# Observational study to investigate safety and effectiveness of lorlatinib as first line treatment for ALK-gene rearranged unresectable advanced/recurrent NSCLC patients in Japan clinical setting

**First published:** 05/06/2024

**Last updated:** 23/04/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000117

**Study ID**

1000000117

**DARWIN EU® study**

No

**Study countries**

☐ Japan

**Study description**

The overall objective is to describe special interested AEs with information regarding dose modification, and effectiveness of lorlatinib as first line treatment in clinical setting in Japan.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Pfizer

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

**Last updated:** 01/02/2024

Institution

# Contact details

**Study institution contact**

Ai Murata ai.murata@pfizer.com

Study contact

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**Primary lead investigator**

Yutaka Fujiwara

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned: 12/04/2024

Actual: 12/04/2024

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**Study start date**
Planned: 14/04/2024

Actual: 27/05/2024

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**Date of final study report**
Planned: 31/08/2030

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

Non-Interventional Study Protocol_Ver1.0_reducted.pdf(430.63 KB)

Non-Interventional Study Protocol_Ver2.0_reducted.pdf(656.81 KB)

## 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

**Study type:**

Non-interventional study

**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Study design:**

This is a multicenter, non-interventional study for patients with ALK-positive unresectable advanced/recurrent NSCLC treated with lorlatinib as first line treatment in Japan. The patients will be enrolled both retrospectively and prospectively based on the study initiation date.

**Main study objective:**

The primary objectives are:

1. To characterize Adverse Events of special interests (AESIs: CNS AE, Hyperlipidemia, Edema) for patients treated with lorlatinib.
2. To investigate dose modifications, interruption, or discontinuation (if any), with related timing and reason.
3. To investigate time-to-treatment discontinuation (TTD) of lorlatinib.

## Study drug and medical condition

**Name of medicine**

LORVIQUA

**Name of medicine, 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**

Non-small cell lung cancer

ALK gene rearrangement positive

## Population studied

**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)

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**Estimated number of subjects**

75

# Data management

## Data sources

**Data sources (types)**

Other

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**Data sources (types), other**

Structured and unstructured data from patients' hospital medical records will be abstracted manually by a trained research associate. Data will subsequently be entered into a study-specific electronic data capture system (EDC) via a standardized electronic case report form (eCRF).

## 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