficient in MMR (dMMR) and proficient in MMR (pMMR). Chemotherapy + durvalumab followed by durvalumab + olaparib is a new treatment option for people with tumors proficient in MMR (pMMR).

## Where can I find more information?

- This is a summary of an article titled 'Durvalumab Plus Carboplatin/Paclitaxel Followed by Maintenance Durvalumab With or Without Olaparib as First-Line Treatment for Advanced Endometrial Cancer: The Phase III DUO-E Trial' originally published in the *Journal of Clinical Oncology*: Westin SN *et al*. *J Clin Oncol*. 42(3); 283–299 (2024). You can read the full article at: https://ascopubs.org/doi/10.1200/JCO.23.02132
- You can find more information about DUO-E at: https://clinicaltrials.gov/study/NCT04269200
- If you are or were a study participant and have questions about the results of this study, please speak with the doctor or staff at your study center.
- People should ask their healthcare providers for more information about the benefits and risks of any treatment.

**You can read more about endometrial cancer at the following websites:**

- The American Cancer Society: www.cancer.org/cancer/endometrial-cancer.html
- The International Gynecologic Cancer Society: www.igcs.org/womens-cancers/
- ENGAGe: www.engage.esgo.org/brochures/cancer-fact-sheets/uterine-endometrial-cancer/

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### Disclosure statement

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