EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 April 2016
EMA/CHMP/296595/2016
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation

Active substance: alemtuzumab

Procedure No. EMEA/H/C/PSUSA/00010055/201509

Period covered by the PSUR: 13 March 2015 – 12 September 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for alemtuzumab, the scientific conclusions of CHMP are as follows:

Listeriosis/Listeria meningitis

Medicines that have a modulating effect on the immune system as Lemtrada might be associated with an increased risk of opportunistic infections. A total of 5 case reports all originating from the EU were identified. One alemtuzumab -treated MS clinical trial patient, enrolled in study CAMMS223, developed listeria meningitis and four spontaneous post-marketing cases of either systemic listeriosis or *Listeria monocytogenes* meningitis.

Bradycardia as an infusion related adverse reaction

Seventy-one cases (in 55 patients) of bradycardia (two of which were assessed as serious, the remainder as non-serious) were reported in clinical trials. A total of 1,505 alemtuzumab patients were exposed in these trials. In addition, thirty-nine cases of bradycardia (eight of which were assessed as serious, the remainder as non-serious) were reported from alemtuzumab post-marketing reports as of 01 May 2015. Each of the ten serious cases involving bradycardia occurred in the context of infusion-associated reactions.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing alemtuzumab were warranted. The section 4.4 of the summary of product characteristics and the relevant sections of the package leaflet were updated.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for alemtuzumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing alemtuzumab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.