15 September 2016
EMA/CHMP/587633/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Parsabiv

etelcalcetide

On 15 September 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 Parsabiv, intended for the treatment of secondary hyperparathyroidism. The applicant for this medicinal product is Amgen Europe B.V.

Parsabiv will be available as 2.5, 5 and 10 mg vials containing a solution for injection. The active substance of Parsabiv is the synthetic peptide etelcalcetide, a calcimimetic agent (ATC code: H05BX04) which reduces parathyroid hormone (PTH) secretion by the parathyroid gland through binding and activation of the calcium-sensing receptor.

The benefits with Parsabiv are its ability to reduce abnormally elevated serum PTH levels in patients with chronic kidney disease on haemodialysis therapy, in order to mitigate the adverse consequences of secondary hyperparathyroidism in these patients. The most common side effect is a decrease of serum calcium levels. Other common side effects are muscle spasms, diarrhoea, nausea and vomiting.

The full indication is: "Parsabiv is indicated for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy".

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

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