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: 07/08/2017

Study Ongoing

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

Ongoing

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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

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

Name of medicine

GIOTRIF

Medical condition to be studied

Non-small cell lung cancer

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

3000

Study design details

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.

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