A Prospective non-interventional study (NIS) of trastuzumab deRuxtecan (T-DXd) for adult patients with advanced HER2-pOsitive gaStric or gastroesoPhageal junction (GEJ) adEnocarcinoma who have Received a prIor Trastuzumab-based regimen, accompanied by a disease registrY of patients treated with conventional therapies in a real-world setting in Europe (PROSPERITY).

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000340

EU PAS number

EUPAS1000000340

Study ID

1000000340

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium
- ☐ Germany
- ☐ Italy
- ☐ Portugal

Study status

Planned

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**

Daiichi-Sankyo Europe GmbH

Germany

First published: 23/07/2024

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Institution | Pharmaceutical company

Contact details

Study institution contact

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Primary lead investigator

Petra Laeis

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

Date of final study report

Planned: 30/09/2027

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Data collection methods:

Primary data collection

Study design:

Multinational, multicenter, prospective observational, non-interventional study with trastuzumab deruxtecan in adult patients with advanced HER2-positive gastric or GEJ adenocarcinoma who have received a prior trastuzumab-based regimen in a real-world setting in Europe

Main study objective:

The primary objective is to describe the effectiveness of T-DXd based on real-world Time to Next Treatment (rwTTNT1) in adult patients with advanced HER2-positive gastric or GEJ adenocarcinoma who have received a prior trastuzumab-based regimen in a real-world setting.

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

Medical condition to be studied

Gastric cancer

Population studied

Short description of the study population

Adult patients planned to be treated with T-DXd or conventional therapies for advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen

Data management

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