GioTag: Real-world data study on sequential therapy with Gi(l)otrif®/ afatinib as first-line treatment followed by osimertinib in patients with EGFR mutation positive advanced non-small cell lung cancer

First published: 29/09/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21037

Study ID

30134

DARWIN EU® study

No

Study countries

Austria
Canada
Germany
Israel
Italy
Japan
Singapore
Slovenia
Spain
Taiwan
United States

Study description

The observational study is designed to determine the time on treatment of afatinib (Gi(l)otrif®) as first-line therapy in patients with EGFR mutation-positive NSCLC followed by osimertinib in case the T790M resistance mutation was developed in real-world setting and to collect data on osimertinib’s resistance mechanisms (when available) in order to provides insights on treatment sequence that could inform on the most beneficial treatment sequence in patients diagnosed with advanced EGFR mutation-positive NSCLC.

Study status

Finalised

Research institutions and networks

Institutions

Maximilian Hochmair

Multiple centres: 45 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maximilian Hochmair

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/05/2017

Actual: 02/05/2017

Study start date

Planned: 15/01/2018

Actual: 28/12/2017

Data analysis start date

Planned: 30/06/2018

Actual: 29/06/2018

Date of final study report

Planned: 30/09/2018

Actual: 26/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

Observational study designed to provide information on treatment efficacy or possible benefit on the targeted population.

Data collection methods:

Secondary use of data

Main study objective:

Primary:To determine the time on treatment of afatinib (Gi(l)otrif®) as first-line therapy in patients with EGFR mutation-positive NSCLC followed by osimertinib in case the T790M resistance mutation was developed in real-world setting.
Secondary:To collect data on acquired resistance mechanism to osimertinib.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XE13) afatinib

afatinib

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

Patients with EGFR mutation-positive Non-small cell lung cancer (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)

Special population of interest

Other

Special population of interest, other

Non-small cell lung cancer patients

Estimated number of subjects

190

Study design details

Outcomes

Time on treatment with afatinib (Gi(l)otrif®) followed by osimertinib. Type and proportion of acquired resistance mutations after osimertinib.

Data analysis plan

The primary endpoint is time on treatment which will be analyzed using Kaplan-Meier method, and the median along with two-sided 90% confidence interval will be displayed (use the Greenwood’s formula for estimation of standard errors).In the analyses of time-to-event endpoint, missing or incomplete data are managed by standard survival analysis techniques. For patient still on treatment, time on treatment will be censored at the date of data collection. The secondary endpoint is the different types of resistance mutations identified at the time of discontinuation of osimertinib treatment will be systematically reviewed and categorized. The proportion of patients with different types of mutations after categorization will be summarized descriptively. Baseline conditions and demographics will be analyzed with descriptive statistics. The frequency of treatment interruption and dose reduction of both afatinib (Gi(l)otrif®) and osimertinib will be summarized through descriptive statistics.

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

Retrospective patient-based data collection from patients' medical records

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