# Key Takeaway

The key takeaway from the study is that the combination of palbociclib plus AI as first-line therapy for HR+/HER2‒ MBC in postmenopausal women or men resulted in a significant improvement in overall survival (OS) and real-world progression-free survival (rwPFS) compared to AI alone. This benefit was observed across most subgroups examined. Additionally, a substantial proportion of patients in both treatment groups received a CDK4/6 inhibitor as second-line treatment.

# Phonetics

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

# Introduction

The study discussed the disease of breast cancer, specifically focusing on HR+/HER2- metastatic breast cancer (MBC). Breast cancer is a type of cancer that forms 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 it accounts for 6% of breast cancer cases. The 5-year survival rate for metastatic breast cancer is 29.0%. The majority of breast cancer cases are HR+/HER2- (68%), which means that the cancer cells have hormone receptors for estrogen and progesterone but do not have the HER2 protein. Treatment recommendations for HR+/HER2- MBC include the use of a cyclin-dependent kinase 4/6 (CDK4/6) inhibitor in combination with endocrine therapy. Palbociclib is a CDK4/6 inhibitor that has shown positive results in clinical trials, such as the PALOMA-2 trial, where it significantly prolonged median progression-free survival in patients with HR+/HER2- MBC. Real-world evidence, which is used to validate the efficacy and safety of a drug in routine clinical practice, has also shown the effectiveness of palbociclib in combination with endocrine therapy for HR+/HER2- MBC. However, real-world data on overall survival are limited. The purpose of this study was to evaluate the overall survival and progression-free survival of palbociclib plus aromatase inhibitor (AI) versus AI 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 in HR+/HER2– metastatic breast cancer. This study aims to evaluate the real-world effectiveness of palbociclib in combination with aromatase inhibitors compared to aromatase inhibitors 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 terms of demographics, comorbidities, and treatment adherence. Real-world evidence helps capture the effectiveness and safety of treatments in a broader patient population.

The study was a retrospective analysis of electronic health records (EHRs) from the Flatiron Health Analysis Database. It included data from >280 cancer clinics (~800 sites of care) representing >2.4 million actively treated US patients with cancer. The study analyzed patients who met inclusion criteria between February 3, 2015 and March 31, 2020, with a follow-up period until September 30, 2020. The study used a patient attrition diagram (Figure 1) and derived data from structured and unstructured EHRs.

# Study Details

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.

The study included women aged ≥18 years with confirmed HR+/HER2‒ MBC. The total number of patients was not mentioned. The study analyzed data from patients who received palbociclib plus AI or AI alone as first-line therapy for MBC between February 3, 2015 and March 31, 2020. The duration of follow-up was until September 30, 2020. No information regarding ethnicity or race was provided.

# 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/).