14 December 2017
EMA/CHMP/813650/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Crysvita

burosumab

On 14 December 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Crysvita, intended for the treatment of X-linked hypophosphataemia. Crysvita was designated as an orphan medicinal product on 15 October 2014. The applicant for this medicinal product is Kyowa Kirin Limited.

Crysvita will be available as a solution for injection (10 mg/ml, 20 mg/ml and 30 mg/ml). The active substance of Crysvita is burosumab, a human monoclonal antibody that binds to and inhibits the activity of fibroblast growth factor 23 (ATC code: M05BX05). Inhibiting the activity of elevated serum fibroblast growth factor 23 in X-linked hypophosphataemia reduces the loss of phosphate from the kidney and other metabolic abnormalities, which are considered to be causative of the disease's bone changes.

The benefits with Crysvita are its ability to reduce the loss of phosphate from the kidney, to improve abnormally low serum phosphate concentrations and to reduce the severity of rickets as shown in x-rays. The most common side effects are injection site reactions, headache, and pain in extremities.

The full indication is: "Crysvita is indicated for the treatment of X-linked hypophosphataemia with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons."

It is proposed that Crysvita be prescribed by physicians experienced in the management of patients with metabolic bone diseases.

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.

[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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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