Treatment patterns and clinical effectiveness outcomes of palbociclib in combination with aromatase inhibitor (AI) or fulvestrant in hormone receptor positive (HR+)/human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer patients: an observational study using Flatiron Electronic Health Record (EHR) database

First published: 22/09/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS21045

Study ID

21046

DARWIN EU® study

No

Study countries

United States

Study description

This is an observational study using de-identified EHR data from Flatiron Health Analytic Database. The main objective is to describe patient demographics, clinical characteristics, treatment patterns and clinical effectiveness outcomes in a cohort of HR+/HER2- breast cancer patients who initiated palbociclib (Ibrance®) in combination with an AI or fulvestrant for treatment of advanced or metastatic disease, using flatiron HER database. The study population includes adult patients diagnosed with breast cancer identified from FI database between 01 January 2011 and 30 June 2017 (defined as “study period”) and who initiated palbociclib for treatment of advanced or metastatic disease on or after 03 February 2015. Information on patient demographics, clinical characteristics, treatment characteristics, CBC monitoring patterns and clinical effectiveness outcomes will be identified.

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

Wanning Xu

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/07/2017

Actual: 06/07/2017

Study start date

Planned: 21/07/2017

Actual: 21/07/2017

Date of final study report

Planned: 15/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc.

Study protocol

Palbociclib A5481076 PROTOCOL AMENDMENT 2_FINAL_22AUG2017_PASS registration version.pdf (512.21 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The main objective is to describe patient demographics, clinical characteristics, treatment patterns and clinical effectiveness outcomes in a cohort of HR+/HER2- breast cancer patients who initiated palbociclib (Ibrance®) in combination with an AI or fulvestrant for treatment of advanced or metastatic disease, using flatiron HER database.

Study drug and medical condition

Medicinal product name

IBRANCE

Medical condition to be studied

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

Study design details

Outcomes

Patient demographics, clinical characteristics, treatment patterns, effectivness outcomes

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Data analysis plan

All analyses will be descriptive in nature and no statistical tests of hypotheses will be performed. Patient demographics, clinical characteristics and/or treatment patterns will be presented for all patients and will be explored by line of therapy (provided data are sufficient). Descriptive statistics will be reported for continuous variables (eg, age, time from initial breast cancer diagnosis to metastatic diagnosis) using the mean, median, 25th and 75th quantiles, minimum, maximum, and standard deviation. Categorical variables (eg, region, stage at initial diagnosis) will be reported using frequencies and proportions. The calculation of percentages will always include the missing category in the case of missing values. Counts of missing observations will thus be included in the denominator and presented as a separate category. Kaplan-Meier figures will be generated for “time to” variables and related statistics will be reported.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Flatiron electronic health record database

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