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

First published: 09/12/2024

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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

Medicinal product name

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

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.

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