

# 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:** 14/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS36813

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### Study ID

36814

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### DARWIN EU® study

No

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### Study countries

United States

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### **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.

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### **Study status**

Finalised

## Contact details

### **Study institution contact**

Jonathan Kish [jonathan.kish@cardinalhealth.com](mailto:jonathan.kish@cardinalhealth.com)

**Study contact**

[jonathan.kish@cardinalhealth.com](mailto:jonathan.kish@cardinalhealth.com)

### **Primary lead investigator**

Jonathan Kish

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Planned: 29/05/2018

Actual: 29/05/2019

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## **Study start date**

Planned: 08/05/2020

Actual: 08/05/2020

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## **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 Ingelheim

# Study protocol

[1200-0325 CTP.pdf](#) (891.3 KB)

# Regulatory

## **Was the study required by a regulatory body?**

No

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

Not applicable

## Other study registration identification numbers and links

1200-0325

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Other

#### **If 'other', further details on the scope of the study**

Afatininb after failure of IO

#### **Data collection methods:**

Secondary use of data

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**Main study objective:**

1) demographic and clinical characteristics of patients 2) 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

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**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  $\geq$  18 years

Exclusion Criteria:

1. Received pembrolizumab in combination with platinum-based chemotherapy as part of an interventional clinical trial.
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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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Lung cancer patients

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### **Estimated number of subjects**

200

## Study design details

### **Outcomes**

1) demographic and clinical characteristics of patients 2) time on treatment 3) description of IR events

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### **Data analysis plan**

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](#)

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## **Data sources (types), other**

Patients' medical records

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No