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: 13/04/2026

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

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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

Study start date
Planned: 14/04/2024

Actual: 27/05/2024

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)

Ver6.0 Non-Interventional Study Protocol.pdf (699.09 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

Medicinal product name

LORVIQUA

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

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)

Estimated number of subjects

75

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)

Other

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