Safety and effectiveness of LORLAtinib as a FIRST-line treatment in an ALK-positive Advanced Non-Small Cell Lung Cancer Spanish population. (LORLA-FIRST).

First published: 04/06/2025

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Study | Planned

Administrative details

EU PAS number

EUPAS1000000406

Study ID

1000000406

DARWIN EU® study

No

Study countries

Spain

Study description

The study is an observational, non-interventional, prospective and multicenter trial that evaluate the real world safety and effectiveness of lorlatinib as a first-line treatment in patients with ALK-positive non-small cell lung cancer (NSCLC) in Spain.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ernest Nadal

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/11/2024

Actual: 20/11/2024

Study start date
Planned: 01/06/2025

Date of final study report
Planned: 31/05/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B7461054_Non-Interventional Study Protocol_V1.0_10APR2025_Redacted.pdf

(15.13 MB)

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

B7461054

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Other

If ‘other’, further details on the scope of the study

Evaluate the real-world safety and effectiveness of Lorlatinib

Data collection methods:

Primary data collection

Study design:

The study is an observational, non-interventional, prospective and multicenter trial that evaluates the real-world safety and effectiveness of lorlatinib as a first-line treatment in patients with ALK-positive advanced NSCLC in Spain.

Main study objective:

To describe all the spectrum of the adverse events (AEs) of Lorlatinib Common terminology criteria for adverse events (CTCAE v6.0) and its mitigation strategies, with special interest in CNS (Central Nervous system) AEs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Lorbrena

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

LORLATINIB

Anatomical Therapeutic Chemical (ATC) code

(L01ED05) lorlatinib

lorlatinib

Medical condition to be studied

Non-small cell lung cancer

Non-small cell lung cancer stage IV

Population studied

Short description of the study population

Patients in 20 Spanish hospitals (clinics, or and primary care centers) must have a confirmed diagnosis of locally advanced and/or metastatic NSCLC with an ALK rearrangement identified by an approved diagnostic test, be older or equal than 18 years and have initiated first-line therapy with lorlatinib at least 7 days and up to 28 days prior to enrolment in the study according to routine clinical practice.

They must also sign an informed consent and have a minimum of predetermined data recorded in their medical records. Socio demographic data about the patient's gender, age, height, weight at the treatment initiation will be collected.

Additional socio demographic data will be collected: race, along with details regarding their smoking habits, as well as exposure to asbestos and previous personal and family history of cancer, particularly in first-degree relatives.

Patients included in clinical trials are also excluded.

Age groups

- Adults (18 to < 65 years)
- Elderly (≥ 65 years)

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

116

Study design details

Setting

The study population includes adult patients aged 18 years or older diagnosed with non-small cell lung cancer who are carriers of the ALK gene rearrangement recruited in an 18-month estimated period from 20 high specialized hospitals at the country level who have started first-line therapy with lorlatinib according to label prescription, with treatment duration of at least 7 days and up to 28 days.

Data analysis plan

The safety assessment will be based primarily on the frequency and severity of AEs.

AEs will be summarized by presenting the number and percentage of these figures in the total number of patients.

The absolute and variable frequencies of each AE with respect to the total number of reported AEs will also be presented.

Descriptive analyses will be carried out to evaluate the objectives of the study.

Categorical variables are described by their absolute and relative frequency.

Continuous variables are described with total n, valid n, n unavailable, means, standard deviation, quartiles, minimum and maximum.

Survival analysis will be performed using Kaplan Meier method.

A Cox regression model will be carried out to find independent variables

associated with overall survival or time until disease progression.

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

The investigators will collect the data of the patients included in an electronic data collection form (e-CRF) designed specifically for this study and developed by the CRO in charge at the beginning of the study.

The data will be stored in an access database protected by password and only accessible to authorized personnel.

Descriptive and survival analyses will be performed to evaluate the study objectives, using the Kaplan-Meier method and the Cox model.

The AEs will be summarized by presenting the frequency distribution and percentage of these in the total number of patients and will be coded according to the CTCAE v6.0.

Brain MRI will be collected at baseline and in case of CNS toxicity.

Images will be anonymized and centrally analyzed to assess Fazekas scale, morphometric and radiomic features that will be correlated with CNS toxicity.

Baseline CT scan will be collected to determine the body composition. Images will be anonymized and centrally analyzed to assess radiomic features that will be correlated with CNS toxicity.
Baseline body CT scan and brain MRI and first tumor assessment will be collected to determine body composition and to compare radiomic characteristics in patients who developed CNS AEs with those who did not.

Data sources (types)

Electronic healthcare records (EHR)

Non-interventional study

Other

Data sources (types), other

Patient Reported Outcome (PRO)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No