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





### Administrative details

**EU PAS number** 

EUPAS1000000277

**Study ID** 

1000000277

**DARWIN EU® study** 

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
<b>Last updated:</b> 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

### 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

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

#### **Medicinal product name**

**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)</li>

- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)
- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)</li>
  - 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