Comparative Effectiveness of Sotorasib Versus Docetaxel Monotherapy in Second Line and Beyond (2L+) Among Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) in the Cancer Analysis System Database in England (20240164)

First published: 06/12/2024

Last updated: 20/03/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000405

EU PAS number

EUPAS1000000405

Study ID

1000000405

DARWIN EU® study

No

Study countries

United Kingdom

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: 22/05/2024

Actual: 22/05/2024

Study start date
Planned: 10/12/2024

Actual: 10/12/2024

Data analysis start date
Planned: 17/03/2025

Actual: 17/03/2025

Date of final study report
Planned: 30/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This study is being funded by Amgen Inc.

Study protocol

Protocol-Published Original sotorasib 20240164 (2).pdf(708.82 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

20240164

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:

Comparative, retrospective, new-user cohort study using secondary real-world data to generate evidence on the comparative effectiveness of sotorasib versus docetaxel monotherapy in 2L+.

Main study objective:

To compare overall survival in patients with locally advanced or metastatic NSCLC who initiated treatment with sotorasib monotherapy versus docetaxel monotherapy in 2L+.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Comparative, retrospective, new-user cohort study

Study drug and medical condition

Name of medicine

LUMYKRAS

DOCETAXEL

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

DOCETAXEL

SOTORASIB

Anatomical Therapeutic Chemical (ATC) code

(L01CD02) docetaxel

docetaxel

(L01XX73) sotorasib

sotorasib

Population studied

Short description of the study population

Patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who had received at least 1 prior systemic therapy

Age groups

Adults (18 to < 65 years)

Special population of interest

Other

Special population of interest, other

Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)

Estimated number of subjects

1290

Study design details

Comparators

Docetaxel

Outcomes

The outcome variables to be assessed are overall survival (OS), time to next treatment or death (TTNTD), time to treatment discontinuation or death (TTDD)

Data analysis plan

The study will describe baseline demographics, clinical and tumor characteristics.

Propensity score-based weighting will account for baseline confounding, with covariate balance assessed using standardized mean differences (SMDs). Kaplan-Meier methods and Cox proportional hazards regression will evaluate treatment effectiveness, reporting median survival times, confidence intervals, and hazard ratios (HRs), with unadjusted and adjusted HRs provided based on propensity score weighting, prior therapies, and molecular variables for the overall population and stratified by treatment group.

Data management

Data sources

Data sources (types)

Clinical trial

Disease registry

Non-interventional study

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

Yes