Post-marketing surveillance of Lenvima in patients with unresectable thyroid cancer in Japan (LEN01T)

First published: 02/08/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS14555

Study ID

33058

DARWIN EU® study

No

Study countries

☐ Japan

Study description

All patients with unresectable thyroid cancer administered Lenvima in Japan will be registered and monitored for safety, and efficacy (overall survival at one year and response rate)

Study status

Finalised

Research institutions and networks

Institutions

Eisai

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Institution

Multiple centres: 40 centres are involved in the study

Contact details

Study institution contact

Yvonne Lamb qppv_office@eisai.net

Study contact

qppv_office@eisai.net

Primary lead investigator

Yvonne Lamb

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/04/2016

Study start date

Actual: 20/05/2016

Date of final study report

Planned: 31/12/2017

Actual: 17/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai Inc

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

E7080-M081-501

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

To monitor the safety (and efficacy) of lenvatanib in patients with unresectable thyroid cancer in Japan, to assess incidence of adverse events in post marketing setting, e.g. hypertension

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Intensive monitoring schemes, Post-marketing surveillance

Study drug and medical condition

Name of medicine

LENVIMA

Medical condition to be studied

Thyroid neoplasm

Population studied

Short description of the study population

Patients with unresectable thyroid cancer administered Lenvima in Japan.

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

Thyroid cancer patients

Estimated number of subjects

400

Study design details

Data analysis plan

The analysis method is primarily descriptive: DemographicsConcomitant medicationsAdverse eventsEfficacy (overall response rate and survival at one year)

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