Prospective Observational Study of Mobile App-Based Patient-Reported Outcomes in Advanced Breast Cancer in Asia (MADELINE ASIA)

First published: 16/04/2018

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Study Finalised

Administrative details

EU PAS number

EUPAS23593

Study ID

50391

DARWIN EU® study

No

Study countries

Hong Kong

India

Malaysia

Taiwan

Study description

Prospective Observational Study of Mobile App-Based Patient-Reported Outcomes in Advanced Breast Cancer in Asia. The primary objectives are to assess and describe clinical and patient-reported outcomes (PROs) in women with locally advanced/unresectable or metastatic (ABC/mBC) HR+/HER2– breast cancer receiving palbociclib in combination with an aromatase inhibitor or fulvestrant as per product label.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 11 centres are involved in the study

Contact details

Study institution contact

Singh Manmohan manmohan.singh@pfizer.com

Study contact

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Primary lead investigator

Singh Manmohan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/12/2017

Actual: 17/12/2017

Study start date

Planned: 01/10/2019

Actual: 12/03/2020

Data analysis start date

Planned: 01/06/2022

Actual: 12/03/2020

Date of final study report

Planned: 01/12/2022

Actual: 01/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A5481109 Approved Madeline Asia Final Study Protocol March 2018 v0.8_CLEAN COPY..._.pdf (551.88 KB)

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 list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Main study objective:

The primary objectives of this prospective non-interventional study (NIS) are to assess and describe patient-reported outcomes (PROs) in women with locally advanced/unresectable or metastatic (ABC/mBC) HR+/HER2– breast cancer receiving: IBRANCE in combination with Aromatase inhibitor or fulvestrant as per product label

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, multicenter study

Study drug and medical condition

Medicinal product name

IBRANCE

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

PALBOCICLIB

Medical condition to be studied

Breast cancer

Population studied

Short description of the study population

The study population included patients aged 18 years or older diagnosed with advanced or metastatic breast cancer received treatment with palbociclib.

Inclusion Criteria:

1. Owns or has regular access to an Apple iPhone (version 5.0 or higher with latest software: iOS 9.0 or higher) or Android phone (eg, Nexus or Galaxy with latest software: version 4.4.2 or higher).
2. Adult women (≥18 years of age) with diagnosis with advanced or metastatic breast cancer not amenable to resection or radiation therapy with curative intent.
3. Documented evidence of HR+ tumor based on the patient's most recent tumor biopsy.
4. Documented evidence of an HER2– tumor based on the patient's most recent tumor biopsy. HER2– is determined as an immunohistochemistry score of 0/1+ or negative by in situ hybridization (FISH/CISH/SISH) defined as a HER2/CEP17 ratio <2 or, for single probe assessment, a HER2 copy number <4).
5. Initiating first, second or third line treatment with one of the following therapies: palbociclib and an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with advanced or metastatic disease as per label, or palbociclib with fulvestrant if the patient has experienced disease progression following endocrine therapy as per label, or other approved therapy as the first treatment for advanced or metastatic breast cancer, or initiating other approved therapy as the second or third treatment for ABC or mBC.
6. Evidence of a personally signed and dated informed consent form document indicating that the patient has been informed of all pertinent aspects of the study.
7. Able to read and understand English or Mandarin Chinese .
8. Willing and able to complete data entry via smart phone (iphone or android) mobile app.

Exclusion Criteria

1. Patient is initiating neoadjuvant systemic therapy.
2. In the judgment of the investigator, the patient’s life expectancy is fewer than 3 months at the time of diagnosis of ABC or mBC.
3. The patient is participating in any interventional clinical trial that includes investigational or marketed products. Patients participating in other investigator initiated research or non-interventional studies can be included as long as their standard of care is not altered by the study.
4. The patient is on active treatment for other malignancies other than ABC or mBC.
5. Patient eligibility should be reviewed, documented, and confirmed by an appropriately qualified member of the investigator’s study team before patients are enrolled in the study.

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)

Special population of interest

Other

Special population of interest, other

Patients with advanced or metastatic breast cancer

Estimated number of subjects

100

Study design details

Data analysis plan

Descriptive analyses only, no hypotheses being tested

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)

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