Information for Healthcare Professionals

11 January 2022

ALECENSA (alectinib), Warning and Precaution and Specific Dose Modification Guidance for Management of Haemolytic Anaemia

Dear Healthcare professional, Hoffmann-La Roche in agreement with European Medicines Agency and the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan would like to inform you of the following

Summary

- Haemolytic anaemia has been reported in clinical trials and post-marketing setting, and is considered a risk of Alecensa.
- A recent cumulative analysis of cases of haemolytic anaemia showed that modification of Alecensa dosing led to improvement of the majority of the haemolytic anaemia events with reported outcome.
- Alecensa should be withheld and appropriate laboratory testing should be initiated if haemoglobin concentration is below 10 g/dl and haemolytic anaemia is suspected.
- If haemolytic anaemia is confirmed, Alecensa treatment should be withheld until resolution of the event and resumed at a reduced dose or permanently discontinued. The dose reduction schedule is outlined in the dose and administration section of the Prescribing Information (PI).

Background on the safety concern

Alecensa (alectinib, RO5424802, CH5424802) is indicated for the first-line treatment of patients with anaplastic lymphoma kinase-positive (ALK+), locally advanced or metastatic non-small cell lung cancer (NSCLC) and for the treatment of patients with ALK+, locally advanced or metastatic NSCLC who have progressed on or are intolerant to crizotinib.

Haemolytic anaemia has been reported in clinical trials, with an uncommon frequency, and in the post-marketing setting.

A recent cumulative analysis of the 'Haemolytic disorders' cases showed that modification of Alecensa/Alecensaro dosing led to improvement of the majority of the haemolytic anaemia events with reported outcome.

Haemolytic anaemia is considered a clinically significant adverse drug reaction and it can be mitigated through appropriate use of the drug. Because, in some cases, haemolytic anaemia might require medical intervention, the prescribers must be informed of this risk, in order to initiate the appropriate laboratory workup, which is not part of the routine laboratory testing, to confirm the diagnosis of haemolytic anaemia, as well as to apply an alectinib dose modification.

In light of these observations, it is recommended that:

- Alecensa/Alecensaro should be withheld and appropriate laboratory testing should be initiated, if haemoglobin concentration is below 10 g/dl and haemolytic anaemia is suspected.
- If haemolytic anaemia is confirmed, Alecensa treatment should be withheld until resolution of the event and resumed at a reduced dose or permanently discontinued.

The benefit-risk profile of Alecensa, in the approved indications, continues to be favorable.

The Prescribing Information is being updated, in order to introduce the above recommendations into the 'Warnings and Precautions' and 'Dosage and Administration' sections.

Call for reporting

Healthcare professionals should report any adverse events, which are suspected to be associated with the use of Alecensa
It is important to inform any Suspicious Adverse Event Report of products. It will help continuously assess the risk/benefits. Healthcare professionals should report any suspicious adverse event reports online to the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan via website: www.pharm.am , emailing: vigilance@pharm.am via tel.: (374 60) 830073, (+374 10) 230896 street hot line: (+374 10) 200505; (+374 96) 220505.

You may also contact to Local person for Pharmacovigilance for Hoffmann- La Roche products in Armenia Acti Group LLC, Gayane Ghazaryan via following contacts: mob.: +374 91 796688, email: gayaneh.ghazaryan@gmail.com; or back up, Nune Karapetyan via following contacts: mob: +374 91 721153 or email: nune.karapetyan.roche@gmail.com.

You may also direct your reports to Roche Georgia LLC via following contacts: tel.: +995 322 506284; +995 322 507284 or email: georgia.safety@roche.com:

▼ Alecensa (alectinib) is subject to additional monitoring. This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Company Contact Point

In case of additional information, you may contact to Gayane Ghazaryan, a Local person for Pharmacovigilance for Hoffmann-La Roche products in Armenia Acti Group LLC, Gayane Ghazaryan via following contacts: mob.: +374 91 796688, email: gayaneh.ghazaryan@gmail.com.

Yours sincerely,

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