LOREA _ ANALYSIS OF THE EFFECTIVENESS AND SAFETY OF LORLATINIB IN UNTREATED ALK-POSITIVE NSCLC PATIENTS IN A FRENCH REAL-WORLD CONTEXT

First published: 01/07/2026

Last updated: 01/07/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000111

Study ID

1000000111

DARWIN EU® study

No

Study countries

France

Study description

This study is a national prospective cohort that aims to analyse the effectiveness and safety of lorlatinib in a real-world setting. More precisely, the study aims at understanding the reasons why some patients should switch from lorlatinib to another treatment, being due to disease progression or toxicity, and reduce attrition rate.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

Cleanweb

Contact details

Study institution contact

Delphine Berzin RWD-FRA@pfizer.com

Study contact

RWD-FRA@pfizer.com

Primary lead investigator

Nicolas GIRARD

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/01/2024

Actual: 31/01/2024

Study start date

Planned: 09/04/2024

Actual: 09/04/2024

Date of final study report

Planned: 31/01/2029

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

B7461051 : internal ID number

EUDRACT number : 2024-A00637-40

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)

Safety study (incl. comparative)

Study design:

The LOREA study was designed as a French multicenter, observational prospective cohort, to collect data concerning ALK-positive locally advanced or metastatic NSCLC patients treated with lorlatinib in first line, as per standard of care (see Figure 1 - Study design).

Main study objective:

• Primary objective

To evaluate Progression Free Survival (PFS) rate, assessed by investigator in a real-world setting, of ALK- positive locally advanced or metastatic NSCLC patients treated with lorlatinib in first-line.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Lorlatinib

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

LORLATINIB

Anatomical Therapeutic Chemical (ATC) code

(L01ED05) lorlatinib

lorlatinib

Population studied

Short description of the study population

This study can fulfill its objectives only if appropriate participants are enrolled. The eligibility criteria are designed to select participants for whom participation

in the study is considered appropriate.
Prospective approval of protocol deviations to recruitment and enrollment criteria, also known as protocol waivers or exemptions, is not permitted.

The target population includes ALK-positive locally advanced or metastatic NSCLC patients for whom Lorlatinib was initiated in first line during the inclusion period, expected to be 18 months to reach sample size.
For each patient, follow-up will extend from the date of inclusion to the end of data collection or date of withdrawn consent or the date of death whichever comes first. The end of data collection will correspond to the end of study visit: 25 months after the inclusion of the patient, or one month after the date of lorlatinib withdrawn due to toxicity or disease progression.

Age groups

- **Adult and elderly population (≥18 years)**

Estimated number of subjects

90

Study design details

Setting

Approximately 30 sites are expected to participate in the study.
Eligible patients, with ALK-positive locally advanced or metastatic NSCLC for whom lorlatinib treatment is planned, will be proposed the study during a routine visit. Patients will be included in the study after providing informed consent.

Data analysis plan

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed and maintained by the sponsor. The SAP may modify the plans outlined in the protocol; any major modifications of primary endpoint definitions or their analyses would be reflected in a protocol amendment.
The statistical analysis will be mainly descriptive. Summary statistics will be presented for continuous variables, by way of n, n missing (if any), mean, standard deviation (SD), median, first and third quartiles (Q1 and Q3), minimum and maximum. Qualitative/categorical variables will be presented in terms of number and percentage of each modality and number of missing and non-missing observations. Unless otherwise stated, the percentages will only be calculated for the modalities provided, excluding missing data.
Effectiveness will be assessed on the I(FAS) defined as all eligible and treated patients. Safety will be assessed on the Safety Analysis Set defined as all treated patients.
PFS and OS will be described using the Kaplan-Meier method. Survival function estimates will be provided at 12, 24 and 36 months with 95% CIs that will be derived using the log-log transformation according to Kalbfleisch and Prentice, with back transformation to a CI on the untransformed scale. The median event-free time will be estimated with a 95% CI calculated according to the Brookmeyer and Crowley method.
Subgroup analyses (absence/presence of CNS metastases at baseline) will be conducted for all effectiveness endpoints.

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.

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