Non-Interventional Study - Use of lorlatinib in treatment-naïve adult patients with metastatic or locally advanced anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC) from India. (B7461047)

First published: 18/03/2024

Last updated: 23/09/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000025

Study ID

1000000025

DARWIN EU® study

No

Study countries

India

Study description

This is an ambispective, multi-center, observational study investigating the safety and effectiveness of lorlatinib in advanced ALK-positive NSCLC patients in India according to the local labelling information.

This study will be conducted by design of retro-prospective approach. Therefore, there is no visit or activity mandated for the patients by this study. The investigator will collect patient’s data and record the information on each patient’s Case Report Form (CRF).

All patients diagnosed with advanced ALK-positive NSCLC with or without brain metastases, treatment naïve for metastatic disease, and prescribed lorlatinib according to routine clinical practice at up-to 10 centers in India and willing to participate will be followed for 18 months after taking informed consent from them.

All assessments described in this protocol are performed as part of normal clinical practice or standard practice guidelines for the patient population and healthcare provider specialty in India where this noninterventional study is being conducted.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Indegene Limited

Contact details

Study institution contact

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Primary lead investigator

Nishtha Sehra

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/04/2023

Actual: 18/04/2023

Study start date
Planned: 15/03/2024

Actual: 09/05/2024

Date of final study report
Planned: 15/12/2026

Sources of funding

- Pharmaceutical company and other private sector

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 type:

Non-interventional study

Data collection methods:

Combined primary data collection and secondary use of data

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

LORLATINIB

Medical condition to be studied

Non-small cell lung cancer

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No