Assessment of Real-World Outcomes Associated with Afatinib (Gilotrif) Use in Patients with Solid Tumors Harboring NRG1 Gene Fusions (Afatinib (Gilotrif) Use in Solid Tumors Harboring)

First published: 23/09/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS43164

Study ID

43431

DARWIN EU® study

No

Study countries

☐ United States

Study description

Obtaining real-world data describing the real-world outcomes associated with afatinib in patients with NRG1 fusion-positive solid tumors is valuable, and such data may be used to explore potential use of afatinib in other indications through label expansion requests to the U.S. Food and Drug Administration (FDA) and other agencies.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 13 centres are involved in the study

Networks

Cardinal Health Oncology Provider Extended Network (OPEN)

Contact details

Study institution contact

Kristie Fernamberg kristie.fernamberg@boehringer-ingelheim.com

Study contact

kristie.fernamberg@boehringer-ingelheim.com

Primary lead investigator

AndrewJ Klink

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/12/2019

Actual: 13/12/2019

Study start date

Planned: 15/10/2020

Actual: 15/10/2020

Date of final study report

Planned: 17/09/2021

Actual: 17/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

Final Protocol_NIS_1200.335_Afatinib_NRG1 .pdf (1.08 MB)

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Characteristics of patients with NRG1 gene fusion-positive solid tumors treated with afatinib, and the characteristics of those treated with another systemic therapy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Gilotrif

Medical condition to be studied

Neoplasm

Population studied

Short description of the study population

Approximately 20 or more unique providers will participate in this research study.

Providers who meet the following criteria will be eligible to participate:
1) Are board-certified oncologist/hematologist.
2) Have treated/are treating at least one eligible patient with an NRG1 fusion-positive solid tumor.
3) Are able to participate in research approved by an external institutional review board (IRB).
4) Agree to participate in data quality assurance/control processes.
Providers will be asked to select eligible patients chronologically, starting with the first patient who first initiated any line of afatinib or chemotherapy, on or after 01/01/2017 through 03/31/2020.
Inclusion Criteria:
• Adults, 18 years of age or older, at the time of diagnosis with any solid tumor.
• Confirmed NRG1 gene fusion in any solid tumor.
• Initiated afatinib or other systemic therapy (in any line of therapy) for treatment of a solid tumor with NRG1 gene fusion on or after 01/01/2017 through 03/31/2020.
• Followed up for ≥3 months after initiation of afatinib or other systemic therapy (unless deceased prior to 3 months of follow-up).
Exclusion Criteria:
• Treatment with any TKI/ErbB-directed therapy other than afatinib

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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

Pregnant women

Other

Special population of interest, other

Solid tumor

Estimated number of subjects

110

Study design details

Outcomes

ORR, DOCB, DOR, TOT, TTP, PFS, OS, AE

Data analysis plan

Demographic and clinical characteristics were reported via descriptive analyses, including counts and frequencies for dichotomous and categorical variables, while measures of centrality (mean, median) and spread (min, max, standard deviation, interquartile range, as appropriate) were used for continuous variables. These characteristics were described at the time of initial diagnosis of advance/metastatic disease and at the time of initiation of each line of therapy received. For disease response, the point estimate for ORR and associated 95% confidence interval were calculated for each cohort. The Kaplan-Meier method was used to estimate any time to event outcome including DOR, DOCB, TOT, TTP, PFS, and OS to account for any right censoring (e.g. patient had not discontinued therapy, patient had not progressed or died). Incidence and severity of AEs were summarized and displayed in number/percentage. All safety endpoints were analyzed descriptively.

Documents

Study results

CHSS_BI NRG1 CRF_Final Study Report.pdf (3.26 MB)

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

Electronic case report forms (eCRF), Patient's medical charts

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