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

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: 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: 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: 12/12/2025

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:

Secondary use of data

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

Name of medicine, other

LUMAKRAS® (sotorasib)

Drug 1: sotorasib

Drug 2: docetaxel

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

DOCETAXEL

SOTORASIB

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 (≥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

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