25 July 2024
EMA/CHMP/333263/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ituxredi

rituximab

On 25 July 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ituxredi, intended for the treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis and pemphigus vulgaris.

The applicant for this medicinal product is Reddy Holding GmbH.

Ituxredi will be available as a 100 mg and 500 mg concentrate for solution for infusion. The active substance of Ituxredi is rituximab, a monoclonal antibody antineoplastic agent (ATC code: L01X C02). Rituximab binds specifically to the transmembrane antigen CD20 on B lymphocytes, inducing cancer cell death via apoptosis.

Ituxredi 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 Ituxredi has comparable quality, safety and efficacy to MabThera (rituximab). More information on biosimilar medicines can be found here.

The full indication is:

> Ituxredi is indicated in adults for the following indications:
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> Non-Hodgkin's lymphoma (NHL)
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> Ituxredi is indicated for the treatment of previously untreated adult patients with stage III-IV follicular lymphoma in combination with chemotherapy.
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> Ituxredi maintenance therapy is indicated for the treatment of adult follicular lymphoma patients responding to induction therapy.

[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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Ituxredi monotherapy is indicated for treatment of adult patients with stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after chemotherapy.

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

Ituxredi in combination with chemotherapy is indicated for the treatment of paediatric patients (aged ≥ 6 months to < 18 years old) with previously untreated advanced stage CD20 positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL)/Burkitt leukaemia (mature B-cell acute leukaemia) (BAL) or Burkitt-like lymphoma (BLL).

Chronic lymphocytic leukaemia (CLL)

Ituxredi 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 Ituxredi or patients refractory to previous Ituxredi plus chemotherapy.

See section 5.1 for further information.

Rheumatoid arthritis

Ituxredi 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.

Ituxredi 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

Ituxredi, 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).

Ituxredi, in combination with glucocorticoids, is indicated for the induction of remission in paediatric patients (aged ≥ 2 to < 18 years old) with severe, active GPA (Wegener's) and MPA.

Pemphigus vulgaris

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

Ituxredi 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.