“Palbociclib plus Aromatase- inhibitor as first-line treatment for Hormone Receptor (HR)-positive /Human Epidermal Growth Factor Receptor 2 (HER2)-negative locally advanced or metastatic breast cancer patients in Italy: a retrospective observational study (Palbo-Italy)”

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Study Planned

Administrative details

EU PAS number

EUPAS1000000352

Study ID

1000000352

DARWIN EU® study

No

Study countries

☐ Italy

Study description

CDK4/6-inhibitors are the standard of care as first line treatment of HR+/HER2- locally advanced (LA) or metastatic breast cancer (MBC) patients 9-11, as a consequence of positive results from large phase III trials showing a statistically significant and clinically meaningful progression-free survival (PFS) benefit favoring these agents compared to endocrine therapy (ET) alone 16, 38-40. Based on existing evidences, the Italian Regulatory Agency (AIFA) authorized the reimbursement of Palbociclib, Ribociclib and Abemaciclib in combination with endocrine therapy for the treatment of HR+/HER2- LA/MBC patients in 2017 41, 2018 42,43 e 2019 44 respectively.

Patient populations in the real-world setting can vary from those enrolled in clinical trials. Real-world studies provide the unique opportunity to generate evidences on clinical benefit of oncological treatments in a broader population compared to highly-selected patients enrolled in randomized controlled trials (RCT), adding complementary information 45-48. Multiple factors are contributing to the increased interest in RWE, including changes in technology and advancing analytical methods 49, novel types and variety of RWD 50 and the increasing acceptance of RWE from regulatory agencies, Health Technology Assessment (HTA) bodies, and payers 49, 51-55.

For these reasons, the collection of effectiveness and safety data of approved drugs is of clinical interest and can help the decision-making process at many levels.

In Italy there is not a National Cancer Registry to collect structured real-world data on licensed drugs, but there is a clinical need to collect local real-world data to provide a picture of Italian breast cancer usual care. Although there are many real-world studies evaluating palbociclib in the real-life context, the Italian population is often absent or underrepresented.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

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Primary lead investigator

Elena Lattoni

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/02/2025

Study start date
Planned: 01/12/2025

Data analysis start date
Planned: 01/12/2025

Date of final study report
Planned: 25/01/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A5481184_ STUDY PROTOCOL PALBO ITALY _V1.0 _28March2025_Redacted.pdf
(8.16 MB)

Regulatory

Was the study required by a regulatory body?
Unknown

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

retrospective observational study

Data collection methods:

Secondary use of data

Study design:

Non-interventional, retrospective, single arm cohort study in Italy.

Main study objective:

Real-world time to treatment discontinuation for patients treated with palbociclib+aromatase inhibitor as 1st line treatment

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

IBRANCE

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

PALBOCICLIB

Anatomical Therapeutic Chemical (ATC) code

(L01EF01) palbociclib

palbociclib

Medical condition to be studied

Breast cancer

Population studied

Short description of the study population

HR+/HER2- locally advanced or metastatic breast cancer patients treated in first-line with palbociclib+aromatase inhibitor (+/- LHRH analog according to menopausal status) between January 1st, 2018 and June 30th, 2022 in Italy.

Study design details

Setting

This retrospective observational study aims to include HR+/HER2- locally advanced or metastatic breast cancer patients treated with palbociclib + aromatase inhibitor as 1st line treatment between January 1st , 2018 and June 30th, 2022 at approximately 12 sites across all Italian territory. The estimated sample size is of approximately 600 patients. Eligible patients must meet Italian reimbursed indications and inclusion criteria. Patients will be evaluated for

eligibility in a consecutive way across the study period. Patients who switched to palbociclib as a consequence of inacceptable toxicity from another CDK4/6-inhibitor are excluded to avoid confounders in the evaluation of the primary endpoint.

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.

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