# An ambispective, observational, multi-center study of first-line Lorlatinib in patients with ALK-positive non-small cell lung cancer in Korea (Lorlatinib NIS)

**First published:** 06/11/2026

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Study Planned

## Administrative details

**EU PAS number**

EUPAS1000001141

**Study ID**

1000001141

**DARWIN EU® study**

No

**Study countries**

Korea, Republic of

**Study description**

This study is an ambispective, non-interventional, observational, multi-center cohort study of patients who have received lorlatinib as a part of routine clinical practice prescribed by accredited physicians at Korean healthcare centers. No formal comparison group is included in this study. The study includes both retrospective and prospective data collection. The retrospective component will include data from subjects treated with lorlatinib prior to study enrollment, collected from existing medical records. The prospective component will involve the ongoing follow-up of subjects after enrollment. Subjects who are receiving lorlatinib at the time of study enrollment or are eligible for follow-up thereafter may be included in the prospective follow-up, provided that informed consent for study participation has been obtained.

The study can be performed in Korean health care centers where lorlatinib is prescribed to treat adult patients with ALK-positive NSCLC as first-line treatment according to the local label and the Korean National Health Insurance reimbursement criteria.

Each investigator will enroll patients with ALK-positive NSCLC who have discontinued, are currently receiving, or are planned to initiate lorlatinib as first-line treatment.

Approximately 103 adult (≥19 years) patients diagnosed with ALK-positive NSCLC will be enrolled in this study.

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 the countries where this noninterventional study is being conducted.

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**Study status**

Planned

## Research institutions and networks

# Institutions

## Pfizer

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution contact**

Ju-Won Woo ju-won.woo@pfizer.com

**Study contact**

ju-won.woo@pfizer.com

**Primary lead investigator**

Ju-Won Woo

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Planned: 30/09/2026

Actual: 23/09/2026

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**Study start date**

Planned: 15/01/2027

**Date of final study report**
Planned: 15/07/2029

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer Pharmaceuticals Korea Ltd.

## 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 topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Study design:**

This study is an ambispective, non-interventional, observational, multi-center cohort study of patients who have received lorlatinib as a part of routine clinical practice prescribed by accredited physicians at Korean healthcare centers.

**Main study objective:**

Primary objective

• To evaluate the real-world effectiveness of first-line lorlatinib in patients with ALK-positive NSCLC in Korea, as measured by real-world objective response rate (ORR), real-world progression-free survival (PFS), and overall survival (OS).

Secondary objectives

• To further characterize the real-world effectiveness of first-line lorlatinib in patients with ALK-positive NSCLC in Korea, including intracranial effectiveness, duration of response, and disease control.

• To describe the frequency and incidence of adverse events (AEs), adverse drug reactions (ADRs), unexpected AEs/ADRs, serious adverse events (SAEs),

serious adverse drug reactions (SADRs), and unexpected SAEs/SADRs among patients receiving first-line lorlatinib in routine clinical practice in Korea.
• To further describe adverse events of special interest, severity of adverse events, and actions taken in response to adverse events among patients receiving first-line lorlatinib in routine clinical practice in Korea.
• To describe real-world treatment patterns associated with first-line lorlatinib use, including time to treatment discontinuation, time to next treatment, prior and subsequent systemic anti-cancer therapies, concomitant medications, treatment re-initiation following temporary interruption, and continuation of lorlatinib beyond disease progression.
Exploratory Objectives
• To explore clinical and treatment-related factors associated with early progression on lorlatinib, including genetic profiles when available.
• To explore intracranial disease management patterns among patients with baseline brain metastases, including the use and timing of brain-directed radiotherapy.
• To explore treatment re-initiation characteristics following temporary interruption of lorlatinib due to adverse events, including time to treatment re-initiation and dose at re-initiation.

## Study Design

**Non-interventional study design**
Cohort

## Study drug and medical condition

**Medicinal product name**

LORVIQUA

**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

# Population studied

**Short description of the study population**

The study population consists of adult patients (≥19 years) with ALK-positive NSCLC who initiated first-line lorlatinib treatment on or after December 01, 2021, the market launch date in Korea. These patients represent the real-world population receiving routine lorlatinib treatment consistent with its locally approved indication.

**Estimated number of subjects**

103

# Study design details

**Setting**

This study will be conducted at multiple healthcare centers in Korea where lorlatinib is prescribed as part of routine clinical practice. Eligible patients with

ALK-positive NSCLC who initiate first-line lorlatinib treatment will be enrolled and followed according to routine clinical care. Patient enrollment is planned from January 2027 through July 2028. The study is expected to continue until approximately January 2029, including follow-up and data collection activities.

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**Comparators**

None

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**Outcomes**

Primary Endpoint

• Real-world Objective Response Rate (ORR)

• Overall survival (OS)

• Real-world Progression free survival (PFS)

Secondary Endpoint

• Real-world Intracranial Objective Response Rate (IC-ORR)

• Real-world Intracranial Progression free survival (IC-PFS)

• Duration of Response (DoR)

• Disease control rate (DCR)

• Time-to-treatment discontinuation (TTD)

• Time to next treatment (TTNT)

• Frequency and incidence rates of AEs/ADRs, unexpected AEs/ADRs, SAEs/SADRs, and unexpected SAEs/SADRs

• Frequency and incidence rates of AESIs

• Severity of AEs (graded per NCI CTCAE v5.0).

• Actions taken for AEs (treatment interruption, dose reduction, withdrawal)

Exploratory Endpoints

• Time to brain-directed radiotherapy

• Time to lorlatinib treatment re-initiation following temporary interruption due to adverse events

• Dose at re initiation of lorlatinib treatment following temporary interruption

due to adverse events

- Treatment continuation pattern of lorlatinib beyond disease progression
- Patterns of Prior and Subsequent Systemic Anti-Cancer Therapy (SACT)
- Use of Concomitant Medications
- Exploration of Early Progression on lorlatinib

# 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 data source

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**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