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

First published: 24/10/2016

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39939

EU PAS number

EUPAS15951

Study ID

39939

DARWIN EU® study

No

Study countries

☐ United States

Study description

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: 1) IBRANCE in combination with letrozole or fulvestrant as per product label (GROUP 1) or 2) Approved therapies for ABC/mBC other than IBRANCE (GROUP 2)

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

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Institution

Multiple centres: 30 centres are involved in the study

Contact details

Study institution contact

Lynn McRoy

Study contact

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Primary lead investigator

Lynn McRoy

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2016

Actual: 06/03/2016

Study start date

Planned: 23/12/2016

Actual: 02/02/2017

Date of final study report

Planned: 29/09/2020

Actual: 20/08/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

Study protocol

A5481074 Madeline Final Study Protocol_22July2016.pdf(1.28 MB)

A5481074_PROTOCOL_AMENDMENT 1_20JUN2017.doc_1.pdf(2.53 MB)

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:1) IBRANCE in combination with letrozole or fulvestrant as per product label (GROUP 1) or2) Approved therapies for ABC/mBC other than IBRANCE (GROUP 2)

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, multicenter longitudinal study

Study drug and medical condition

Name of medicine

IBRANCE

Medical condition to be studied

Breast cancer stage IV

Population studied

Short description of the study population

Two independent patient groups were included in the study for the purpose of describing the experiences of those on palbociclib and those on other treatments for aBC/mBC:

Group 1: Patients initiating palbociclib treatment

- Approximately 150 to 300 women with HR+/HER2− aBC/mBC who were initiating

o P+AI as initial endocrine-based therapy for postmenopausal women with aBC/mBC per label; OR

o P+Ful for patients with disease progression following endocrine therapy for aBC/mBC per label

Group 2: Patients with aBC/mBC initiating first-, second-, or third-line treatment with any regimen other than those containing palbociclib

- Approximately 150 patients who were initiating treatment with any regimen other than those containing palbociclib for aBC/mBC in first, second, or third lines of treatment

Inclusion Criteria

Patients must have met all of the following inclusion criteria to be eligible for the study:

- Owned or had regular access to an Apple iPhone (version 5.0 or higher with

latest software: iOS 9.0 or higher) or Android phone (e.g., Nexus or Galaxy with latest
software: version 4.4.2 or higher).
- Adult women (≥ 18 years of age) with diagnosis of adenocarcinoma of the breast with evidence of mBC/aBC not amenable to resection or radiation therapy with curative intent
- Documented evidence of HR+ tumor based on the patient's most recent tumor biopsy.
- Documented evidence of an HER2− tumor based on the patient's most recent tumor biopsy. HER2− was 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).
- Initiating first-, second-, or third-line treatment with one of the following therapies: P+AI as initial endocrine-based therapy for postmenopausal women with aBC/mBC as per label, or P+Ful if the patient had experienced disease progression following endocrine therapy as per label, or other approved therapy as the first treatment for aBC/mBC, or initiating other approved therapy as the second or third treatment for aBC/mBC.
- Evidence of a personally signed and dated informed consent form document indicating that the patient had been informed of all pertinent aspects of the study.
- Able to read and understand English
- Willing and able to complete collection of data via mobile app.

Exclusion Criteria

Patients meeting any of the following criteria were not included in the study:
- Patient was initiating neoadjuvant systemic therapy.
- In the judgment of the investigator, the patient's life expectancy was fewer

than 3 months at the time of diagnosis of aBC/mBC.
- The patient was participating in any interventional clinical trial that included investigational or marketed products. Patients participating in other investigator-initiated research or non-interventional studies could be included as long as their standard of care was not altered by the study.
- The patient was on active treatment for other malignancies other than aBC/mBC.

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

Breast Cancer patients

Estimated number of subjects

175

Study design details

Data analysis plan

Descriptive analyses only, no hypotheses being tested

Documents

Study results

A5481074 Non-Interventional Final Study Report_Final v1.0_24AUG2020.pdf

(8.96 MB)

Study publications

Richardson D, Zhan L, Mahtani R, McRoy L, Mitra D, Reynolds M, Odom D, Hollis K...

Data management

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