Real-World Effectiveness of Afatinib (Gilotrif) Following Immunotherapy in the Treatment of Metastatic, Squamous Cell Carcinoma of the Lung: A Multi-Site Retrospective Chart Review Study in the U.S. (Afatinib post IO)

First published: 18/08/2020

Last updated: 16/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS36813

Study ID

36814

DARWIN EU® study

No

Study countries

United States

Study description

1) To describe the demographic and clinical characteristics of patients who, after failure of 1L pembrolizumab in combination with chemotherapy, received either afatinib in 2L or chemotherapy in 2L (single-agent, doublet, and by specific regimen). 2) To describe time on treatment for patients who, after failure of 1L pembrolizumab in combination with chemotherapy, received either afatinib in 2L or chemotherapy in 2L (single-agent, doublet, and by specific regimen).3) To describe the incidence of severe (grade 3 or higher) irAEs of specific interest (including pneumonitis, colitis, hepatitis, interstitial lung disease, higher indeterminate pulmonary events, death, or discontinuation of therapy due to toxicity) during 2L treatment with afatinib or chemotherapy following failure of 1L pembrolizumab in combination with chemotherapy.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jonathan Kish

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 29/05/2018

Actual: 29/05/2019

Study start date
Planned: 08/05/2020

Actual: 08/05/2020

Date of final study report
Planned: 18/08/2020

Actual: 18/08/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheilm

Study protocol

1200-0335_CTP_final-rule_Redacted.pdf (1.35 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

1200-0325; NCT04750824

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:

Secondary use of data

Study design:

Retrospective cohort study

Main study objective:

1) demographic and clinical characteristics of patients2) time on treatment 3) description of IR events

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Gilotrif

Medical condition to be studied

Lung cancer metastatic

Population studied

Short description of the study population

Providers will select patients meeting the study eligibility criteria as describe below. Providers will be asked to select eligible patients chronologically, starting with the first patient who first initiated 2L afatinib or chemotherapy on or after 06/01/2018 but at least 3 months prior to data collection, and then randomly from that point forward until they have submitted their maximum number of

patients or no further patients are evaluable.

Inclusion Criteria:

1. Diagnosis of squamous or mixed histology non-small cell lung cancer.

2. Treated with pembrolizumab in combination with platinum-based chemotherapy as initial therapy for advanced or metastatic disease (stage IIIB or IV).

- First cycle of pembrolizumab received after 06/01/2018
- Permanently discontinued 1L pembrolizumab treatment.

3. Initiated second-line treatment at least 3 months prior to the date of data collection.

with either :

- Afatinib
- Any chemotherapy

4. Age ≥ 18 years

Exclusion Criteria:

1. Received pembrolizumab in combination with platinum-based chemotherapy as part of an interventional clinical trial.

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

Lung cancer patients

Estimated number of subjects

200

Study design details

Setting

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

Outcomes

1) demographic and clinical characteristics of patients2) time on treatment 3) description of IR events

Data analysis plan

descriptive statistics

Documents

Study results

1200-0335_Synopsis.pdf (438.59 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)

Electronic healthcare records (EHR)

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