**Key**

**takeaway** What is the key takeaway from this study?

• In US routine clinical practice, patients with metastatic hormone receptorpositive

breast cancer who received palbociclib plus an aromatase inhibitor

as their first treatment lived longer than those who received an aromatase

inhibitor alone.

**Phonetics Find out how to say medical terms used in this summary**

**Anastrozole**

< an-AS-troh-zole >

**Aromatase**

< ah-ROH-muh-tays >

**Endocrine**

< EN-doh-kryn >

**Exemestane**

< EK-seh-MEH-stayn >

**Inhibitor**

< in-HIH-bih-ter >

**Letrozole**

< LEH-truh-zole >

**Metastatic**

< meh-tuh-STA-tik >

**Palbociclib**

< PAL-boh-SY-klib >

**Introduction** What does this study look at?

What is hormone receptor–positive/human epidermal growth

factor receptor 2–negative (HR+/HER2– ) breast cancer?

• Although breast cancer is often thought of as one disease, there are many

different types, each of which responds differently to the various available

treatments.

• Some breast cancer cells called HER2-positive cells have a lot of a protein

called HER2 on their surface, which causes the cells to grow faster. Other

breast cancer cells have lower amounts of this protein and are called

HER2-negative (HER2− for short) breast cancer.

• Some people with HER2− breast cancer have hormonea receptors (or HRs

for short) on their breast cancer cells. This is known as HR positive (HR+ for

short) breast cancer.

– When people have both hormone receptors and low amounts of HER2

protein on their breast cancer cells, it is called HR+/HER2− breast cancer.

• More than two out of three breast cancers are both HR+ and HER2–.

• Metastatic breast cancer is cancer that has spread from the breast to other

parts of the body.

– Six out of every 100 patients with breast cancer already have metastatic

breast cancer at the time of the original diagnosis (also known as *de novo*

metastatic breast cancer).

– For patients with breast cancer that is already metastatic at the time of

diagnosis, just under 30% are alive at 5 years after diagnosis.

What is palbociclib?

• Palbociclib is a CDK4/6 inhibitor.

• Cyclin-dependent kinases 4 and 6 (or CDK4/6) are proteins found in both

healthy and cancer cells that help to control how quickly cells grow and divide.

• Cells of HR+/HER2− breast cancers often have increased amounts of cyclin

D1, the binding partner of CDK4/6, which leads to continuous activation of

CDK4/6 and uncontrolled growth. Palbociclib blocks CDK4/6, helping to stop

or slow down growth of the tumor.

• Palbociclib is approved for the initial treatment of metastatic HR+/HER2–

breast cancer in combination with an AI, in postmenopausal women and

in men.

What was the aim of this study?

• This study looked at whether adding palbociclib to an AI helped patients

with metastatic HR+/HER2– breast cancer to live longer.

• Using information collected from routine clinical practice in the United States,

overall survival in patients treated with palbociclib + AI was compared with

patients treated with an AI only.

What does this summary describe?

• Compared with clinical trials, patients in real life can be older, sicker, or have

more diseases in addition to the breast cancer being treatedb, which can

impact the effectiveness of a drug or increase the risk of side effects.

• This study looked at whether patients treated with palbociclib + AI in real life

lived longer than those treated with an AI alone.

• The Flatiron Health database has information from more than 3 million

patients who have received treatment for cancer in the US, followed over

time. The investigators looked at the database to find information from

patients with HR+/HER2– metastatic breast cancer who were treated with

palbociclib + AI or AI alone between February 2015 and September 2020.

• Survival information was compared in 2888 patients who were treated with

palbociclib + AI or AI therapy alone as their first treatment during this

time period.

aHormones are chemical messengers in the body

b Termed comorbid conditions, these can include diseases such as diabetes, cardiovascular diseases, etc.

Patients with these diseases are often excluded from participating in clinical trials.

Researchers wanted to find out…

• Whether patients with metastatic HR+/HER2– breast cancer treated with

palbociclib + AI in real life lived longer than those who were treated with

an AI alone.

**Study**

**details** Who took part in this study?

• Postmenopausal women or men aged 18 years or older with metastatic

HR+/HER2– breast cancer.

• Patients who started palbociclib + AI or AI alone as their first therapy

between February 2015 and March 2020.

2,888

patients with

HR+/HER2– breast cancer

**1,324** received **palbociclib + AI**

**1,564** received **an AI alone**

Among the 2,888 included patients:

**68%** were White

**39%** had bone-only disease

**35%** had *de novo* metastatic breast cancer

**29%** had lung or liver involvement

the median age was **70 years**

**Results** What were the results of the primary analysis of

the study?

• Patients who were treated with palbociclib + AI in real world setting

lived longer than those treated with an AI alone, even after adjusting for

differences in patient characteristics of the two groups at or before starting

the treatment.

The risk of death in patients treated with **palbociclib + AI**

was reduced by **24%** compared to those treated with **AI** alone.

**Length of time half of the patients lived after**

**starting treatment**

**49\_months 43\_months**

The results of this study may differ from those of other studies. Researchers should make treatment

decisions based on all available evidence, not on the results of a single study.

**Conclusions** What were the main conclusions reported

by the study authors?

• This large real-world study showed that, in routine clinical practice, patients

treated with palbociclib + AI lived longer than those treated with an AI alone.

• These results support the use of palbociclib + AI as the standard initial

treatment given to patients with metastatic HR+/HER2– breast cancer.

**More**

**information** Who sponsored this study?

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

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New York, NY, 10017

Phone (United States): TBC

**The sponsors would like to thank all the patients who contributed the information used in**

**this study.**

Where can I find more information?

For more information on this study, please visit:

View ESMO Scientific Abstract

For more information on clinical studies in general, please visit:

**https://www.clinicaltrials.gov/ct2/about-studies/learn**

**http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are**