Retrospective Assessment of Treatment Patterns and Outcomes Associated with Palbociclib in Combination With Letrozole in Postmenopausal Women With HR+/HER2– Advanced Breast Cancer

First published: 23/06/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26344

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

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Institution

Multiple centres: 7 centres are involved in the study

Contact details

Study institution contact

Debanjali Mitra

Study contact

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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

Name of medicine

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

A5481064 Non-Interventional Study Report_FINAL_16Oct2018_PASS.pdf(843.85 KB)

Data management

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

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown