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

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# 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 regulator	y body?
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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

### **Medicinal product name**

**I FNVIMA** 

### 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

# **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