Non-interventional, real-world study of patients with early stage, human epidermal growth factor receptor 2 (HER2) positive breast cancer (BC) receiving Trazimera (VESTA)

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# Administrative details

EU PAS number
EUPAS32829
Study ID
32830
DARWIN EU® study
No
Study countries
Netherlands
Norway

#### Study description

The purpose of this observational study is to collect and analyze data in adult patients with early stage (stage 0-3) HER2 positive BC initiating treatment with Trazimera (cohort 1) or trastuzumab and transitioning to Trazimera (cohort 2) in a real-world setting. This non-interventional study (NIS) post authorization safety study (PASS) is conducted voluntarily by the marketing authorization holder. There will be no imposed experimental intervention, required visits, or study related procedures and treatment with Trazimera is determined solely by the patient's physicians separately and irrespective of the decision to participate in this study. The data captured and reported will reflect a real-world approach to the treatment of patients with BC administered Trazimera. This is an ambispective (retrospective and prospective) observational, multi-site, multicountry, study conducted in adult patients who are receiving Trazimera as neoadjuvant or adjuvant therapy for the treatment of BC, using 2 cohorts of patients. In cohort 1, the study plans to recruit up to 200 subjects with early stage BC, in which the participating physician has decided to treat with Trazimera as Brief description of the study The purpose of this observational study is to collect and analyze data in adult patients with early stage (stage 0-3) HER2 positive BC initiating treatment with Trazimera (cohort 1) or trastuzumab and transitioning to Trazimera (cohort 2) in a real-world setting. This non-interventional study (NIS) post authorization safety study (PASS) is conducted voluntarily by the marketing authorization holder. There will be no imposed experimental intervention, required visits, or study related procedures and treatment with Trazimera is determined solely by the patient's physicians separately and irrespective of the decision to participate in this study. The data captured and reported will reflect a real-world approach to the treatment of patients with BC administered Trazimera

#### **Study status**

Planned

### Research institutions and networks

## Institutions

## Pfizer

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Institution

## Contact details

### **Study institution contact**

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Study contact

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### **Primary lead investigator**

Ahmed Shelbaya

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Planned: 12/03/2018 Actual: 12/03/2018

Study start date

Planned: 20/12/2019

#### Data analysis start date

Planned: 02/01/2021

#### Date of interim report, if expected

Planned: 30/03/2021

#### **Date of final study report**

Planned: 30/03/2022

## Sources of funding

Pharmaceutical company and other private sector

## More details on funding

Pfizer, Inc

## Study protocol

Pfizer B3271014 Trazimera Real World Evidence Protocol v1 05Sep2019.pdf (1014.52 KB)

# Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

# Methodological aspects

#### Study type:

Non-interventional study

#### Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

#### Main study objective:

To describe treatment patterns in patients with early stage (stage 0-3) HER2 positive BC and treated with Trazimera, including combination therapies, as neoadjuvant or adjuvant treatment in a real-world setting

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### **Medicinal product name**

TRAZIMERA

#### Medical condition to be studied

HER2 positive breast cancer

## Population studied

#### Age groups

- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### **Estimated number of subjects**

350

# Study design details

#### **Outcomes**

Duration of treatment, treatment adherence, treatment discontinuation rates and rationale, Demographic characteristics, tolerability, patient reported quality of life, and healthcare resource utilization

### Data analysis plan

Descriptive statistics to characterize treatment patterns, tolerability, demographics, patient related quality of life, and healthcare resource utilization

## 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

Prospective patient-based data collection

## 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**

# Data characterisation

### **Data characterisation conducted**

No