A Prospective, Non-Interventional, Post-Marketing Observational Study Evaluating the Effectiveness and Safety of Selpercatinib Capsules in Adults and Pediatric Patients with Advanced or Metastatic RET Fusion-Positive Thyroid Cancer

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Study Planned

Administrative details

EU PAS number

EUPAS105321

Study ID

105322

DARWIN EU® study

No

Study countries

China

Study status

Planned

Research institutions and networks

Institutions

Peking Union Medical College Hospital

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Institution

- Union Hospital, Tongji Medical College, University of Science and Technology, Wuhan
- Zhejiang Cancer Hospital, Hangzhou
- Shanghai Tenth People's Hospital
- The Affiliated Hospital of Xuzhou Medical University

Contact details

Study institution contact

Ding Ding ding_ding1@lilly.com

Study contact

ding_ding1@lilly.com

Primary lead investigator

Yansong Lin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/10/2022

Actual: 27/10/2022

Study start date

Planned: 03/01/2024

Data analysis start date

Planned: 30/01/2026

Date of final study report

Planned: 30/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly

Study protocol

LY3527723 J2G-GH-B003 Observational Study Protocol - approved.pdf (1.06 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of this study is to evaluate the effectiveness of selpercatinib by assessing real-world objective response rate (rwORR) in a routine clinical practice setting during the follow-up period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Retevmo

Anatomical Therapeutic Chemical (ATC) code

(L01EX22) selpercatinib

selpercatinib

Medical condition to be studied

Thyroid cancer

Population studied

Age groups

- Adolescents (12 to < 18 years)
- 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

15

Study design details

Outcomes

rwORR, rwPFS, rwDoR, rwDCR

Data analysis plan

Primary Objective Analyses: The rwORR will be summarized using descriptive analysis, described in terms of frequencies and percentages, and provide a 95% CI.

Secondary Objective Analyses: Time-to-event analyses (rwPFS and rwDoR) will be performed using Kaplan-Meier estimates to calculate median and 95% CI and estimates at specific time points (e.g. 6 months, 12 months). Patients who are alive and without documented PD as of a data analysis cut-off date will be right-censored. The censoring date will be determined from the date of last follow-up to the patient without progression. rwDCR will be summarized using descriptive analysis, described in terms of frequencies and percentages, and provide a 95% CI.

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