A descriptive study of potential sight threatening event and severe visual loss following exposure to XALKORI (crizotinib)

First published: 29/03/2016

Last updated: 23/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS12963

Study ID

44928

DARWIN EU® study

No

Study countries

- Albania
- Argentina
- Armenia
- Aruba

- Australia
- Austria
- Bahrain
- Belarus
- Belgium
- Belize
- Bosnia and Herzegovina
- Bulgaria
- Canada
- Cayman Islands
- Chile
- China
- Colombia
- Costa Rica
- Croatia
- Cyprus
- Denmark
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Estonia
- Finland
- France
- Germany
- Greece
- Guatemala
- Honduras
- Hong Kong
- Hungary

- Iceland
- India
- Indonesia
- Ireland
- Israel
- Italy
- Jamaica
- Japan
- Jordan
- Kazakhstan
- Korea, Republic of
- Kuwait
- Latvia
- Lebanon
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malaysia
- Mexico
- Montenegro
- Morocco
- Netherlands
- New Zealand
- Norway
- Oman
- Panama
- Peru
- Philippines

- Poland
- Portugal
- Qatar
- Romania
- Russian Federation
- Saudi Arabia
- Singapore
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Taiwan
- Thailand
- Trinidad and Tobago
- Tunisia
- Türkiye
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- Uzbekistan
- Venezuela, Bolivarian Republic of
- Western Sahara
- Yemen
- Zambia
- Zimbabwe
- Åland Islands

Study description

Crizotinib is a selective small-molecule inhibitor of the anaplastic lymphoma kinase (ALK) receptor tyrosine kinase (RTK) and its oncogenic variants (ie, ALK fusion events and selected ALK mutations). Crizotinib is also an inhibitor of the hepatocyte growth factor receptor (HGFR, c-Met), ROS1, and Recepteur d'Origine Nantais (RON) RTKs. Crizotinib has received full or conditional approvals for the treatment of patients with ALK-positive advanced non-small cell lung cancer (NSCLC) in over 85 countries including the United States, the European Union, and Japan. This post-marketing requirement by the US FDA is a post-authorization safety study (PASS) designed to collect data on potential sight threatening event (PSTE) and severe visual loss (SVL) in patients being treated with crizotinib.

Study status

Finalised

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

De Luise Cynthia cynthia.deluise@pfizer.com

Study contact

cynthia.deluise@pfizer.com

Primary lead investigator

De Luise Cynthia

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/02/2016

Actual: 09/02/2016

Study start date

Planned: 31/03/2016

Actual: 31/03/2016

Date of final study report

Planned: 31/12/2021

Actual: 04/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

A8081062_FINAL_PROTOCOL_CLEAN_16MAR 2016_register.doc.pdf (1.98 MB)

A8081062_Protocol_Amendment_1 28 April 2017_EU PAS.doc.pdf (4.04 MB)

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

Data collection methods:

Primary data collection

Main study objective:

The objective of the study is to evaluate the frequency of risk factors for and sequelae of Potential sight threatening event (PTSE)/Severe visual loss (SVL) following exposure to crizotinib

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive, Non-interventional, enhanced Pharmacovigilance, global study

Study drug and medical condition

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

CRIZOTINIB

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

To be eligible for the study, patients must have been treated with crizotinib and have AE/SAE reports indicative of Potential Sight-threatening Event (PSTE)/Severe Visual Loss (SVL) received from study data sources between March 31, 2016 and March 31, 2021. All reports indicative of PSTE/SVL in patients that have been treated with crizotinib are included, regardless of the indication for use of crizotinib. This will allow for comprehensive analysis of PSTE/SVL cases for the study.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- 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

Non-small cell lung cancer patients

Estimated number of subjects

50

Study design details

Data analysis plan

The study population will consist of all PSTE/SVL reports received within the study period. All statistical analyses will be descriptive. Demographics and clinical characteristics will be tabulated. Risk factors for and outcomes of PSTE/SVL will be described and summarized overall, by grade or by indication as appropriate. Frequencies and percentages will be presented for categorical variables. For continuous variables, means, standard deviations, and ranges, or medians and inter quartile ranges, will be reported as appropriate. Detailed methodology for summary of data collected in this study will be documented in a Statistical Analysis Plan (SAP), which will be dated, filed and maintained by the sponsor. The SAP may modify the plans outlined in the protocol, any major modifications of the protocol would be reflected in a protocol amendment.

Documents

Study results

a8081062-report-body.pdf (5.05 MB)

Study report

a8081062-abstract.pdf (1.8 MB)

A8081062-first-interim-report.pdf (1.54 MB)

Study, other information

A8081062-first-interim-report.pdf (1.54 MB)

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

Prospective patient-based data collection, Pfizer sponsored ongoing crizotinib clinical trials, Pfizer sponsored ongoing crizotinib NI Primary Data Collection studies, non Pfizer sponsored ongoing crizotinib clinical trials, and other solicited data sources.

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