Real life safety, effectiveness and quality of life of trastuzumab deruxtecan in patients with metastatic or unresectable HER2-positive breast cancer: a French ambispective multicentre 2 year-follow-up cohort study

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000341

Study ID

1000000341

DARWIN EU® study

No

Study countries

France

Study status

Ongoing

Research institutions and networks

Institutions

Daiichi-Sankyo Europe GmbH

Germany

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Institution **Pharmaceutical company**

Euraxi Pharma

Contact details

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Primary lead investigator

Pr. Jean-Yves Pierga

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/10/2021

Actual: 28/10/2021

Study start date

Planned: 31/03/2021

Actual: 14/12/2021

Date of interim report, if expected

Actual: 08/02/2024

Date of final study report

Planned: 30/09/2024

Sources of funding

- Pharmaceutical company and other private sector

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

NCT05149014

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

National (France), multicentre, ambispective, longitudinal, observational study

Main study objective:

To describe the safety of T-DXd in real life conditions, i.e. the occurrence of T-DXd-related ADRs of interest:

-Any grade:

o ILD / pneumonitis,

o Gastro-intestinal disorders (nausea / vomiting),

o Alopecia,

o Left ventricular ejection fraction (LVEF) decrease,

- Grade ≥ 3 (according to NCI-CTCAE v5.0): other T-DXd-related ADRs.

The primary endpoint is the percentage of subjects with at least one T-DXd related ADR of interest during the 2 years following the start of administration of T-DXd.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ENHERTU

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

TRASTUZUMAB DERUXTECAN

Medical condition to be studied

Breast cancer

Population studied

Short description of the study population

Unresectable or metastatic HER2+ breast cancer, treated at least once with T-DXd (under the ATU or after the market authorization according to the drug SmPC).

Estimated number of subjects

270

Study design details

Setting

Planned recruitment period: 13 months.

Study duration per patient: at most 2 years.

- From 9 months to 1.5 year in the ATU cohort

o FPI: 14/12/2021

o LPO: 06/2024

- At most 2 years in the post-MA cohort.

Data management

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