27 June 2013
EMA/377379/2013
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Lemtrada

(Alemtuzumab)

On 27 June 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lemtrada 12 mg alemtuzumab in 1.2 ml (10 mg/ml) concentrate for solution for infusion intended for the treatment of relapsing remitting multiple sclerosis. The applicant for this medicinal product is Genzyme Therapeutics Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The approved indication is: "treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features ".

Alemtuzumab is a humanized monoclonal antibody directed against the cell surface glycoprotein CD52. The mechanism by which alemtuzumab exerts its therapeutic effects in multiple sclerosis is not fully elucidated. However, research suggests immunomodulatory effects through depletion and repopulation of lymphocytes.

The benefits with Lemtrada are its ability to reduce the relapse rate and slow disability progression. The most common side effects are infusion associated reactions (including headache, flushing, nausea, urticaria, rash, pruritus, pyrexia and fatigue), upper respiratory tract infection, urinary tract infection, lymphopenia and leukopenia. In addition, side effects pertaining to the thyroid gland (including over-active or under-active thyroid gland, or goitre and auto-immune conditions) were commonly observed in patients treated with alemtuzumab.

A pharmacovigilance plan for Lemtrada will be implemented as part of the marketing authorisation.

Treatment with Lemtrada should be initiated and supervised by a neurologist experienced in the treatment of patients with MS. Specialists and equipment required for the timely diagnosis and management of the most frequent adverse reactions, especially autoimmune conditions and infections, should be available.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Resources for the management of hypersensitivity and/or anaphylactic reactions should be available.

Patients treated with Lemtrada must be given the Patient Alert Card and Patient Guide and be informed about the risks of Lemtrada.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Lemtrada and therefore recommends the granting of the marketing authorisation.