

# Brigatinib-5007: A Cohort Study to Describe the Occurrence of Early-Onset Pulmonary Events in Patients with Anaplastic Lymphoma Kinase-Positive Advanced Non-Small Cell Lung Cancer Treated with Brigatinib: A Post-Authorisation Safety Study

**First published:** 26/02/2020

**Last updated:** 06/11/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS32383

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### Study ID

44170

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### DARWIN EU® study

No

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## Study countries

-  Austria
  -  Denmark
  -  Finland
  -  France
  -  Germany
  -  Ireland
  -  Netherlands
  -  Norway
  -  Sweden
  -  United Kingdom
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## Study description

This is a multi-centre, prospective, single-arm cohort study. This study will characterize the occurrence and risk factors of Early-onset Pulmonary Event (EOPEs) and will assess the effectiveness of the brigatinib Patient Alert Card among Anaplastic Lymphoma Kinase-Positive (ALK+) advanced Non-small Cell Lung Cancer (NSCLC) patients newly treated with brigatinib. The investigators will collect the baseline information on patient's demographics, NSCLC clinical characteristics, medical history, prior and concurrent cancer therapies, recent or concurrent medications. In this study there are no additional diagnostics, procedures, or clinic visits, other than what a patient would receive as part of the routine standard of care. The data collection will be performed using electronic case report forms (eCRFs). The data is anticipated to be collected between April 2020 and October 2024. The study aims to enroll 120 patients who initiated treatment with brigatinib. The study is planned to be conducted in Austria, Denmark, Finland, France, Germany, Ireland, Netherlands, Norway, Sweden, and the United Kingdom. The overall duration of the study is 42 days. All patients will be contacted approximately 30 days after brigatinib initiation to complete the Patient Alert Card questionnaire. The patients will be contacted

again up to 2 times in case of non-response, around Day 35 and Day 42.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Takeda

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Institution

#### Millennium Pharmaceuticals

## Contact details

### Study institution contact

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Study contact

[trialogdisclosures@takeda.com](mailto:trialogdisclosures@takeda.com)

### Primary lead investigator

Jin-Liern Hong

Primary lead investigator

## Study timelines

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

Planned: 01/03/2020

Actual: 28/04/2020

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### **Study start date**

Planned: 28/02/2021

Actual: 15/01/2021

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### **Data analysis start date**

Planned: 31/03/2024

Actual: 14/05/2024

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### **Date of final study report**

Planned: 31/12/2024

Actual: 09/09/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Study protocol

[Brigatinib-5007 EU PASS-Protocol\\_v2\\_Redacted.pdf](#) (1.81 MB)

[Brigatinib-5007 EU PASS-Protocol\\_v2\\_Redacted.pdf](#) (1.81 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

#### Study type list

##### **Study topic:**

Disease /health condition  
Human medicinal product

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##### **Study type:**

Non-interventional study

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

Assessment of risk minimisation measure implementation or effectiveness  
Effectiveness study (incl. comparative)

**Main study objective:**

The primary objective of the study is to describe the occurrence of EOPEs in ALK positive advanced NSCLC patients treated with brigatinib in real-world practice.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

BRIGATINIB

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**Anatomical Therapeutic Chemical (ATC) code**

(L01XE43) brigatinib

brigatinib

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**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)
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### **Estimated number of subjects**

180

## Study design details

### **Outcomes**

The primary outcomes will assess the occurrence of adjudicated EOPEs occurring within 14 days after the initiation of brigatinib. The secondary outcome will include the success rate of Patient Alert Card.

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### **Data analysis plan**

Descriptive statistics will be used which comprise the number of observations, mean, standard deviation, median, minimum, and maximum for continuous variables, as well as number and percent for categorical variables. The association of potential risk factors with EOPEs will be evaluated by univariable logistic regression models and will be quantified using odds ratios with 95 percent (%) confidence intervals.

## Documents

### **Study results**

[Brigatinib-5007\\_CSR Synopsis\\_09-Sep-2024.pdf](#) (701.67 KB)

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## 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

Information on pulmonary event will be recorded by investigator in the eCRF. Data will be collected via phone interview about patient receiving, reading, and using the Patient Alert Card.

## 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