Real-World Effectiveness of Afatinib (Gilotrif) Following Immunotherapy in Combination with Chemotherapy for Treatment of Metastatic Squamous Cell Carcinoma of the Lung: A Multi-Site Retrospective Chart Review Study in the United States

First published: 08/02/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS41157

Study ID

41158

DARWIN EU® study

No

Study countries

United States

Study description

To describe the demographic and clinical characteristics, the time on treatment, and the incidence of severe (grade 3 or higher) immune-related AEs of specific interest in 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).

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lori Minasi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/08/2019

Actual: 22/08/2019

Study start date
Planned: 13/01/2020

Actual: 08/05/2020

Date of interim report, if expected
Actual: 17/08/2020

Date of final study report
Planned: 26/02/2021

Actual: 22/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

BI-afatinib post IO NSCLC_NISed protocol final 1.9.20 clean (008).pdf (840.5 KB)

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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess the time on treatment for patients who, after failure of 1L pembrolizumab in combination with chemotherapy, received either afatinib in 2L or chemotherapy in 2L

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multi-site study

Study drug and medical condition

Medicinal product name, other

Gilotrif

Study drug International non-proprietary name (INN) or common name

AFATINIB

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

The study population involved patients aged 18 years or older diagnosed with squamous or mixed histology non-small cell lung cancer received treatment with pembrolizumab in combination with platinum doublet chemotherapy as 1st line treatment followed by either afatinib or chemotherapy as 2nd line treatment.

Inclusion Criteria:

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

 Treated with pembrolizumab in combination with platinum-based chemotherapy as initial therapy for advanced or metastatic disease (stage IIIB or IV).
o First cycle of pembrolizumab containing therapy received after 06/01/2018.
o Permanently discontinued 1L pembrolizumab containing treatment.
 Initiated second-line treatment at least 3 months prior to data collection with either:
o Afatinib
o Any chemotherapy
 Age ≥ 18 years

Exclusion Criteria:
 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)

Special population of interest

Other

Special population of interest, other

Patients with non-small cell lung cancer

Estimated number of subjects

200

Study design details

Outcomes

To describe the demographic and clinical characteristics, the time on treatment, and the incidence of severe (grade 3 or higher) immune-related AEs of specific interest in 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).

Data analysis plan

Descriptive analysis of demographics, clinical characteristics, and treatment history of patients treated in 2L with afatinib and those treated in 2L chemotherapy. Time on treatment will be described in each 2L cohort (with no comparisons made) using the Kaplan-Meier method, and the median, along with two-sided 95% confidence intervals, and 3-, 6-, 9- and 12-month rates of discontinuation will be reported. Time on treatment is defined in months as the interval from the start of 2L treatment until the end of 2L treatment or death date by any cause. Incidence rates of severe irAEs of specific interest during 2L afatinib treatment or 2L chemotherapy will be estimated as the number of events divided by the total person-years of follow-up. Additionally, the incidence rates among patients who completed 2L therapy will be reported.

Documents

Study results

Afatinib RWE_March 2021 Clin Lung Cancer.pdf (378.82 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