Japanese REal-world data for treatment of afatinib (GIotrif®) in first-line setting and Subsequent Therapies for patients with advanced EGFR mutation-positive lung adenocarcinoma (J-REGISTER)

First published: 26/03/2021

Last updated: 17/12/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS40322

Study ID

40323

DARWIN EU® study

No

Study countries

Japan

Study description

The primary objective is to confirm Time on Treatment (TOT) related to afatinib treatment as first-line therapy in patients with Epidermal Growth Factor Receptor (EGFR) mutation-positive Non-Small Cell Lung Cancer (NSCLC). The observation in the real-world setting of the time from the start of the first-line afatinib until the end of subsequent treatment in this study will provide insights on the sequence of treatment for patients. The Japanese healthcare system will enable this study to evaluate multiple treatment options after afatinib treatment.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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

Masaya Mizushima

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/12/2019

Actual: 20/12/2019

Study start date

Planned: 01/04/2021

Data analysis start date

Planned: 31/10/2022

Date of final study report

Planned: 31/01/2023

Actual: 24/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

Study protocol

1200-0322_protocol_redacted.pdf (1.37 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

NCT04795245

https://www.clinicaltrials.gov/ct2/show/NCT04795245?term=afatinib&draw=2&rank=2

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)

Data collection methods:

Secondary use of data

Study design:

This was a non-interventional, multi-center study from existing data of patients treated with afatinib as the first-line treatment. The study involved secondary use of data which was extracted retrospectively once patients were enrolled into this study

Main study objective:

The primary objective is to confirm TOT related to afatinib treatment as first-line therapy(TOT1) in patients with EGFR mutation-positive NSCLC.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

GIOTRIF

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

AFATINIB

Anatomical Therapeutic Chemical (ATC) code

(L01EB03) afatinib

afatinib

Medical condition to be studied

Lung carcinoma cell type unspecified stage IV

EGFR gene mutation

Population studied

Short description of the study population

Patients with EGFR mutation- positive NSCLC.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

1000

Study design details

Setting

This NIS study enrolled 857 patients at 40 sites in Japan. Patients information was chosen for patients treated with afatinib in the first-line setting in each study site after its launch on 7 May 2014 on a regular basis. In first round of data extraction, the data was extracted retrospectively once patients were enrolled into this study. A second round of data extraction was performed for additional follow-up one year after completion of first round data extraction. The data extraction was started on 01 Apr 2021 and ended on 07 Nov 2022

Outcomes

1.TOT from the start of afatinib until end of subsequent therapies in the second-line setting or death by any cause 2.TOT from start of the second-line treatment until end of the second-line treatment or death by any case (TOT2) 3.overall survival 4.survival rate at 18 and 36 months 5.time to initial dose reduction of afatinib 6.proportion of patients with dose modifications of afatinib

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Data analysis plan

TOT with afatinib (TOT1)will be analysed using Kaplan-Meier method, and the median along with two-sided 95% confidence interval (CI) will be displayed

Documents

Abstract of study report

1200-0322_Synopsis.pdf (252.95 KB)

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

Exposure registry

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