Multicentre, multi-country, prospective, observational, post-authorisation safety study to describe the incidence of discontinuation due to diarrhoea within the first 3 months of treatment with neratinib, in adult breast cancer patients treated in extended adjuvant in a real world setting: the NERLYFE study

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48088

EU PAS number

EUPAS41584

Study ID

48088

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Czechia
- ☐ Germany
- ☐ United Kingdom

Study description

The study is a European multi-country, multicentre, prospective, observational, PASS with the primary objective of monitoring the incidence of permanent discontinuations due to diarrhea in the first 3 months of treatment with neratinib in the approved indication. It will be conducted as follows: -Core phase: covering the first 3 months of neratinib treatment and evaluating the incidence of permanent discontinuations due to neratinib-related diarrhoea, diarrhoea patterns and diarrhoea management. The accessibility and understanding of information provided in the Educational Materials (EM), adherence to recommendations described in the EM and impact of the EM on diarrhoea patterns will also be assessed. -Extended phase: continuing patient monitoring until neratinib treatment completion up to 12 months and evaluating the cumulative incidence of permanent discontinuations due to neratinib-related diarrhoea, diarrhoea patterns and diarrhoea management at 6 and 12 months as well as treatment maintenance and impact of treatment-related diarrhoea on quality of life over 12 months. The study will address treating physicians (i.e. investigators) experienced in the administration of anti-cancer medicinal products and prescribing neratinib to their patients, and

patients for whom the investigator has decided to begin treatment with neratinib in extended adjuvant in accordance with the approved SmPC and local clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

Covance

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Institution

Clinical Development

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Roberta VALENTI

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/12/2020

Study start date
Planned: 16/05/2022

Actual: 09/05/2022

Date of final study report
Planned: 30/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pierre Fabre Médicament

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To describe the incidence of discontinuation due to diarrhoea within the first 3 months of treatment with neratinib, in adult breast cancer patients treated in extended adjuvant in a real-world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01EH02) neratinib

neratinib

Medical condition to be studied

Diarrhoea

Additional medical condition(s)

Early 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

368

Study design details

Outcomes

Incidence of permanent discontinuation due to diarrhoea within the first 3 months of treatment with neratinib in the approved indication in Europe. Description of diarrhoea patterns. Assessment of educational material

effectiveness (accessibility, knowledge and adherence). Impact of treatment-related diarrhoea on quality of life as assessed by the Systemic therapy-induced diarrhoea assessment tool (STIDAT) questionnaire

Data analysis plan

Analysis will be inherently descriptive and information will be reported in summary tables. Summary data will be provided for all variables collected and the data will be reported overall and by country (if relevant). Continuous variables will be summarized using descriptive statistics. The 95% two-sided Confidence Interval (CIs) of means will be calculated when appropriate using the standard method (Standard normal distribution). Categorical variables will be summarized by numbers and proportions. The 95% two-sided CIs of proportions will be calculated when appropriate using the Wald method. Missing data will not be imputed. Time-to-event endpoints will be expressed in months. For the description, Kaplan-Meier estimates (product-limit estimates) will be presented with a summary of associated statistics including the corresponding two-sided 95% confidence intervals. The Kaplan-Meier curve will also be presented. Individual patient listings will also be provided.

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