

# Treatment outcomes in older patients with metastatic breast cancer receiving palbociclib plus an aromatase inhibitor: a plain language summary

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First draft submitted: 18 January 2023; Accepted for publication: 29 February 2024; Published online: 27 March 2024

## Summary

### What is this summary about?

This summary describes an article published in the medical journal *Frontiers in Oncology* in September 2023. The article reports results from a study that looked at breast cancer treatments for older patients aged 75 years or older. The study focused on a type of cancer called HR+/HER2- metastatic breast cancer. HR+/HER2- stands for hormone receptor-positive/human epidermal growth factor receptor 2-negative. This study evaluated whether older patients with this type of cancer benefited from the combination of two medicines – palbociclib and an aromatase inhibitor – compared with taking an aromatase inhibitor alone.









### How was the study in this summary carried out?

The Flatiron database contains medical records for people with cancer in the US. This study used deidentified health care information from this database. ‘Deidentified’ means that all information that could identify an individual was removed to protect individuals’ privacy. People in this study received treatment in routine care and not in a clinical trial.

### What do the results mean?

Older patients who took palbociclib plus an aromatase inhibitor lived longer than those who took an aromatase inhibitor alone. Older patients who took palbociclib plus an aromatase inhibitor also lived longer without their cancer getting worse and started chemotherapy later than those who took an aromatase inhibitor alone. These results support using palbociclib plus an aromatase inhibitor as the first treatment for patients aged 75 years or older with HR+/HER2- metastatic breast cancer.

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

- **Aromatase:** ah-ROH-muh-tays 
- **Cyclin:** SY-klin 
- **Estrogen:** EH-struh-gen 
- **Inhibitor:** in-HIH-bih-ter 
- **Kinase:** KY-nase 
- **Metastatic:** meh-tuh-STA-tik 
- **Palbociclib:** PAL-boh-SY-klib 
- **Progesterone:** proh-JES-teh-rone 

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

The original article ‘Real-world treatment patterns and effectiveness of palbociclib plus an aromatase inhibitor in patients with metastatic breast cancer aged 75 years or older’ is published in the journal *Frontiers in Oncology*. You can read this article for free at: <https://www.frontiersin.org/journals/oncology/articles/10.3389/fonc.2023.1237751/full>



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

The purpose of this plain language summary is to help you understand the findings from recent research. This summary reports the results of a single study. The results of this study may differ from those of other studies. Health care professionals should make treatment decisions based on all available evidence, and not based on the results of a single study.

Palbociclib is approved to treat the condition under study that is discussed in this summary.

## Who is this article for?

This summary is for older patients with breast cancer and their caregivers, patient advocates, and health care professionals. This summary can help people learn about treatment options for HR+/HER2- metastatic breast cancer.

## Who sponsored this study?

This study was **sponsored** by Pfizer Inc.

**Sponsor:** a sponsor is a company organisation that oversees and pays for a clinical research study. The sponsor also collects and analyses the information that was generated during the study.

## Why was this study carried out?

Breast cancer commonly affects older people. People in the United States (US) have a **median age** of 63 years at breast cancer diagnosis. People aged 65 years and older represent 45% of new breast cancer cases in the US. However, a limited number of older patients usually join cancer clinical trials. As a result, doctors often have little information to guide treatment decisions for older patients.

**Median age:** the middle age of people in the US at breast cancer diagnosis. This means that half of the people are younger, and the other half are older than the median age at breast cancer diagnosis.

Clinical trials often have strict criteria about who can participate. Patients who take other medicines or have other illnesses sometimes cannot join a clinical trial. Compared with younger patients, older patients are more likely to take other medicines or have other illnesses. As a result, older patients are often not allowed to participate in clinical trials.

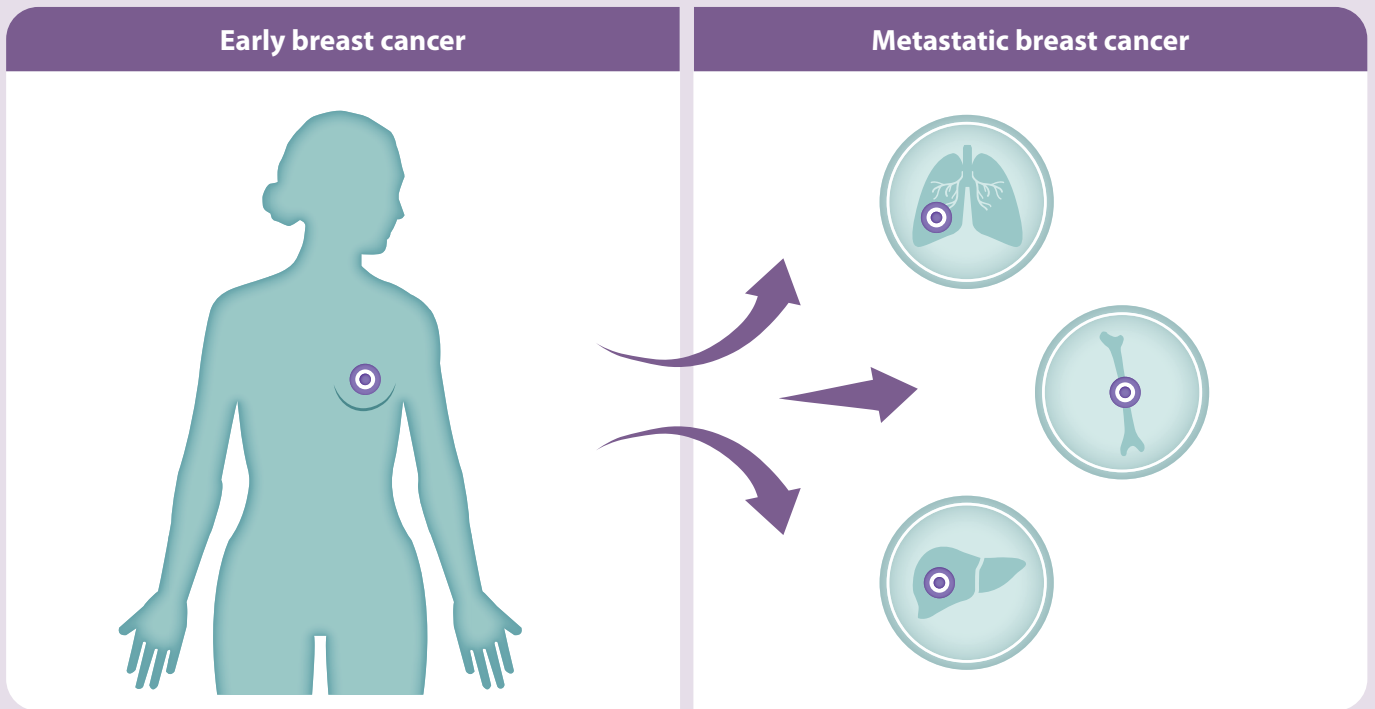
Once a treatment is approved for use, doctors may then prescribe it for a broader set of patients in routine care. People with metastatic breast cancer treated in routine care are often older or sicker than those treated in clinical trials.

Researchers can learn more about how medicines work in older patients by studying medical records from routine care. Researchers call this type of research a real-world study.

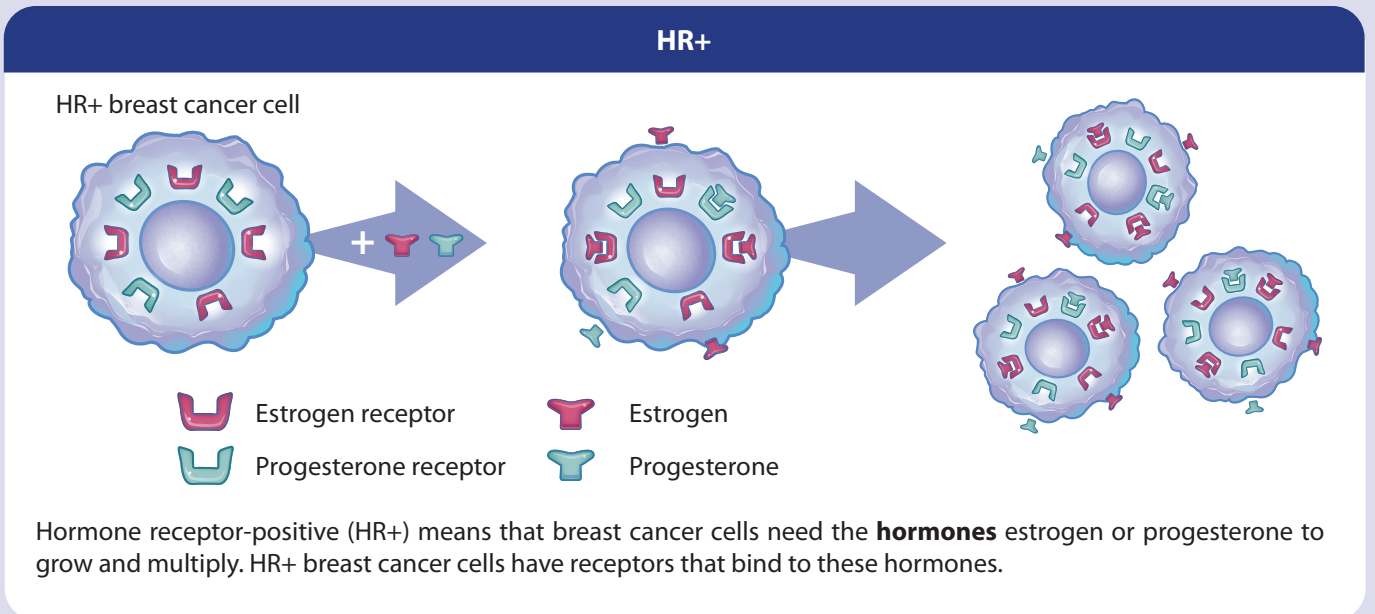
In this real-world study, researchers compared treatments in patients aged 75 years or older with HR+/HER2- metastatic breast cancer. Specifically, they compared treatment with palbociclib plus an aromatase inhibitor versus an aromatase inhibitor alone.

## What does metastatic breast cancer mean?

Metastatic means that the cancer has spread from the original site, in this case the breast, to other places in the body. Common sites of breast cancer spread include the lungs, bones or liver.



### What does HR+/HER2- breast cancer mean?

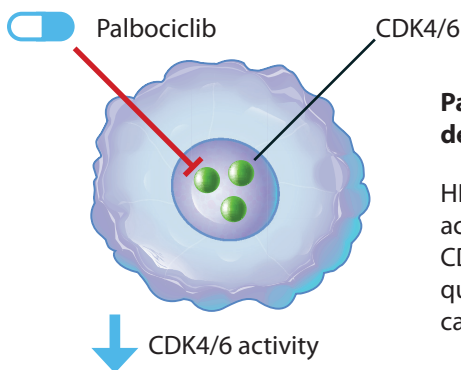


**Hormones:** chemical messengers made naturally by the body.

HER2-	HR+/HER2-
<p>Human epidermal growth factor receptor 2 (HER2) is a protein involved in cell growth and survival. HER2-negative (HER2-) means that breast cancer cells have little or no HER2 protein.</p>	<p>HR+/HER2- refers to a type of breast cancer that is both HR+ and HER2-.</p> <p>HR+/HER2- is the most common type of breast cancer.</p>

## How does the combination of palbociclib and an aromatase inhibitor work to treat cancer?

### What is palbociclib?



**Palbociclib is a type of medicine called a cyclin-dependant kinase 4 and 6 (CDK4/6) inhibitor.**

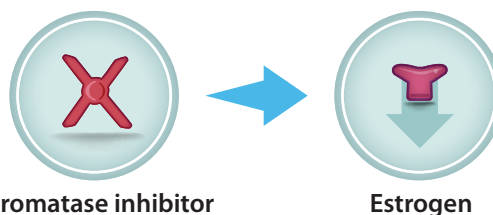
HR+/HER2- breast cancer cells often have increased activity of the **enzymes** CDK4 and CDK6. Increased CDK4/6 activity causes cells to grow and divide too quickly. Palbociclib blocks CDK4/6 activity, which can slow tumor growth.

**Enzymes:** proteins that work to speed up chemical reactions in the body.

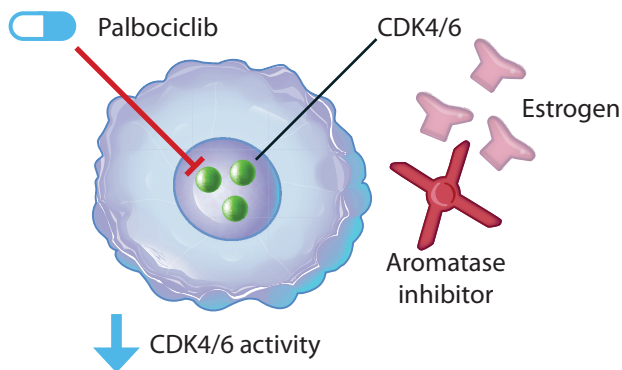
### What is an aromatase inhibitor?

An aromatase inhibitor is a type of medicine that lowers estrogen levels in the body.

Lowering estrogen levels can help slow the growth of HR+ breast cancer.



### How does combining palbociclib and an aromatase inhibitor work?



**People with HR+/HER2- metastatic breast cancer can receive treatment with both palbociclib and an aromatase inhibitor.**

These medicines work together to help control the growth of cancer cells.

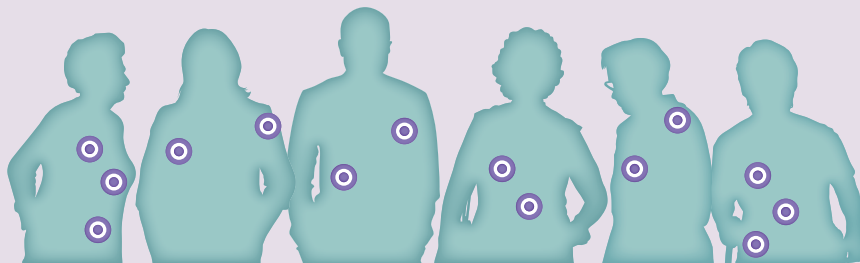
## How was this study carried out?

This study used deidentified health care information from the Flatiron Database. This database contains electronic medical records from over 3 million people treated for cancer in the US. These individuals received treatment in routine care and not in a clinical trial.



## People were selected for this study if they met the following criteria:

- Aged 75 years or older
- Diagnosed with HR+/HER2- metastatic breast cancer
- Received palbociclib plus an aromatase inhibitor or an aromatase inhibitor alone as their first treatment for metastatic breast cancer between February 2015 and March 2020



### Treatment 1



Palbociclib plus an aromatase inhibitor

### Treatment 2



An aromatase inhibitor alone

Researchers compared the following treatment outcomes in people who received palbociclib plus an aromatase inhibitor versus an aromatase inhibitor alone:

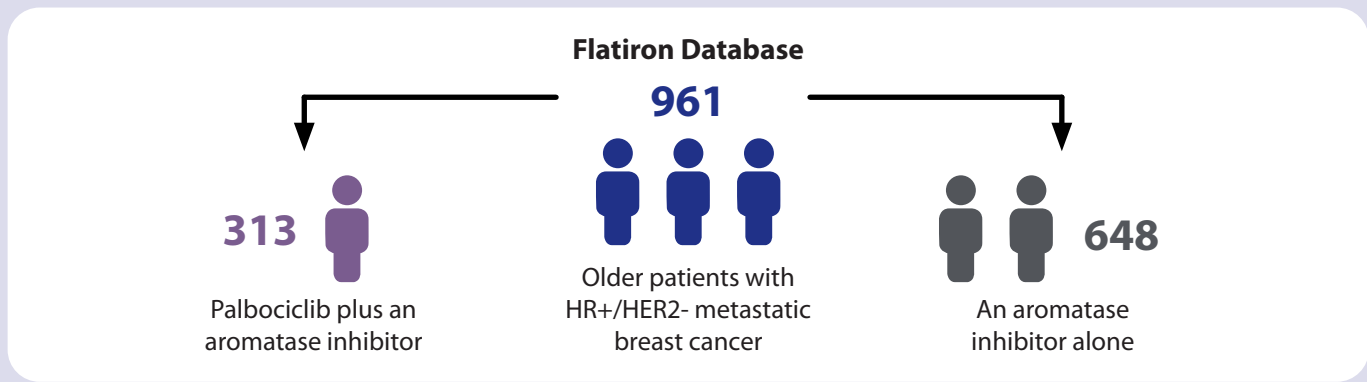
- How long a person lived after starting treatment
- The length of time before a person's cancer got worse
- The length of time before starting chemotherapy (a medicine that kills cancer cells)

In routine care, people may receive different treatments based on individual characteristics. For example, treatment decisions can be based on a person's age, overall health, or **stage of disease**. Therefore, researchers used an advanced statistical approach to balance characteristics between the two treatment groups. This approach made the groups similar so that researchers could properly compare treatment outcomes.

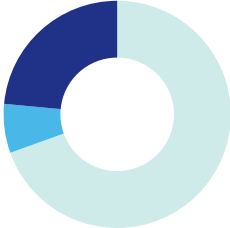
**Stage of disease:** a way of indicating how large the tumor is and how far it has spread.

## Who was included in this study?


From the database, researchers collected information on 961 older patients with HR+/HER2- metastatic breast cancer who met the study criteria.




## Among the 961 older patients included in the study:




- **668 (69.5%)** were White
- **67 (7.0%)** were Black
- **226 (23.5%)** were of race other than White or Black




**276 (29%)** had cancer that had spread to the lungs or liver



Median age at metastatic breast cancer diagnosis was **80 years** old



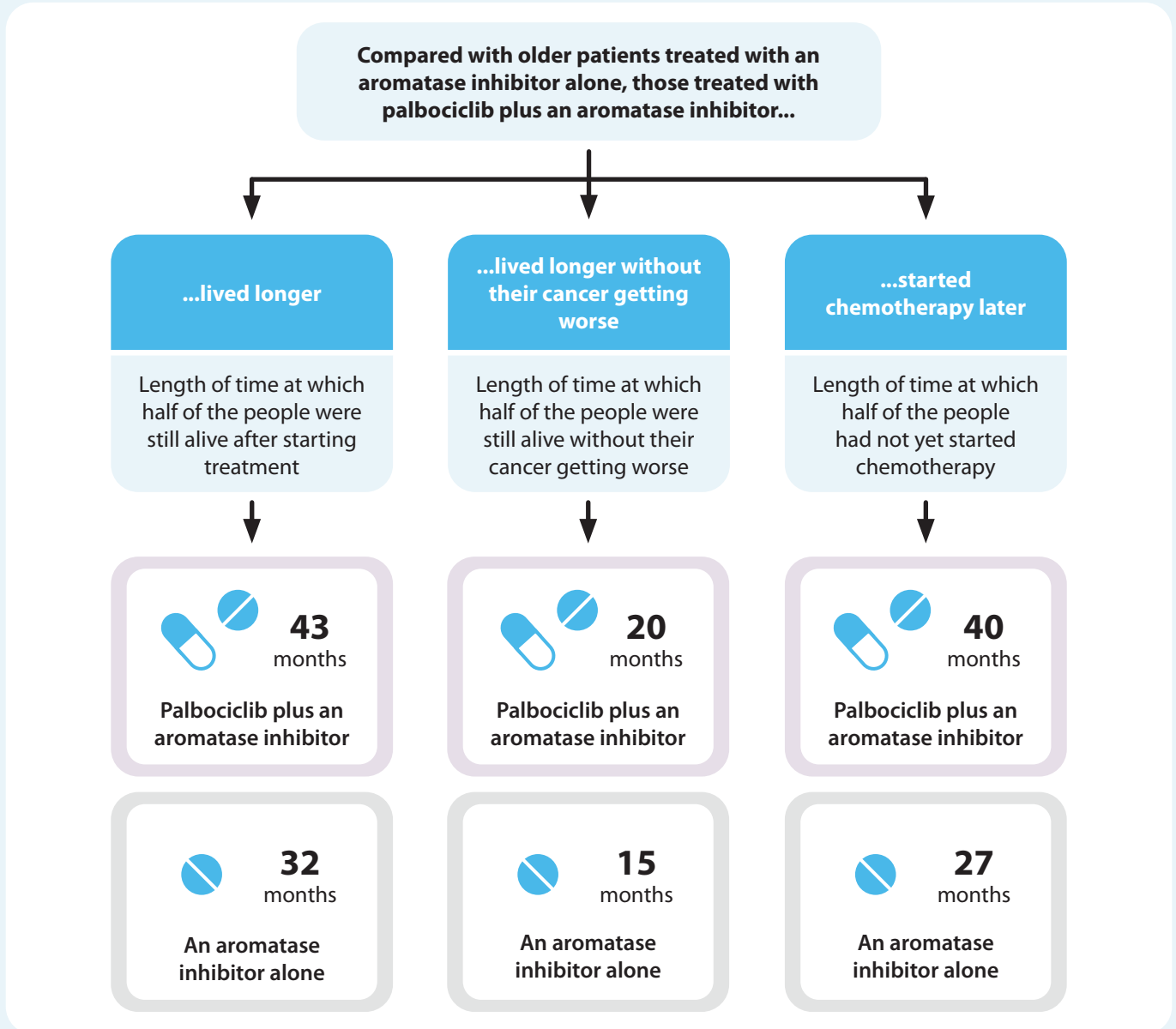
**376 (39%)** had cancer that had spread only to the bones



**952 (99%)** were female

## What were the key results from this study?

Researchers compared outcomes after balancing other characteristics between the two treatment groups.



The recommended starting dose of palbociclib is 125 milligrams per day for most patients. To decrease the risk of side effects, some patients may start palbociclib at a dose lower than 125 milligrams per day. Others may start palbociclib at the recommended dose, but later have their dose adjusted to ease side effects.

In this study, researchers found a record of the starting palbociclib dose for 306 patients. Of these 306 patients, 230 (75%) started palbociclib at a dose of 125 milligrams per day and 76 (25%) started palbociclib at a dose lower than 125 milligrams per day.

Of 230 patients who started palbociclib at the recommended dose of 125 milligrams per day, 89 (39%) had their dose reduced later on.

## What do the results of this study mean?

This real-world study compared outcomes between older patients (aged 75 years or older) receiving palbociclib and an aromatase inhibitor versus those receiving an aromatase inhibitor alone. Researchers found that older patients who took palbociclib plus an aromatase inhibitor lived longer than those who took an aromatase inhibitor alone. Older patients who took palbociclib plus an aromatase inhibitor also lived longer without their cancer getting worse and started chemotherapy later than those who took an aromatase inhibitor alone. Taken together, these results support using palbociclib plus an aromatase inhibitor as the first treatment for patients aged 75 years or older with HR+/HER2– metastatic breast cancer.

## What were the limitations of this study?

This study used information from a health care database. This database may have missing or inaccurate information. This database did not have information on any side effects that patients may have experienced while receiving treatment.

In many clinical trials, researchers randomly assign patients to different treatment groups. This helps make sure that patient characteristics are balanced between treatment groups. In contrast, in this real-world study, patients were not randomly assigned to receive palbociclib plus an aromatase inhibitor or an aromatase inhibitor alone. Instead, researchers used statistical methods to account for differences between the groups of people treated with palbociclib plus an aromatase inhibitor or an aromatase inhibitor alone. However, these methods may not have accounted for all differences between these two groups. Therefore, it is possible that other factors besides the medicines received might have impacted the results.

This study's results may differ from the results of other studies that evaluate these medicines in different groups of people. Doctors should consider all available evidence and not base treatment decisions on a single study.

## Where can I find additional resources about this real-world study?

The original article 'Real-world treatment patterns and effectiveness of palbociclib plus an aromatase inhibitor in patients with metastatic breast cancer aged 75 years or older' is published in the journal *Frontiers in Oncology*. You can read this article for free at: <https://www.frontiersin.org/journals/oncology/articles/10.3389/fonc.2023.1237751/full>

The full citation for this article is: Brufsky A, Liu X, Li B, *et al.* Real-world treatment patterns and effectiveness of palbociclib plus an aromatase inhibitor in patients with metastatic breast cancer aged 75 years or older. *Front Oncol.* 13, 1237751 (2023).

- Patients in this study started treatment with palbociclib and an aromatase inhibitor or an aromatase inhibitor alone between February 2015 and March 2020. Researchers stopped collecting information about these patients on 30 September 2020.
  - For more information on this real-world study, please visit: <https://clinicaltrials.gov/study/NCT05361655>
  - For more information on breast cancer, please visit: <https://www.breastcancer.org/>
  - For more information on clinical research in general, please visit: <https://www.clinicaltrials.gov/study-basics/learn-about-studies>
  - For more information on real-world studies in general, please visit: <https://link.springer.com/article/10.1007/s40290-022-00456-6>



### Acknowledgments

The authors thank all the people who contributed to the information used in this study.

### Competing interests disclosure

Adam Brufsky has received grants from Agendia and AstraZeneca, and consulting fees or honoraria from AstraZeneca, Pfizer, Novartis, Lilly, Genentech/Roche, Seagen, Daiichi Sankyo, Merck, Agendia, Sanofi, and Puma. Xianchen Liu, Benjamin Li, Lynn McRoy, and Connie Chen are employees of and stockholders in Pfizer. Rachel M. Layman reports advisory/consultancy fees from Novartis, Eli Lilly, Pfizer, and Celcuity, and research/grant funding from Pfizer, Novartis, Eli Lilly, Zentalis, Puma, Celcuity, Accutar Biotechnology, and Arvinas. Hope S. Rugo reports sponsored research to her institution from Pfizer, Merck, Novartis, Eli Lilly, Roche, Daiichi-Sankyo, Seagen, MacroGenics, Sermonix, Boehringer Ingelheim, Polyphor, AstraZeneca, Ayala, and Gilead, and honoraria from Puma, Samsung, and Mylan. 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.

### Financial disclosure

This study was sponsored by Pfizer Inc. 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.

### Writing disclosure

Medical writing support was provided by Diana Avery, PhD, of Oxford PharmaGenesis Inc., Newtown (PA, USA) according to Good Publication Practice guidelines (GPP3), and was funded by Pfizer Inc.

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