Alecensa Survey to Prescribers: Effectiveness Measure to Investigate the Correct Implementation of Alecensa Label Guidance by Prescribers

First published: 03/04/2019

Last updated: 17/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS29244

Study ID

37931

DARWIN EU® study

No

Study countries

Austria

Belgium

Germany

Hungary
Italy
Spain
Sweden
United Kingdom

Study description

The aim of this study is to evaluate the effectiveness of Alecensa's risk minimization measures (RMM) for the important identified risks (interstitial lung disease (ILD)/pneumonitis, hepatoxicity, bradycardia, photosensitivity, severe myalgia, and CPK elevations) as outlined in the risk management plan (RMP) and label, by assessing their correct implementation by Health Care Professionals (HCPs).

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Walter Bordogna global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Walter Bordogna

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/11/2018

Study start date

Planned: 01/06/2019

Actual: 22/05/2019

Date of final study report

Planned: 01/12/2020

Actual: 23/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd

Study protocol

ALECENSA_Final Redacted_02 April 2019.pdf (791.76 KB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Survey to evaluate how HCPs understand and correctly implement the risk minimization measures for Alecensa

Data collection methods:

Primary data collection

Main study objective:

To assess the awareness, knowledge, and clinical practices of HCPs regarding the specific important identified risks related to Alecensa and their related minimization measures.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XE36) alectinib

alectinib

Population studied

Short description of the study population

All HCPs (i.e., oncologists and pulmonologists) in the study countries who can be identified as potential prescribers of Alecensa and have not provided their general opt out will be considered as the target population.

Inclusion criteria:

HCPs (i.e., either oncologists or pulmonologists) must meet the following criteria for study entry:

1. HCPs must have treated patients (newly initiated or repeated administration/prescription) with ALK-positive NSCLC with Alecensa according to local label at least once in the 6 months prior to taking the survey

Exclusion criteria:

Inactive and retired HCPs (when documented information is available to identify them) will be deleted from the contact lists before randomization. HCPs who meet any of the following criteria will be excluded from study entry:

1. HCPs who are not involved in patient treatment
2. HCPs who may have conflicts of interest with the survey (i.e., HCPs employed by regulatory bodies, pharmaceutical industries)
3. Employment by Roche, or any research organization/vendor contracted by Roche to administer the survey

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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)

Estimated number of subjects

200

Study design details

Outcomes

Proportion of HCPs aware of the important identified risk and related minimization measures for Alecensa, 1. Proportion of HCPs knowledgeable about important risks, specific monitoring, dose modification2. Proportion of HCPs answering the clinical practice questions in compliance to the Summary of Product Characteristics (SPC)

Data analysis plan

The effectiveness of risk minimization measures will be defined by the proportion of HCPs aware of the identified risk and related minimization measures for Alecensa, the proportion of HCPs knowledgeable of the important risks, specific monitoring, and dose modification of Alecensa, and the proportion of HCPs answering the clinical practice questions in the questionnaire in compliance with the summary of product characteristics.

Documents

Study results

Final CSR Synopsis, Study BO40643_redacted_A.pdf (1.75 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

Questionnaires provided to HCPs that have treated patients with Alecensa

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