

# 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

### 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.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto: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

### 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

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
- 

## **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

### 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**

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