A prospective, non-interventional study (NIS) with trastuzumab deruxtecan for patients with HER2-low expressing unresectable and/or metastatic breast cancer accompanied by a disease registry of patients treated with conventional chemotherapy (DESTINY Breast Respond HER2-low Europe)

First published: 23/07/2024

Last updated: 24/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000277

Study ID

1000000277

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland

Study description

This non-interventional study will investigate the effectiveness of T-DXd, the demographic and clinical characteristics of the patients, treatment patterns, tolerability, management of Adverse Drug Reactions (ADRs), and patient experience of T-DXd, in patients with HER2-low unresectable and/or metastatic breast cancer. Patients will be treated according to the proposed indication statement in the Summary of Product Characteristics (SmPC).
In addition, data on conventional chemotherapy (i.e., including but not limited to capecitabine, eribulin, gemcitabine, paclitaxel and nab-paclitaxel) will be collected in a disease registry part of the study. The same inclusion criteria will be applied to patients on conventional chemotherapy. The disease registry part will allow us to understand treatment patterns and outcomes on conventional chemotherapy before the introduction of T-DXd in this patient setting.

Study status

Ongoing

Research institutions and networks

Institutions

Clinical, Regulatory and Safety, Cerner Enviza

Germany

First published: 15/03/2022

Last updated: 05/02/2025

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jean Yves Pierga

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/06/2023

Actual: 06/06/2023

Study start date
Planned: 31/03/2024

Actual: 26/01/2024

Date of final study report
Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Daiichi Sankyo Europe GmbH

Study protocol

DB-RespondHER2low_ShortSynopsis_V2_0_FINAL_20240429_clean.pdf(93.64 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

NCT05945732

Link to clinicaltrials.gov

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Multinational, multicenter, prospective observational, noninterventional study

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

Anatomical Therapeutic Chemical (ATC) code

(L01FD04) trastuzumab deruxtecan

trastuzumab deruxtecan

Medical condition to be studied

HER2 low breast cancer

Population studied

Short description of the study population

Setting:

• 1350 patients from different countries and care settings (primary care and

secondary care and different specialties)

The study population consists of adult patients with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

1350

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)

Other

Data sources (types), other

As this is a non-interventional study, only data on clinical routine practice will be documented. To facilitate accurate recording of data, patients can optionally fill in a memory aid to note important details.

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

Unknown