Retrospective Assessment of Treatment
Patterns and Outcomes Associated with
Palbociclib in Combination With Letrozole in
Postmenopausal Women With HR+/HER2Advanced Breast Cancer

First published: 23/06/2016

Last updated: 01/04/2024





Administrative details

EU PAS number	
EUPAS13869	
Study ID	
26344	
DARWIN EU® study	
No	
Study countries	
United States	

Study description

To describe the patient and clinical characteristics, treatment patterns, and clinical outcomes of patients who received palbociclib plus letrozole for the treatment of HR+/ HER2- advanced breast cancer.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 7 centres are involved in the study

Contact details

Study institution contact

Debanjali Mitra debanjali.mitra@pfizer.com

Study contact

debanjali.mitra@pfizer.com

Primary lead investigator

Debanjali Mitra

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/09/2015

Actual: 12/09/2015

Study start date

Planned: 30/06/2016

Actual: 01/08/2016

Data analysis start date

Planned: 01/08/2016

Actual: 01/12/2017

Date of final study report

Planned: 31/10/2016

Actual: 16/10/2018

Sources of funding

Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

A5481064 Breast Cancer Retrospective Study Protocol 02June2016 FINAL.pdf (498.32 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to evaluate treatment patterns and outcomes among patients who received palbociclib plus letrozole

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective medical record review

Study drug and medical condition

Medicinal product name

IBRANCE

Medical condition to be studied

Breast cancer metastatic

Population studied

Short description of the study population

Postmenopausal Women With HR+/HER2- Advanced Breast Cancer who received palbociclib plus letrozole.

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)

Special population of interest

Other

Special population of interest, other

Advanced Breast Cancer patients

Estimated number of subjects

130

Study design details

Data analysis plan

Descriptive analyses only, no hypotheses being tested

Documents

Study results

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)

Other

Data sources (types), other

Patients' medical records

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Unknown Check completeness Unknown

Check stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown