Effectiveness of LORlatinib as a Real-World, first-line treatment in ALK-positive Advanced or Metastatic Non-Small Cell Lung Cancer Patients in Italy(LOR-ALK).

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Study | Planned

Administrative details

EU PAS number

EUPAS1000000856

Study ID

1000000856

DARWIN EU® study

No

Study countries

Italy

Study description

This is an observational, non-interventional, prospective, multicenter, and international wide study with the category of a PASS, which primary endpoint will describe the effectiveness of Lorlatinib as real-world PFS, assessed by the physician.

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

Bruno Gori

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/12/2025

Study start date
Planned: 28/02/2026

Date of final study report
Planned: 30/09/2030

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

B7461061_NIS PASS Study Protocol_Completed Review NISRC-O_V1.1_19May2026 (1)_Redacted.pdf (3.98 MB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is an observational, non-interventional, prospective, multicenter, and international wide study with the category of a PASS, which primary endpoint will describe the effectiveness of Lorlatinib as real-world PFS, assessed by the physician.

Main study objective:

• To describe the Progression Free Survival (PFS) rate: PFS rate at 18-months.

• To describe Time to the Next Treatment (TTNT) defined as the period from the start of the treatment to the start of the next line of treatment.

Study Design

Non-interventional study design

Case-control

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

Lung cancer metastatic

Population studied

Short description of the study population

The study population includes adult patients aged 18 years or older diagnosed with NSCLC in Italy

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 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

80

Study design details

Setting

The study population includes adult patients aged 18 years or older diagnosed with NSCLC in Italy, who are carriers of the ALK gene rearrangement. Molecular diagnosis of ALK rearrangement is routinely performed in patients with NSCLC according to the diagnostic guidelines of the Italian Association of Medical Oncology (AIOM).

Outcomes

(PFS, TTNT, ORR, DOR, DCR, IC-RR, time to brain radiation, duration of intracranial response, DOT, cumulative incidence of BM in patient population at 12 and 18 months, PFS2, IC-TTP, proportion of patients with extracranial progression and sites of progression, any resistance mechanism with testing (e.g. liquid biopsy) after disease progression as per clinical practice in each center., proportion of patients with oligoprogression, OS as well as PFS, ORR, and DOT for subsequent line after Lorlatinib), QoL and PRO (EORTC QLQ-C30, EORTC QLQ-LC13, WPAI:GH) and safety (AEs, SAEs, non-serious AEs). AE, serious adverse events (SAE), and scenarios involving: exposure during breast feeding, medication error, overdose, misuse, lack of efficacy; exposure during pregnancy (EDP),

occupational/environmental exposure and treatment-associated mortality as well as time to onset and duration of AEs.

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 sources (types)

Electronic healthcare records (EHR)

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

Unknown