

# 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:** 15/10/2024

Study

Ongoing

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/1000000056>

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### **EU PAS number**

EUPAS1000000056

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### **Study ID**

1000000056

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## DARWIN EU® study

No

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### Study countries

United States

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### 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.

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### 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](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

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**Study start date**

Planned: 05/02/2024

Actual: 10/02/2024

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**Data analysis start date**

Planned: 15/02/2024

Actual: 15/02/2024

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**Date of interim report, if expected**

Planned: 30/06/2024

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**Date of final study report**

Planned: 12/12/2025

## Sources of funding

- No external funding

## Regulatory

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

No

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

**Name of medicine**

DOCETAXEL

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**Name of medicine, other**

LUMAKRAS® (sotorasib)

Drug 1: sotorasib

Drug 2: docetaxel

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

DOCETAXEL

SOTORASIB

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**Anatomical Therapeutic Chemical (ATC) code**

(L01CD02) docetaxel

docetaxel

(L01XX73) sotorasib

sotorasib

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**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
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**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)

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### **Estimated number of subjects**

471

## Study design details

### **Setting**

Community oncology practices and several academic centers throughout the US.

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### **Comparators**

Docetaxel monotherapy or combination therapy in 2L+ setting.

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### **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.

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### **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

**Data source(s), other**

Flatiron Health (FH) Enhanced Datamart (EDM)

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**Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Yes

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Unknown