Real World Evaluation of Sotorasib among Chinese Non-Small Cell Lung Cancer Patients (20240175)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000636

Study ID

1000000636

DARWIN EU® study

No

Study countries

☐ China

Study status

Planned

Research institutions and networks

Institutions

Amgen

United States

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Institution

Ruijin-Hainan Hospital Shanghai Jiao Tong University School of Medicine Hainan Boao Research Hospital

Boao Evergrande International Hospital

Boao Super Hospital

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/07/2025

Study start date
Planned: 30/08/2025

Data analysis start date
Planned: 28/02/2026

Date of final study report
Planned: 30/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc

Study protocol

Protocol-Published Original sotorasib 20240175 redacted.pdf(463.13 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

20240175

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a retrospective medical chart review study of Chinese participants treated with sotorasib in real-world and clinical settings in BOAO Pilot Zone and Hong Kong SAR.

Main study objective:

The main objective of the study is to characterize the safety profile of sotorasib.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective medical chart review study.

Study drug and medical condition

Name of medicine, other

LUMAKRAS® (sotorasib)

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

Adult participants with KRAS p.G12C-mutated locally advanced or metastatic NSCLC and previously treated with at least 1 prior systemic therapy that have received sotorasib treatment in either location of BOAO Pilot Zone and Hong Kong Special Administrative Region (SAR).

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

115

Study design details

Setting

Two regions will be included in the study, ie, BOAO Pilot Zone and Hong Kong SAR. Until data cut-off date, approximately 100 sotorasib treated participants in

Hainan BOAO Pilot Zone, and about 15 participants in Hong Kong SAR, will be eligible for medical chart review.

Outcomes

Primary outcomes

1. Number of participants experiencing adverse events (AE) after sotorasib initiation

Secondary outcomes

1. Overall survival (OS) from initial date of sotorasib use to date of death

Exploratory

· Describe real-world PFS of sotorasib

· Describe any reported quality of life scores or lung cancer-related respiratory symptom scores before and after treatment of sotorasib

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Data analysis plan

The analyses of all objectives will be performed using descriptive statistical methods. No hypotheses testing is planned.

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 source(s), other

o Internal system of hospitals in BOAO Pilot Zone

o Clinical Data Analysis and Reporting System (CDARS) database in Hong Kong SAR

o Electronic Patient Record/Clinical Management System [EPR/CMS] in Hong Kong SAR

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes