Non-Interventional Study - Use of Iorlatinib 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





### Administrative details

#### **EU PAS number**

EUPAS1000000025

#### Study ID

1000000025

#### **DARWIN EU® study**

No

#### **Study countries**

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#### 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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Study 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:** 

#### **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