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

First published: 27/09/2012

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/16776

EU PAS number

EUPAS3014

Study ID

16776

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-normal disease receiving their first cytotoxic chemotherapy and/or targeted therapy (1500 patients)•Patients with HR-positive tumors receiving their first HT for advanced disease (500 patients) Patients who started their first systemic treatment for advanced breast cancer within 1 month prior to enrollment into this OCS will be eligible. A total of approximately 2000 patients will be enrolled. In order to assure that treatment patterns over time are represented in the study, the number of sites activated will be determined by projections to achieve complete enrollment over approximately 18-24 months.

Study status

Planned

Research institutions and networks

Institutions

Marquette General Health System

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Institution

Contact details

Study institution contact

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Study contact

genentechclinicaltrials@druginfo.com

Primary lead investigator

Aaron Scholnik

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2006

Study start date

Planned: 02/06/2008

Date of final study report

Planned: 02/06/2008

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genentech

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

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Study Design

Non-interventional study design

Cohort

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

1500

Study design details

Data analysis plan

TBD

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