

# Comparative effectiveness of sotorasib versus docetaxel in second line and beyond (2L+) among patients with advanced non-small cell lung cancer (NSCLC) in the Flatiron Health (FH) Enhanced Datamart (EDM)

**First published:** 25/03/2024

**Last updated:** 27/01/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000056

---

### Study ID

1000000056

---

### DARWIN EU® study

No

---

### Study countries

 United States

---

### Study description

To compare overall survival in KRAS G12C advanced NSCLC patients initiating treatment with sotorasib monotherapy versus docetaxel monotherapy or combination therapy in 2L setting.

---


### Study status

Ongoing

## Research institutions and networks

### Institutions

**Amgen**

 United States

**First published:** 01/02/2024

**Last updated:** 27/03/2026

**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: 03/01/2024

Actual: 15/01/2024

---

### Study start date

Planned: 05/02/2024

Actual: 10/02/2024

---

### Data analysis start date

Planned: 15/02/2024

Actual: 15/02/2024

---

### Date of interim report, if expected

Planned: 30/06/2024

---

### Date of final study report

Planned: 27/02/2026

## Sources of funding

- No external funding

## Regulatory

**Was the study required by a regulatory body?**

No

---

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

Non-EU RMP only

**Other study registration identification numbers and links**

20230266

**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)

**Data collection methods:**

**Study design:**

This study will comprise of two cohorts: Sotorasib cohort: KRAS p.G12C-mutated advanced NSCLC patients who initiated sotorasib monotherapy in 2L/2L+ between 28 May 2021 (date of US FDA approval) and 30 Sep 2022; Docetaxel cohort: KRAS p.G12C-mutated advanced NSCLC patients who initiated docetaxel.

**Main study objective:**

To compare overall survival in KRAS p.G12C-mutated advanced NSCLC patients initiating treatment with sotorasib monotherapy versus docetaxel monotherapy or combination therapy in second line (2L) setting, within the US FH EDM.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

LUMAKRAS® (sotorasib)

Drug 1: sotorasib

Drug 2: docetaxel

---

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

DOCETAXEL

### **Anatomical Therapeutic Chemical (ATC) code**

(L01CD02) docetaxel

docetaxel

(L01XX73) sotorasib

sotorasib

---

### **Medical condition to be studied**

Non-small cell lung cancer

## Population studied

### **Short description of the study population**

- Patients with advanced NSCLC will be identified from the Flatiron Health EDM
  - Flatiron Health EDM includes over 280 community oncology practices and several academic centers throughout the US
- 

### **Age groups**

- **Adult and elderly population ( $\geq 18$  years)**
    - Adults (18 to < 65 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**

471

## Study design details

## Setting

Community oncology practices and several academic centers throughout the US.

---

## Comparators

Docetaxel monotherapy or combination therapy in 2L+ setting.

---

## Outcomes

Primary Outcome:

- Overall survival (OS) of participants treated with sotorasib monotherapy versus docetaxel monotherapy or combination therapy in 2L setting.

Secondary Outcome:

- OS of participants treated with sotorasib monotherapy versus docetaxel monotherapy or combination therapy in 2L+ setting.
- 

## Data analysis plan

Nonparametric methods will be used to estimate OS. Median OS and corresponding 95% confidence intervals (CIs) will be calculated using Kaplan-Meier estimates. The estimated survival probabilities for OS and corresponding 95% CIs will be presented for patients at 6- and 12-months.

## 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**

Flatiron Health (FH) Enhanced Datamart (EDM)

---

### **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**

Unknown