A Retrospective Cohort Study to Characterize Patient Characteristics and Treatment Outcomes Among Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC) in the French Epidemiological Strategy and Medical Economics Advanced or Metastatic Lung Cancer (ESME-AMLC) Database (20190402)

First published: 05/05/2021

Last updated: 29/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS40706

Study ID

50487

DARWIN EU® study

No

Study countries

France

Study description

A retrospective cohort study of locally advanced (stage IIIB/C) or metastatic (stage IIIB/C) non-small cell lung cancer (NSCLC) in the French Epidemiological Strategy and Medical Economics Advanced or Metastatic Lung Cancer (ESME-AMLC) Data Platform.

The study population consists of adult (≥ 18 years of age) patients diagnosed with locally advanced or metastatic (stage IV) non squamous NSCLC between 1 Jan 2015 – 30 Jun 2022.

Patients are followed up from the date of diagnosis of advanced or metastatic NSCLC until death or date of last contact whichever occurs first.

Study status

Finalised

Research institutions and networks

Institutions

Unicancer

France

First published: 01/02/2024

Last updated: 22/11/2024

Institution | Laboratory/Research/Testing facility | Not-for-profit

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/08/2020

Study start date

Planned: 15/09/2020

Actual: 15/09/2020

Data analysis start date

Planned: 15/12/2020

Actual: 15/12/2020

Date of final study report

Planned: 30/06/2024

Actual: 27/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

The main objective of this study is to estimate overall survival (OS) and real-world progression-free survival (rwPFS) of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Non-small cell lung cancer

Population studied

Age groups

- 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

45.178

Study design details

Outcomes

• Overall survival (OS) of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC

• Real world progression-free survival (rwPFS) of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC

• OS and rwPFS of patients with locally advanced or metastatic NSCLC, overall and by biomarker status

• Biomarker testing rates

• Prevalence of KRAS G12C mutation

• Demographics

• Medical history

• Clinical characteristics

• Tumor characteristics

• Treatment patterns

• Concomitant medications

• Genetic mutation profile

Data analysis plan

There are no formal hypotheses for the study. Descriptive analyses will be performed. For continuous variables, descriptive statistics will be presented. For categorical variables, the number and percentage of patients in each category will be reported with 95% two-sided CIs.

To describe time-to-event, Kaplan-Meier (KM) curves will be plotted, and KM estimates will be calculated.

Documents

Study results

ESME_CBP_2023-17_Abstract_ISPE_VF_2024.02.09 (1).pdf (639.6 KB)

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

ESME-AMLC France

Data sources (types)

Disease registry

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