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)

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000277

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 institution and networks

Institutions

Clinical, Regulatory and Safety, Cerner Enviza
Germany
First published: 15/03/2022
Last updated 06/03/2024
Institution
Non-Pharmaceutical company
ENCePP partner

Contact details

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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

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

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