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

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 Jean-Michel.Vauthier@pfizer.com

Study contact

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