

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

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### **Study ID**

1000000277

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**DARWIN EU® study**

No

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### **Study countries**

- Austria
  - Belgium
  - Denmark
  - France
  - Italy
  - Netherlands
  - Norway
  - Portugal
  - Spain
  - Sweden
  - Switzerland
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### **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.

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### **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**

[Angelika.Wientzek-Fleischmann@daiichi-sankyo.eu](mailto:Angelika.Wientzek-Fleischmann@daiichi-sankyo.eu)

### 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

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**Study start date**

Planned: 31/03/2024

Actual: 26/01/2024

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**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

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

Not applicable

## Other study registration identification numbers and links

NCT05945732

[Link to clinicaltrials.gov](https://clinicaltrials.gov)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

Multinational, multicenter, prospective observational, noninterventional study

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

ENHERTU

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

TRASTUZUMAB DERUXTECAN

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**Anatomical Therapeutic Chemical (ATC) code**

(L01FD04) trastuzumab deruxtecan

trastuzumab deruxtecan

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**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.

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**Age groups**

- **Adult and elderly population ( $\geq 18$  years)**
  - Adults (18 to < 65 years)

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Elderly ( $\geq$  65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)
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### **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](#)

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown