# Key Takeaway

The study discussed and found out the overall survival (OS) and real-world progression-free survival (rwPFS) of palbociclib plus aromatase inhibitor (AI) versus AI alone in postmenopausal women and men with HR+/HER2- metastatic breast cancer (MBC) in routine clinical practice in the United States. The study had the longest index period from palbociclib approval and included an extended follow-up time of ≥6 months.

# Phonetics

The document does not provide any information about the phonetics used in the study.

# Introduction

The diseases/conditions discussed in the study are breast cancer, specifically HR+/HER2- metastatic breast cancer (MBC), and the treatment with the CDK4/6 inhibitor palbociclib in combination with endocrine therapy. Breast cancer is a malignant tumor that develops in the cells of the breast. In 2021, it was estimated that there would be 281,550 new cases of female breast cancer diagnosed and 43,600 deaths. Metastatic breast cancer refers to breast cancer that has spread to distant tissues, and the 5-year survival rate for this stage is 29.0%. HR+/HER2- refers to the hormone receptor status and HER2 status of the breast cancer cells. The majority of breast cancer cases are HR+/HER2- (68%). Palbociclib is a CDK4/6 inhibitor that was approved as a first-line treatment for HR+/HER2- MBC in combination with an aromatase inhibitor or fulvestrant. The PALOMA-2 trial demonstrated that palbociclib plus letrozole significantly prolonged median progression-free survival in patients with HR+/HER2- MBC. Real-world evidence studies have shown the safety and effectiveness of palbociclib plus endocrine therapy in routine clinical practice, with longer progression-free survival and overall survival compared to endocrine therapy alone. The purpose of this study is to evaluate overall survival and progression-free survival of palbociclib plus aromatase inhibitor versus aromatase inhibitor alone in postmenopausal women and men with HR+/HER2- MBC in routine clinical practice in the United States.

Yes, the study specifically focuses on the drug palbociclib. Palbociclib is a cyclin-dependent kinase 4/6 (CDK4/6) inhibitor. It works by inhibiting the activity of CDK4 and CDK6, which are proteins involved in cell cycle progression. By blocking these proteins, palbociclib helps to slow down the growth and division of cancer cells. It is approved for the treatment of hormone receptor-positive, HER2-negative metastatic breast cancer in combination with endocrine therapy. The study aims to evaluate the overall survival and progression-free survival of palbociclib plus aromatase inhibitor versus aromatase inhibitor alone in routine clinical practice.

The aim of the study was to evaluate the overall survival (OS) and real-world progression-free survival (rwPFS) of palbociclib plus aromatase inhibitor (AI) versus AI alone in postmenopausal women and men with HR+/HER2- metastatic breast cancer (MBC) in routine clinical practice in the United States. The study found that palbociclib plus AI was associated with longer OS and rwPFS compared to AI alone, providing further evidence of the effectiveness of this combination therapy in real-world settings.

Patients in routine clinical practice differ from those in clinical trials in several ways. Clinical trials often have strict eligibility criteria, which may exclude certain patient populations, such as those with comorbidities or older age. In contrast, routine clinical practice includes a broader range of patients, including those who may not have met the criteria for clinical trials. Additionally, clinical trials are conducted in controlled settings with close monitoring, while routine clinical practice reflects real-world conditions with variations in healthcare providers, treatment adherence, and follow-up.  
  
The study was carried out using the Flatiron Health Analytic Database, which is a real-world database that includes electronic health records from multiple cancer centers in the United States. The study used this database to evaluate overall survival (OS) and real-world progression-free survival (rwPFS) of palbociclib plus aromatase inhibitor (AI) versus AI alone in postmenopausal women and men with HR+/HER2– metastatic breast cancer (MBC). The study included an extended follow-up time of at least 6 months from the index date to the data cutoff date.

# Study Details 1

From February 3, 2015 to March 31, 2020, a total of 2888 postmenopausal women or men with HR+/HER2‒ MBC were included in the study. Of these, 1324 patients started palbociclib plus AI as first-line therapy, while 1564 patients received AI alone. The median age of patients in both treatment groups was 70 years, and approximately 68% of patients in each group were white. The median duration of follow-up was 23.9 months in the palbociclib plus AI group and 24.5 months in the AI alone group.

# Study Details 2

The study included women aged ≥18 years with confirmed HR+/HER2‒ MBC. The total number of patients was not mentioned. The study duration was from February 3, 2015 to September 30, 2020.

# Results

From February 3, 2015 to March 31, 2020, a total of 2888 postmenopausal women or men with HR+/HER2‒ MBC started palbociclib plus AI (n=1324) or AI alone (n=1564) as first-line therapy. After sIPTW adjustment, the median age was 70 years in both treatment groups. The median duration of follow-up was 23.9 months in the palbociclib plus AI group and 24.5 months in the AI alone group. In terms of overall survival (OS), the median OS was significantly longer in the palbociclib group compared to the AI group. The OS rate at 24, 36, and 48 months were higher in the palbociclib plus AI group compared to the AI alone group. Similar results were observed in the propensity score matching (PSM) analysis. In terms of real-world progression-free survival (rwPFS), the median rwPFS was significantly longer in the palbociclib group compared to the AI group. Consistent rwPFS benefit was observed across most subgroups. Subsequent second-line treatments varied between the two groups.

# Conclusions

The study concluded that treatment with palbociclib plus AI significantly prolonged overall survival (OS) and relative progression-free survival (rwPFS) compared to AI alone in a diverse group of postmenopausal women and men with HR+/HER2- metastatic breast cancer (MBC). These positive results were observed across most subgroups, indicating that palbociclib plus AI should be considered as a standard of care for patients with HR+/HER2- MBC.

# More Information 1

Pfizer Inc funded the study.

# More Information 2

The provided text does not mention the specific source or website where the original article or more information on clinical studies can be found. It is recommended to search for relevant clinical studies or articles on reputable medical research databases or websites such as PubMed (https://pubmed.ncbi.nlm.nih.gov/) or ClinicalTrials.gov (https://clinicaltrials.gov/).