Safety of Palbociclib Among Breast Cancer Patients in the United States

First published: 28/12/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21948

Study ID

35998

DARWIN EU® study

No

Study countries

United States

Study description

Primary Objective:1. Describe patient characteristics and incidence rates for prespecified safety events among all new users of palbociclib. Secondary Objectives:1. Describe patient characteristics and incidence rates for

prespecified safety events among all subgroups of new users of palbociclib, and 2. among all subgroups who also meet algorithm-defined advanced stage ER+/HER2- breast cancer.3. Compare the incidence rates for prespecified safety events between concomitant new users of palbociclib with fulvestrant to all new users of fulvestrant alone (identified before 2015), conduct same comparison among those who also meet algorithm defined advanced breast cancer.4. Compare IRs for acute liver injury (ALI) between concomitant new users of palbociclib with fulvestrant to a) new users of fulvestrant alone identified before 2/1/ 2015 (historical controls) and b) after 2/1/2015 (contemporaneous controls).5. Adjudicate all potential cases of ALI through medical record review.6. Repeat comparative analyses for ALI using only confirmed cases adjusted for outcomeaccuracy.

Study status

Finalised

Research institutions and networks

Institutions

HealthCore

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Institution

Contact details

Study institution contact

Cynthia de Luise cynthia.deluise@pfizer.com

Study contact

cynthia.deluise@pfizer.com

Primary lead investigator

Cynthia de Luise

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/09/2017

Actual: 19/09/2017

Study start date

Planned: 02/01/2018

Actual: 16/01/2018

Data analysis start date

Planned: 05/02/2018

Actual: 12/03/2018

Date of final study report

Planned: 31/05/2020

Actual: 12/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

Study protocol

A5481105_PROTOCOL_19DEC2017 V1.doc.pdf (1.99 MB)

A5481105_Palbo_Protocol_Amendment_Final.Dec 6 2018_1.pdf (751.41 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

What are the incidence rates of safety events among new users of palbociclib in a real-world setting?

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Active surveillance study

Study drug and medical condition

Medicinal product name

IBRANCE

Additional medical condition(s)

HER-2 positive breast cancer

Population studied

Short description of the study population

The study will include all new users of palbociclib aged >18 years.
Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:
1. At least one dispensing for palbociclib from 01 February 2015 through 31 September 2017 OR dispensing for fulvestrant from 01 January 2011 through 31 January 2015 (for secondary objective 3) OR dispensing for fulvestrant from 01 February 2015 through 31 September 2017 (for secondary objective 4); AND
2. Aged 18 years or older at time of first dispensing of a study drug; AND
3. At least three months membership in the HIRD with no dispensings of palbociclib (or any other CDK4/6 inhibitor such as ribociclib) before the first dispensing of palbociclib, as a minimal baseline period to define new use and characterize baseline risk.

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

Breast Cancer patients

Estimated number of subjects

3.300

Study design details

Outcomes

Describe patient characteristics and incidence rates of prespecified safety events among all new users of palbociclib. Compare IRs for safety events among all subgroups of new users of palbociclib.Compare IRs for safety events between new users of palbociclib with fulvestrant and new users of fulvestrant alone (identified < 2/1/2015).Compare IRs for acute liver injury (ALI) between new users of palbociclib with fulvestrant and new users of fulvestrant alone (both historical and contemporaneous controls).

Data analysis plan

1) Descriptive statistics and incidence rates provided for all prespecified safety events among all new users of palbociclib and by subgroups of new users of palbociclib,2) Analyses repeated for those who also meet algorithm-defined advanced breast cancer,3) Unadjusted and propensity score adjusted hazard ratios for all prespecified safety events between new users of palbociclib with fulvestrant and new users of fulvestrant alone (identified prior to 2015), analyses repeated for those who also meet algorithm-defined advanced breast cancer.4) Unadjusted and propensity score adjusted hazard ratios for ALI between new users of palbociclib with fulvestrant and new users of fulvestrant

alone a) identified prior to 2/1/2015 - historical controls and b) after 2/1/2015- contemporaneous controls,5) Adjudicate all potential cases of ALI through review of medical records.6) Comparative analyses will be reanalyzed using confirmed cases, adjusted for outcome accuracy.

Documents

Study results

A5481105 Study Report and Data Tables and Figures.pdf (8.8 MB)

a5481105-study-data.pdf (1.13 MB)

Study, other information

a5481105-abstract.pdf (1.8 MB)

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)

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

No