Descriptive Analyses of Clinical Characteristics and Treatment Patterns of Breast Cancer Patients Initiating Palbociclib (Ibrance®) Treatment in the US Community Oncology Setting

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Study Finalised

Administrative details

EU PAS number

EUPAS16710

Study ID

18408

DARWIN EU® study

No

Study countries

☐ United States

Study description

Palbociclib (Ibrance®) was approved in the United States (US) in February 2015. This study will describe the characteristics of patients initiating treatment with palbociclib in terms of demographic and clinical characteristics, real-world treatment patterns (line of therapy, concomitant use of other chemotherapy/hormonal therapy/supportive drugs), dosing patterns, and adverse event/neutropenia-related outcomes (frequency of monitoring incidence, time to event) among female patients with breast cancer following US approval.

Study status

Finalised

Research institutions and networks

Institutions

Cardinal Health Specialty Solutions

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Melea Ward

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/10/2015

Actual: 15/10/2015

Study start date
Planned: 30/11/2015

Actual: 28/10/2015

Data analysis start date
Planned: 08/01/2016

Actual: 21/12/2015

Date of interim report, if expected
Planned: 01/04/2016

Actual: 08/04/2016

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

Ibrance EMR utilization study NI Study Protocol 03 December 2015 Final (Clean).pdf(793.86 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:

1. Characterize demographic/clinical characteristics of patients initiating treatment with palbociclib (PAL). 2. Describe PAL utilization by line of therapy. 3. Assess the frequency of PAL dose modification. 4. Quantify frequency of CBC including WBC monitoring including the incidence of neutropenia and 5. Describe treatment patterns pre-treatment, concomitantly, and post-PAL treatment.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective observational 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

Breast cancer female patients at least 18 years of age at date of breast cancer diagnosis who had received at least one prescription for palbociclib during the index period and diagnosed with breast cancer (ICD-9 CM 174.x) anytime prior to or on the date of first prescription for palbociclib.

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

800

Study design details

Data analysis plan

This study is a longitudinal, retrospective observational study. It is descriptive in nature. All female breast cancer patients newly initiating treatment with palbociclib between 01 February 2015 and 31 January 2016 will be included from the EMR database. The index date for the analysis is the date of first treatment administration of palbociclib. EMR data will be extracted for each patient backward in time to the first date of diagnosis for BC and forward up to 31 March 2016.

Documents

Study results

A5481067 Abstract.pdf(153.83 KB)

Data management

ENCePP Seal

Conflicts of interest of investigators

A5481067.pdf(2.31 MB)

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