Outcome of progression free survival in patients with advanced or metastatic, hormone receptor positive, HER2-negative breast cancer treated with palbociclib in combination with fulvestrant or letrozole

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Study Ongoing

Administrative details

EU PAS number

EUPAS34260

Study ID

41563

DARWIN EU® study

No

Study countries

Colombia

Study description

An observational, descriptive study with a prospective and retrospective component cohort will be carried out, based on the review of medical records of women with advanced or metastatic, hormonal receptor positive and HER2-negative breast cancer, treated with palbociclib in combination with letrozole or fulvestrant according to the indications approved by National Institute for Drug and Food Vigilance (INVIMA) in Colombia. The index date will be defined as the date of first prescription of palbociclib. Retrospective data extraction will be conducted in 2 phases. In the first phase, data will be extracted on patients that have experienced disease progression, have deceased, have terminated treatment, have been lost to follow up at the time of study initiation (12 months for second line and 30 months for first line). The second phase of data extracted will be on the patients that are on treatment with palbociclib at the time of study initiation and have been followed by their treating physician for the required period of time. More specifically, patients treated with palbociclib in combination with letrozole as first line of treatment will have a maximum collection period of 30 months. For patients with palbociclib in combination with fulvestrant as second line of treatment or greater, they will have a maximum collection period of 12 months. For this study, patient charts will be reviewed in 10 reference HSP located in major cities of Colombia, which will be selected according to their ability to care for cancer patients, approval of the use of palbociclib, and frequency of use of palbociclib. The selected patients should already be under treatment or have been treated with palbociclib in any combination of hormonal therapies. Data collection will take place on 4 time points that correspond to the review of medical records in the 2 phases.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Giovanna Matiz

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/11/2019

Actual: 13/11/2019

Study start date

Planned: 30/06/2020

Actual: 07/07/2020

Data analysis start date
Planned: 11/09/2020

Date of interim report, if expected
Planned: 31/10/2021

Date of final study report
Planned: 30/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer SAS

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To determine the progression free survival in patients with advanced or metastatic, hormone receptor positive, HER2- negative breast cancer, treated with palbociclib in combination with fulvestrant or letrozol

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

PALBOCICLIB

Medical condition to be studied

Breast cancer metastatic

Additional medical condition(s)

Advanced or metastatic, hormonal receptor positive, HER2- negative breast cancer

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

190

Study design details

Outcomes

Progression free survival, Death Objective response Other variables: • Demographic and clinical characteristics • Patterns treatment • Persistence of Treatment • Date of the first treatment for breast cancer • Access to care for

the treatment of metastatic breast cancer • Access to care from the attending physician • Reasons to produce discontinuation or dosage reduction

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Data analysis plan

Descriptive statistics will be produced for all variables. These will include estimates of the mean, standard deviation, 95% confidence intervals of the mean, median, interquartile ranges and frequency distributions for continuous scale variables and frequency distributions for categorical scale variables. Histograms will be produced for both continuous and categorical scale variables while box plots will be produced for continuous scale variables. For the purposes of this study, the baseline will be the time of initiation of treatment with palbociclib. For the follow up periods longitudinal descriptive data will be produced at time intervals that will be dependent on the distribution of follow up visits. Time to event data including time to disease progression, death, partial response, complete response and treatment discontinuation will be described using the Kaplan Meier estimator of the Survival Function.

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)

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