A disease registry study to prospectively observe treatment patterns and outcomes in patients with HER2-positive unresectable locally advanced or metastatic breast cancer

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Study Finalised

Administrative details

EU PAS number

EUPAS23079

Study ID

25870

DARWIN EU® study

No

Study countries

- ☐ Cyprus
- ☐ Greece

Study description

This observational disease registry is a prospective, multicentre non-interventional study designed to observe clinical outcomes, patient-reported outcomes (PROs), QoL and health economics across anti-cancer treatment regimens and sequences during the course of HER2-positive unresectable locally advanced (LA)/metastatic breast cancer (mBC).

Study status

Finalised

Contact details

Study institution contact

Clinical Trials Hoffmann-La Roche
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Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Clinical Trials Hoffmann-La Roche

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/04/2015

Actual: 27/04/2015

Study start date

Planned: 12/10/2016

Actual: 12/10/2016

Data analysis start date

Planned: 12/10/2016

Actual: 12/10/2016

Date of final study report

Planned: 30/11/2024

Actual: 25/11/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

ML28801_Protocol_Redacted.pdf (616.89 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

ML28801

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Healthcare resource utilisation

Other

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

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

Health Economic Assessment

Data collection methods:

Primary data collection

Main study objective:

In patients with unresectable LA or mBC, 1.) To estimate and describe progression-free survival (PFS) and 2.) To describe treatment regimens and their sequencing

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Disease registry

Study drug and medical condition

Medical condition to be studied

Breast cancer

Population studied

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)

Estimated number of subjects

300

Study design details

Outcomes

In patients with unresectable LA or mBC, 1.) To estimate and describe progression-free survival (PFS) and 2.) To describe treatment regimens and their sequencing, To observe and describe overall survival, duration of response, objective response rate, and safety of anti-cancer treatment regimen of different subpopulations of mBC or LA. To observe and describe incidence of and reasons for changes to anti-cancer treatment, treatment of special interest population and incidence of AEs of interest related to Roche products use and their combination partners.

Data analysis plan

The analysis will make use of descriptive statistical methods. Exploratory statistical testing and modelling will be used to highlight interesting aspects of the data. Any test performed will be two-sided and carried out with a 5% α error rate without correction for multiplicity. The main safety parameter is the incidence of SAEs. The proportion of patients experiencing at least one event within each line of treatment will be estimated with 95% Clopper–Pearson confidence intervals (CI). Analysis of PFS and OS is based on the survivor function. The survival function will be estimated using Kaplan–Meier methodology and summarized using the range, the 25th and 75th percentiles, the median overall survival and a 95% CI for the median. The plot of

Kaplan–Meier estimates for the single treatment group will be presented.

Documents

Study report

ML28801-Final CSR Synopsis_Redacted.pdf (631.22 KB)

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)

Disease registry

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