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

First published: 01/07/2025

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000636

Study ID

1000000636

DARWIN EU® study

No

Study countries

China

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Ruijin-Hainan Hospital Shanghai Jiao Tong University School of Medicine, Boao Super Hospital, Boao Evergrande International Hospital, Boao Vanguard Hospital

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

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: 11/08/2025

Actual: 11/08/2025

Data analysis start date
Planned: 02/02/2026

Actual: 02/02/2026

Date of final study report
Planned: 31/07/2026

Actual: 21/07/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc

Study protocol

Protocol-Published Amendment sotorasib 20240175 1 .pdf (615.93 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.

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

Medicinal product name, other

LUMAKRAS® (sotorasib)

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

SOTORASIB

Anatomical Therapeutic Chemical (ATC) code

(L01XX73) sotorasib

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 BOAO Pilot Zone.

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

130

Study design details

Setting

The BOAO Pilot Zone will be the only region included in this study. Until data cut-off date, approximately 100-130 sotorasib treated participants in Hainan BOAO Pilot Zone 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.

Summary results

CONCLUSION

This real-world observational study provides real-world evidence on the safety and effectiveness of sotorasib in Chinese patients with KRAS p.G12C-mutated locally advanced or metastatic NSCLC who received prior systemic therapy. The findings are consistent with the established benefit-risk profile of sotorasib, with no new safety

signals were identified.

Documents

Study report

sotorasib_20240175_Study_Report_Body_Observational_Final_Analysis_ (1).pdf

(11.13 MB)

Data management

Data sources

Data source(s), other

Internal system of hospitals in BOAO Pilot Zone

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

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