EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 May 2017
EMA/CHMP/307683/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tuxella

rituximab

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 Tuxella, intended for the treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). The applicant for this medicinal product is Celltrion Healthcare Hungary Kft.

Tuxella will be available as a 500 mg concentrate for solution for infusion. The active substance of Tuxella 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 GPA and MPA, it reduces the level of B cells involved in their pathogenesis.

Tuxella 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 Tuxella 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)

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

Tuxella 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.

Tuxella 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Chronic lymphocytic leukaemia (CLL)

Tuxella 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 Tuxella or patients refractory to previous Tuxella plus chemotherapy.

See section 5.1 for further information.

Granulomatosis with polyangiitis and microscopic polyangiitis

Tuxella, 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 Tuxella 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.