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

Study ID

44170

DARWIN EU® study

No

Study countries

Austria
Denmark
Finland
France
Germany
Ireland
Netherlands
Norway
Sweden
United Kingdom

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.

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

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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

Study start date
Planned: 28/02/2021

Actual: 15/01/2021

Data analysis start date
Planned: 31/03/2024

Actual: 14/05/2024

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)

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Regulatory

Was the study required by a regulatory body?

Yes

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

Study type:

Non-interventional study

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

Anatomical Therapeutic Chemical (ATC) code

(L01XE43) brigatinib

brigatinib

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)

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.

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)

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No