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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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/32830

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, multi-country, 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

Study type list

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

Name of medicine

TRAZIMERA

Medical condition to be studied

HER2 positive breast cancer

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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

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

Unknown

Data characterisation

Data characterisation conducted

No