

# Understanding Early and Ongoing Treatment Utilization of Palbociclib in a US Community Oncology Setting

**First published:** 14/12/2016

**Last updated:** 30/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS16706

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### Study ID

18421

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

This is a retrospective observational longitudinal rolling cohort study to assess adult metastatic breast cancer patients initiating treatment with palbociclib from February 2015 to January 2016. Data was cumulatively extracted from The US Oncology Network/McKesson Specialty Health electronic health record database every 2 months. Patients on clinical trial were excluded. Demographic and clinical characteristics, prior treatment, dosing patterns, and duration of treatment were characterized.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[US Oncology Network](#)

## Contact details

### Study institution contact

Ward Melea [melea.ward@pfizer.com](mailto:melea.ward@pfizer.com)

**Study contact**

[melea.ward@pfizer.com](mailto:melea.ward@pfizer.com)

### Primary lead investigator

Melea Ward

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Planned: 23/11/2015

Actual: 23/11/2015

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## **Study start date**

Planned: 01/06/2015

Actual: 01/06/2015

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## **Data analysis start date**

Planned: 15/06/2015

Actual: 15/06/2015

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## **Date of interim report, if expected**

Planned: 31/12/2015

Actual: 01/12/2015

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## **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

## 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:**

Disease /health condition

Human medicinal product

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe the demographic and clinical characteristics of patients newly initiating Palbociclib therapy, To describe early treatment utilization of patients newly initiating Palbociclib therapy including time to discontinuation.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Descriptive, retrospective longitudinal study

## Study drug and medical condition

**Medicinal product name**

IBRANCE

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**Medical condition to be studied**

Breast cancer metastatic

## Population studied

**Short description of the study population**

Female breast cancer patients greater than or equal to 18 years of age who initiated Palbociclib between February 1, 2015 and January 31, 2016.

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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**

Metastatic breast cancer patients

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### **Estimated number of subjects**

1500

## Study design details

### **Data analysis plan**

This study is a longitudinal, retrospective observational study. It is descriptive in nature.

## Documents

### **Study results**

[A5481062 Abstract.pdf](#) (148.67 KB)

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## Study report

[A5481062.pdf](#) (1.23 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**

Unknown