START: Real-world study on sequential therapy with afatinib as first-line treatment in patients with epidermal growth factor receptor (EGFR) mutation-positive advanced non-small cell lung cancer (NSCLC)

First published: 21/11/2019

Last updated: 11/11/2021

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44236

EU PAS number

EUPAS32423

Study ID

44236

DARWIN EU® study

No

Study countries

China

Study description

The START study observes afatinib as first-line treatment and sequential therapy in patients with epidermal growth factor receptor (EGFR) mutation-positive advanced non-small cell lung cancer

Study status

Ongoing

Research institutions and networks

Institutions

Zhejiang University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

The First Affiliated Hospital,College of Medicine

Peking Union Medical College Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

West China Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Guangdong Provincial People's Hospital China, Hunan Cancer Hospital China, Hainan Cancer Hospital China, Peking Union Medical College China, West China Hospital, Sichuan University China, The first affiliated hospital of Zhengzhou University China, Shandong Cancer Hospital China, Yunnan Cancer Hospital China, Peking University Third Hospital China, Shenyang Tenth People‘s Hospital China

Contact details

Study institution contact

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Primary lead investigator

Yilong Wu

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/03/2019

Actual: 28/03/2019

Study start date

Planned: 29/05/2020

Actual: 20/05/2020

Data analysis start date

Planned: 15/02/2026

Date of interim report, if expected

Planned: 31/03/2024

Date of final study report

Planned: 30/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim China Investment Co., 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Treatment pattern

Main study objective:

To determine in Chinese patients in real-world setting with EGFR mutation-positive non-small cell lung cancer (NSCLC) the time on treatment (TOT) of afatinib as first-line treatment followed by 3rd generation EGFR-TKI in the event that T790M resistance mutation was developed

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional, prospective study based on newly-collected data

Study drug and medical condition

Name of medicine

GIOTRIF

Medical condition to be studied

Non-small cell lung cancer stage IIIB

Non-small cell lung cancer metastatic

Non-small cell lung cancer stage IV

Population studied

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

750

Study design details

Outcomes

TOT with afatinib as first-line treatment followed by 3rd generation EGFR-TKI in the event of the T790M resistance mutation is developed in patients with EGFR mutation-positive NSCLC. This will be assessed as the time from the start of afatinib as first-line treatment until the last dose of 3rd generation EGFR-TKI. 1.TOT with afatinib as first-line treatment followed by investigator’s choice treatment in event of the T790M negative status in real-world setting2.OS from the start of afatinib until the date of death 3.PFS as judged by an investigator with afatinib in first-line treatment 4.ORR OR is defined as best overall response of CR and PR according to RECIST 1.1 with afatinib in first-line tre...

Data analysis plan

TOT will be analysed using Kaplan-Meier method, and the median TOT along with two-sided 90% confidence interval (CI) will be calculated. PFS and OS will be analysed similarly. ORR, DCR, and acquired resistance mutation type, and AEs will be summarised descriptively by frequency and proportions.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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