EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 May 2017
EMA/CHMP/307703/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ritemvia

rituximab

Medicinal product no longer authorised

On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ritemvia, intended for the treatment of non-Hodgkin's lymphoma (NHL), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). The applicant for this medicinal product is Celltrion Healthcare Hungary Kft.

Ritemvia will be available as a 500 mg concentrate for solution for infusion. The active substance of Ritemvia is rituximab, a monoclonal antibody (ATC code: L01XC02) that binds specifically to the transmembrane protein CD20 found on both malignant and normal B cells. In NHL, this promotes destruction of malignant B cells and thus controls tumour growth. In GPA and MPA, it reduces the levels of B cells involved in their pathogenesis.

Ritemvia is a biosimilar medicinal product. It is highly similar to the reference product Mabthera (rituximab), which was authorised in the EU on 2 June 1998. Data show that Ritemvia has comparable quality, safety and efficacy to Mabthera. More information on biosimilar medicines can be found here.

The full indications are:

"Non-Hodgkin's lymphoma (NHL)

Ritemvia is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy.

Ritemvia maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.

Ritemvia monotherapy is indicated for treatment of patients with stage III-IV follicular lymphoma who are chemo-resistant or are in their second or subsequent relapse after chemotherapy.

Ritemvia is indicated for the treatment of patients with CD20 positive diffuse large B cell non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy.

[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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Granulomatosis with polyangiitis and microscopic polyangiitis

Ritemvia, in combination with glucocorticoids, is indicated for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA)."

It is proposed that Ritemvia be administered under the close supervision of an experienced healthcare professional and in an environment where full resuscitation facilities are immediately available.

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.

Medicinal product no longer authorised