An observational post-marketing surveillance study on the status and factors for the development of peripheral neuropathy in patients with HER2-negative inoperable or recurrent breast cancer in Japan (HAL02T)

First published: 04/09/2014

Last updated: 15/11/2019

Study Finalised

Administrative details

EU PAS number

EUPAS7424

Study ID

32353

DARWIN EU® study

No

Study countries

Japan

Study description

Patients with HER-2 negative inoperable or recurrent breast cancer treated with eribulin will be followed for up to two years to evaulate the incidence of peripheral neuropathy and any factors that influence the incidence. CTCAE grade of peripheral neuropathy will be assessed at baseline and every two months after initiation of treatment.

Study status

Finalised

Research institutions and networks

Institutions

Eisai

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

Yvonne Lamb yvonne_lamb@eisai.net

Study contact

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Primary lead investigator

Yvonne Lamb

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2014

Actual: 01/09/2014

Study start date

Planned: 30/09/2014

Actual: 29/09/2014

Date of final study report

Planned: 28/06/2019

Actual: 25/02/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To clarify the factors affecting the incidence of peripheral neuropathy

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-randomised clinical trial

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

ERIBULIN MESYLATE

Medical condition to be studied

Breast cancer recurrent

Population studied

Short description of the study population

Patients with HER-2 negative inoperable or recurrent breast cancer treated with eribulin.

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)

Special population of interest

Other

Special population of interest, other

Breast Cancer patients

Estimated number of subjects

590

Study design details

Data analysis plan

The analysis method is descriptive and includes assessment of patient history and concomitant medications and assessment of the incidence, latency, resolution and treatment of peripheral neuropathy

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