SANOFI

27-Jun-2019

Alemtuzumab (Lemtrada): New safety information

Dear Healthcare Professional,

Sanofi, in agreement with the SFDA, would like to inform you about new safety information that has been identified from post-marketing use with Lemtrada (alemtuzumab). This includes reports of autoimmune hepatitis and haemophagocytic lymphohistiocytosis, as well as temporally associated serious cardiovascular reactions. The new safety information is in the process of being incorporated into prescribing information.

New risk minimization measures, outlined below, should be followed before and during treatment with alemtuzumab.

Summary

- Patients receiving treatment with alemtuzumab should have vital signs monitored, including blood pressure measurement, before and periodically during alemtuzumab infusion. If clinically significant changes in vital functions are observed, discontinuation of infusion, additional monitoring, including ECG, as well as appropriate interventions, should be considered as guided by clinical status.
- Patients should be informed about the signs and symptoms of infusion reactions, and advised to seek immediate medical attention if any of these symptoms occur following infusion.
- Liver function should be evaluated prior to starting treatment and periodically as per clinical judgment.
- In case of autoimmune hepatitis, hepatic injury, or other serious immune mediated reactions, treatment should only be re-administered following careful consideration, including evaluation of the benefits and risks of further Lemtrada therapy.
- Patients should be advised to immediately seek medical help if they experience symptoms of hepatic injury.

Background information

New safety information from post-marketing use with Lemtrada (alemtuzumab) has been reported and includes fatal cases, cardiovascular adverse events in

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close temporal association with Lemtrada infusions, and immune-mediated adverse reactions.

In light of these emerging post-marketing data, alemtuzumab is suspected to be related to the following:

Autoimmune hepatitis and hepatic injury

Cases of hepatic injury including elevations of serum transaminases and autoimmune hepatitis (including fatal cases) have been reported in patients treated with alemtuzumab. Liver function should be evaluated prior to starting treatment and periodically as per clinical judgment.

Patients should be informed about the risk of hepatic injury and related symptoms, such as nausea, vomiting, abdominal pain, fatigue, loss of appetite, yellow skin or eyes and/or dark urine, or bleeding or bruising more easily than normal. In case of autoimmune hepatitis or hepatic injury, treatment should only be re-administered following careful consideration, including evaluation of the benefits and risks of further Lemtrada therapy.

Other serious reactions temporally associated with alemtuzumab infusion

During post-marketing use, cases of pulmonary alveolar haemorrhage, myocardial ischemia, stroke (including ischaemic and haemorrhagic stroke) and cervicocephalic (e.g. vertebral, carotid) arterial dissection have been reported. Cases may occur following any of the doses during the treatment course. In the majority of cases, time to onset was within 1-3 days of Lemtrada infusion. Patients should be informed about the signs and symptoms of these events, and advised to seek immediate medical attention if any of these symptoms occur.

Vital signs, including blood pressure, should be monitored before and during Lemtrada infusion. If clinically significant changes in vital functions are observed, discontinuation of infusion, additional monitoring, including ECG, as well as appropriate interventions should be considered as guided by clinical status.

Haemophagocytic lymphohistiocytosis (HLH)

During post-marketing use, HLH has been reported in patients treated with Lemtrada. HLH is a life-threatening syndrome of pathologic immune activation characterized by clinical signs and symptoms of extreme systemic inflammation, including fever, swollen lymph nodes, bruising or skin rash. It is associated with high mortality rates if not recognized early and treated. Symptoms have been reported to occur within a few months to four years following the initiation of treatment. Patients who develop disease

manifestations of pathologic immune activation should be evaluated immediately, and a diagnosis of HLH should be considered.

Call for reporting

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to National Pharmacovigilance and Drug Safety Center in SFDA.

Website: https://ade.sfda.gov.sa/
E-mail: npc.drug@sfda.gov.sa
Call center: 19999
Fax: +966-11-2057662

Company contact point

- Should you have any question or require additional information, please call Medical Information at +966-12-6693318, extension number # 1392, or contact them via email: ksa.medicalinformation@sanofi.com.

- For SANOFI Saudi Arabia Pharmacovigilance Center please contact us in the below contact information.

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Kind regards,

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Qualified Person for Pharmacovigilance (QPPV)