Real-World Treatment Effectiveness of Palbociclib in Combination With an Aromatase Inhibitor as First Line Therapy in Post-Menopausal Women and Men With Metastatic Breast Cancer (P-REALITY 3)

First published: 02/07/2021

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS41803

Study ID

41804

DARWIN EU® study

No

Study countries

United States

Study description

This study aims to assess real-world effectiveness in post-menopausal women and men with HR+/HER2- MBC initiating palbociclib + AI or AI alone as first-line therapy during the period on or after 01 February 2015 to on or before 30 June 2020 in the United States. The primary objective is to compare OS in postmenopausal women and men treated with palbociclib + AI versus AI alone as first-line therapy for HR+/HER2- MBC.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Networks

Ontada

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Connie Chen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/12/2020

Actual: 23/12/2020

Study start date

Planned: 01/07/2021

Actual: 14/02/2022

Data analysis start date

Actual: 10/05/2022

Date of final study report

Planned: 31/03/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To compare OS in postmenopausal women and men treated with palbociclib + AI versus AI alone as first-line therapy for HR+/HER2- MBC

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

IBRANCE

Study drug International non-proprietary name (INN) or common name

PALBOCICLIB

Medical condition to be studied

Breast cancer metastatic

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

2000

Study design details

Outcomes

Overall Survival in postmenopausal women and men treated with palbociclib + AI versus AI alone as first-line therapy for HR+/HER2- MBC, rwPFS and rwRR in post-menopausal women and men treated with palbociclib + AI versus AI alone as first-line therapy for HR+/HER2 - MBC during first-line treatment

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Data analysis plan

An IPTW approach will be used to compare palbociclib + AI versus AI alone for the average treatment effect (ATE) on the primary endpoint OS. A weighted log-rank test with the robust variance estimation will be used for the hypothesis testing with the significance level at 1-sided 0.025. Hazard ratio (HR) for OS with the corresponding 2-sided 95% CI will be calculated based on a weighted Cox's proportional hazard model.

Documents

Study report

A5481161 NI Study Report redacted version 30MAY2023_Redacted (1).pdf (4.72 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Chart review

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No