An Observational Study of Treatment Patterns and Safety Outcomes for Metastatic or Locally Recurrent Breast Cancer (AVF4349n)

First published: 01/10/2012

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Study Planned

Administrative details

EU PAS number

EUPAS3017

Study ID

3018

DARWIN EU® study

No

Study countries

United States

Study description

This is a multicenter, prospective OCS designed to follow patients with locally recurrent or metastatic breast cancer in the United States. Two cohorts will be included:- Patients with HER2-negative disease (as determined by the investigator) receiving their first cytotoxic chemotherapy and/or targeted therapy (approximately 825 patients)-Patients with HR-positive disease (as determined by the investigator) receiving their first HT for advanced disease (approximately 425 patients)

Study status

Planned

Research institutions and networks

Institutions

Genentech

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Institution | Other

Contact details

Study institution contact

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Study contact

dalal.darshan@gene.com

Primary lead investigator

Dalal Darshan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/06/2008

Study start date

Planned: 02/06/2008

Date of final study report

Planned: 01/04/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genentech Inc

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

1. To explore differences in clinical outcomes such as response rate (RR), time to treatment failure (TTF), time to next therapy, progression-free survival (PFS), and overall survival (OS) for various subpopulations of advanced breast cancer patients 2.To understand differences in the natural history of advanced breast cancer based on treatment patterns3. To describe specific safety events

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Additional medical condition(s)

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

1.250

Study design details

Outcomes

Clinical Effectiveness EndpointsClinical Safety Endpoints, -Time to loss of work ability for MBC patients who are working at baseline as measured by the WPAI:SHP-Activity Level Scale score over time-Percent of productivity loss due to MBC

Data analysis plan

Safety and effectiveness outcomes will be analyzed using univariate analysis, stratified analysis by relevant baseline risk factors (including HR status, current and prior treatments), and multivariable analysis to adjust for potential confounding factors.TTF, PFS, and OS will be summarized using the Kaplan Meier method. Exploratory model-based analyses will be performed using multivariable Cox regression models to identify factors associated with TTF, PFS, and OS. Patients will be censored at study termination, loss to follow-up, patient’s decision, investigator’s decision, or Sponsor’s decision to terminate study participation, or at the data cutoff date. In addition, point estimates and 95% confidence intervals will be calculated for response rate (RR).

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

Unknown

Data characterisation

Data characterisation conducted

No