20 September 2018
EMA/CHMP/598685/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Poteligeo

mogamulizumab

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Poteligeo, intended for the treatment of mycosis fungoides (MF) or Sézary syndrome (SS), the most common subsets of cutaneous T-cell lymphoma, a rare form of non-Hodgkin's lymphoma. Poteligeo was designated as an orphan medicinal product on 14 October 2016. The applicant for this medicinal product is Kyowa Kirin Limited.

Poteligeo will be available as a 4-mg/ml concentrate for solution for infusion. The active substance of Poteligeo is mogamulizumab, a monoclonal antibody (ATC code: L01XC25) that selectively binds to CC chemokine receptor-4 (CCR4) expressed on the surface of some cancer cells including T-cells of T-cell malignancies, such as MF and SS, resulting in depletion of the target cells.

The benefits with Poteligeo are its ability to improve progression-free survival in patients. The most common side effects are drug eruption (including skin rash), infections (including upper respiratory tract infection and skin infections), infusion related reaction, headache, fatigue, peripheral oedema, pyrexia and gastrointestinal disorders (such as constipation, diarrhoea, nausea, stomatitis).

The full indication is:

"Poteligeo is indicated for the treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy".

It is proposed that Poteligeo be prescribed by physicians experienced in the treatment of cancer.

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.

[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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