A regulatory requirement post-marketing surveillance study to monitor the safety and efficacy of GIOTRIF®(afatinib dimaleate, 20mg, 30mg, 40mg, q.d) in Korean patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with Epidermal Growth Factor Receptor (EGFR) mutation(s) (GIOTRIF rPMS in Korean patients with NSCLC)

First published: 22/04/2015

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS9364

Study ID

20368

DARWIN EU® study

No

Study countries

Korea, Republic of

Study description

To monitor the safety profile and efficacy of GIOTRIF®(afatinib dimaleate, q.d) in Korean patients with locally advanced or metastatic non-small cell lung cancer (NSCLC)

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Study contact

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Primary lead investigator

Sangjin Lee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2014

Actual: 06/11/2014

Study start date

Planned: 01/11/2014

Actual: 11/11/2014

Data analysis start date

Planned: 30/11/2018

Date of final study report

Planned: 28/04/2020

Actual: 05/02/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1200-0235_protocol_SAP_redacted.pdf (402.38 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This was a single arm study with GIOTRIF®. GIOTRIF® was prescribed according to the local label and at the discretion of the treating physician. Since this was a non-interventional study, the drug was not be supplied by the sponsor.

Main study objective:

The main objective is to monitor the safety profile and efficacy of GIOTRIF®(afatinib dimaleate, q.d) in Korean patients with locally advanced or metastatic non-small cell lung cancer (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 DIMALEATE

Anatomical Therapeutic Chemical (ATC) code

(L01EB03) afatinib

afatinib

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

Inclusion criteria:

• Patients who have been started on GIOTRIF® in accordance with the approved label in Korea

• Age ≥19 years at enrolment

• Patients who have signed on the data release consent form

Exclusion criteria:

• Known hypersensitivity to afatinib or any of its excipients

• Patients with rare hereditary conditions of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

• Patients for whom Afatinib is contraindicationed according local label of GIOTRIF®

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

3000

Study design details

Setting

Patients were managed according to the local practice guidelines. The choice of treatment was solely at the discretion of the participating physician. GIOTRIF® was administered according to the approved label in
Korea.

Outcomes

To monitor the safety profile of GIOTRIF, to evaluate the tolerability and efficacy of GIOTRIF

Data analysis plan

Safety analysis will be based on all patients treated. In accordance with local regulation, interim analyses are planned biannually for the initial two years and annually thereafter.

Documents

Study results

1200-0235_Synopsis.pdf (405.76 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

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