Understanding Early and Ongoing Treatment Utilization of Palbociclib in a US Community Oncology Setting

First published: 14/12/2016

Last updated: 30/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18421

EU PAS number

EUPAS16706

Study ID

18421

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a retrospective observational longitudinal rolling cohort study to assess adult metastatic breast cancer patients initiating treatment with palbociclib from February 2015 to January 2016. Data was cumulatively extracted from The US Oncology Network/McKesson Specialty Health electronic health record database every 2 months. Patients on clinical trial were excluded. Demographic and clinical characteristics, prior treatment, dosing patterns, and duration of treatment were characterized.

Study status

Finalised

Research institutions and networks

Institutions

US Oncology Network

Contact details

Study institution contact

Ward Melea

Study contact

melea.ward@pfizer.com

Primary lead investigator

Melea Ward

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/11/2015

Actual: 23/11/2015

Study start date
Planned: 01/06/2015

Actual: 01/06/2015

Data analysis start date
Planned: 15/06/2015

Actual: 15/06/2015

Date of interim report, if expected
Planned: 31/12/2015

Actual: 01/12/2015

Date of final study report
Planned: 28/02/2017

Actual: 28/02/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

CT24-GSOP-RF03 3 0 NI Study Protocol Palbociclib in BC RH 5-12_v2 clean signed.pdf(439.34 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:

To describe the demographic and clinical characteristics of patients newly initiating Palbociclib therapy, To describe early treatment utilization of patients newly initiating Palbociclib therapy including time to discontinuation.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive, retrospective longitudinal study

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

Female breast cancer patients greater than or equal to 18 years of age who initiated Palbociclib between February 1, 2015 and January 31, 2016.

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

Metastatic breast cancer patients

Estimated number of subjects

1500

Study design details

Data analysis plan

This study is a longitudinal, retrospective observational study. It is descriptive in nature.

Documents

Study results

A5481062 Abstract.pdf(148.67 KB)

Study report

A5481062.pdf(1.23 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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