Observational Study on the Safety and Effectiveness of Sotorasib in South Korea (20200009)

First published: 18/04/2023

Last updated: 06/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS104428

Study ID

105849

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

The primary objective is to describe safety of sotorasib in post-marketing clinical practice within
the approved indication by estimating the incidence of adverse events, serious adverse events, adverse drug reactions, serious adverse drug reactions, unexpected adverse events, unexpected serious adverse events, unexpected adverse drug reactions, unexpected serious adverse drug
reactions, leading to discontinuation of sotorasib, and fatal events; as required by the Ministry of Food and Drug Safety (MFDS). The secondary objective is to describe effectiveness of sotorasib in clinical practice within the approved indication by estimating overall response rate (ORR) and clinical outcome measure by the investigator.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

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: 31/10/2022

Actual: 06/03/2023

Study start date

Planned: 18/08/2023

Actual: 13/09/2024

Data analysis start date

Planned: 05/01/2027

Date of final study report

Planned: 13/04/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original sotorasib 20200009 .pdf (764.52 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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)

Other

If ‘other’, further details on the scope of the study

Safety Reporting

Main study objective:

To describe the safety of sotorosib in post-marketing clinical practice within the approved indication.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective and Prospective, observational Study

Study drug and medical condition

Medicinal product name

LUMYKRAS

Medicinal product name, other

Lumakras

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

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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

25

Study design details

Outcomes

Incidence of adverse events, serious adverse events, adverse drug reactions, serious adverse drug reactions, unexpected adverse drug reactions, unexpected serious adverse drug reactions, adverse events leading to sotorasib discontinuation and fatal events. Overall Response Rate (ORR) and clinical outcome measure by the Investigator.

Data analysis plan

The data will be summarized descriptively. The incidence of adverse events will be summarized to include all treatment-emergent adverse events recorded from the start of sotorasib on this study or any worsening of medical conditions initially experienced before initiation of this study.

All adverse events will be graded using the most recent Common Terminology Criteria for Adverse Events (CTCAE) version. The 6-month cumulative incidence of adverse events will be presented as frequency and percentage, and the 95% CI for the incidence estimate using an exact method will be provided. The Full Effectiveness Analysis Set will include all subjects from the Safety Analysis Set who also have at least 1 follow-up tumor assessment to estimate the ORR after initiation of sotorasib.

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

Spontaneous reporting system, prospective and retrospective patient-based data collection

Data sources (types)

Other

Data sources (types), other

Spontaneous reporting system, 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