

# Observational multicentric national longitudinal study evaluating Ibrance (palbociclib) in a real life setting conditions in patients 70 years old and older presenting a locally advanced or metastatic HR+/HER2- breast cancer (PalomAGE)

**First published:** 07/03/2018

**Last updated:** 02/07/2024

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/41239>

---

### EU PAS number

EUPAS23012

---

### Study ID

41239

---

## DARWIN EU® study

No

---

### Study countries

☐ France

---

### Study description

Breast cancer is the first cause of cancer in women and constitutes the leading cause of cancer death in women. The combination of palbociclib and hormonal therapy profits equally to younger and older women, nonetheless the data in the elderly population remain incomplete, in particular the impact of the knowledge of the geriatric parameters and the fragility of the patients on the safety, feasibility and efficacy of these new treatments. A multicentric prospective observatory study will allow obtaining data in a real life context on the feasibility of IBRANCE (palbociclib) in patients aged 70 years and older and presenting a locally advanced or metastatic HR+/HER2- breast cancer.

---

### Study status

Ongoing

## Research institutions and networks

### Institutions

Pfizer

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Multiple centres: 60 centres are involved in the study

## Networks

SoFOG

## Contact details

### Study institution contact

Jean Michel Vauthier

Study contact

[Jean-Michel.Vauthier@pfizer.com](mailto:Jean-Michel.Vauthier@pfizer.com)

### Primary lead investigator

Elisabeth Carola

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/06/2018

Actual: 10/11/2017

---

**Study start date**

Planned: 17/09/2018

Actual: 04/10/2018

---

**Data analysis start date**

Planned: 12/06/2023

Actual: 07/11/2019

---

**Date of interim report, if expected**

Planned: 15/06/2020

Actual: 05/12/2019

---

**Date of final study report**

Planned: 30/11/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## 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:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Other

**If 'other', further details on the scope of the study**

Feasibility of treatment

**Main study objective:**

Evaluate the feasibility of palbociclib treatment in patients aged 70 years and older, and treated for metastatic HR+/HER2- breast cancer. The feasibility of the treatment will be evaluated in terms of treatment discontinuation at 6 months in Cohort B and at 18 months in Cohort A for the following reasons: progression, toxicity, patient choice, death.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

IBRANCE

---

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

PALBOCICLIB

## Population studied

### **Short description of the study population**

La cohort A (n=387) is considered as hormonosentive population and will include patient who received prior adjuvant hormone therapy with no relapse during or within one year of the end of adjuvant hormone therapy And /Or patient who didn't received any prior systemic treatment for their advanced disease. Cohort B (n= 400) is considered as population that can't be included in cohort A

---

### **Age groups**

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

---

### **Estimated number of subjects**

787

## Study design details

### **Outcomes**

Treatment discontinuation at 6 months in Cohort B and at 18 months in Cohort A for the following reasons: progression, toxicity, patient choice, death. Time to treatment failure Factors associated with treatment discontinuation according to patients characteristics from DIALOG G CODE PFS, Radiological and clinical tumor response Safety Quality Of life :QLQC30 & EDL 14 Compliance and

treatment modifications

---

### **Data analysis plan**

Population eligible and assessable for the primary criterion: eligible patients having received at least 1 cycle of palbociclib treatment. Analysis of outcome measures Each cohort (1st line and 2nd line and above) will be analysed independently. No statistical comparison will be performed between the two patient cohorts.

## Documents

### **Study publications**

[Brain E, Grosjean J, Pulido M, Paillaud E, Carola E, Jovenin N, Guillem O, Cheh...](#)

---

## Data management

### ENCePP Seal

#### **Composition of steering group and observers**

[Members of the scientific committee.pdf](#)(18.87 KB)

---

## Data sources

### **Data sources (types)**

[Other](#)

---

#### **Data sources (types), other**

Prospective patient-based data collection

## 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