Special Drug Use-Results Surveillance (all-case) for sotorasib in patients with KRAS G12C-mutated, unresectable, advanced and/or recurrent non-small-cell lung cancer, that has progressed after systemic anticancer therapy in Japan (20210051)

First published: 19/04/2022

Last updated: 02/05/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47965

EU PAS number

EUPAS46655

Study ID

47965

DARWIN EU® study

No

Study countries

Japan

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.

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: 20/04/2022

Actual: 20/04/2022

Study start date
Planned: 01/07/2022

Actual: 30/06/2022

Data analysis start date
Planned: 01/08/2026

Date of final study report
Planned: 01/08/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original sotorasib 20210051 .pdf(5.87 MB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The main objectives of this study are to describe the rate of hepatic impairment, to describe associations between clinical characteristics and hepatic impairment to potentially identify risk factors and to describe the rate of interstitial lung disease (ILD) in all patients treated with sotorasib in post-marketing clinical settings in Japan.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

LUMYKRAS

Name of medicine, 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

Non-small cell lung cancer recurrent

Non-small cell lung cancer stage III

Non-small cell lung cancer stage IIIA

Non-small cell lung cancer stage IIIB

Non-small cell lung cancer stage IV

Additional medical condition(s)

KRAS G12C-mutated and/or Unresectable non-small cell lung 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

300

Study design details

Outcomes

• Patient incidence of hepatic impairment

• Patient incidence of hepatic impairment by patient background

• Patient incidence of ILD,

• Patient incidence of ILD by patient background

• Patient incidence of adverse events (AEs)

• Patient incidence of serious AEs

• Patient incidence of adverse drug reactions (ADRs)

• Patient incidence of serious ADRs

• Patient incidence of ADRs by patient background including hepatic impairment

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Data analysis plan

As the primary analysis, the patient incidences of hepatic impairment and IDL will be summarized. In addition, hepatic impairment will be tabulated by patient characteristics to describe associations between clinical characteristics and

hepatic impairment to potentially identify risk factors. As a secondary analysis, ILD will be tabulated by patient characteristics to describe associations between clinical characteristics and ILD to potentially identify risk factors. In addition, the incidence of all AE and ADR will be tabulated in patients with hepatic impairment and all patients.

Data management

Data sources

Data source(s), other

Data are collected through CRF, which are populated by the investigators.

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