30 January 2020
EMA/CHMP/28049/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ruxience

rituximab

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ruxience, 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), and Pemphigus vulgaris (PV). The applicant for this medicinal product is Pfizer Europe MA EEIG.

Ruxience will be available as 100 mg and 500 mg concentrates for solution for infusion. The active substance of Ruxience 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, MPA and PV it reduces the number of B cells involved in their pathogenesis.

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

The full indications are:

> "Ruxience is indicated in adults for the following indications:
>
> Non-Hodgkin's lymphoma (NHL)
>
> Ruxience is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy.
>
> Ruxience maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.
>
> Ruxience monotherapy is indicated for treatment of patients with stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Ruxience 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.

Chronic lymphocytic leukaemia (CLL)

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

See section 5.1 for further information.

Rheumatoid arthritis

Ruxience 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.

Ruxience 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

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

Pemphigus vulgaris

Ruxience is indicated for the treatment of patients with moderate to severe pemphigus vulgaris (PV)."

It is proposed that Ruxience should 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.