

# 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

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### Study ID

35998

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### DARWIN EU® study

No

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### Study countries

 United States

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### 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 outcome accuracy.

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## 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](mailto:cynthia.deluise@pfizer.com)

Study contact

[cynthia.deluise@pfizer.com](mailto: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

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### **Study start date**

Planned: 02/01/2018

Actual: 16/01/2018

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### **Data analysis start date**

Planned: 05/02/2018

Actual: 12/03/2018

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### **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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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

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**Non-interventional study design, other**

Active surveillance study

## Study drug and medical condition

## Medicinal product name

IBRANCE

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## 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.
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### 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)
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## **Special population of interest**

Other

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## **Special population of interest, other**

Breast Cancer patients

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## **Estimated number of subjects**

3300

# 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).

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## **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)

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No