15 December 2016
EMA/CHMP/813387/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Truxima

rituximab

On 15 December 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Truxima, intended for the treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). The applicant for this medicinal product is Celltrion Healthcare Hungary Kft.

Truxima will be available as a 500 mg concentrate for solution for infusion. The active substance of Truxima 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 and CLL, this promotes destruction of malignant B cells and thus controls tumour growth. In RA, GPA and MPA, it reduces B cells involved in their pathogenesis.

Truxima is a biosimilar medicinal product that is highly similar to the reference product Mabthera (rituximab), which was authorised in the EU on 2 June 1998. Studies have shown Truxima to have comparable quality, safety and efficacy to Mabthera.

The full indications are:

> "Non-Hodgkin's lymphoma (NHL)
>
> Truxima is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy.
>
> Truxima maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.
>
> Truxima 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.
>
> Truxima 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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Chronic lymphocytic leukaemia (CLL)

Truxima in combination with chemotherapy is indicated for the treatment of patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia. Only limited data are available on efficacy and safety for patients previously treated with monoclonal antibodies including Truxima or patients refractory to previous Truxima plus chemotherapy.

See section 5.1 for further information.

Rheumatoid arthritis

Truxima in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARD) including one or more tumour necrosis factor (TNF) inhibitor therapies.

Truxima has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.

Granulomatosis with polyangiitis and microscopic polyangiitis

Truxima, 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 Truxima 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.