14 September 2023
EMA/CHMP/405555/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Yorvipath

palopegteriparatide

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Yorvipath[2], intended for the treatment of chronic hypoparathyroidism in adults. The applicant for this medicinal product is Ascendis Pharma Bone Diseases A/S.

Yorvipath will be available as 168 µg/0.56 ml, 294 µg/0.98 ml and 420 µg/1.4 ml solutions for injection. The active substance of Yorvipath is palopegteriparatide, a transiently pegylated parathyroid hormone (ATC code: H05AA05) that in the body dissociates into parathyroid hormone and binds to and activates cell-surface parathyroid hormone receptors (PTH1R) similar to endogenous parathyroid hormone.

The benefits of Yorvipath are the achievement of serum and urinary calcium levels in the normal range and independence from conventional therapy, as observed in a phase 3, double-blind, placebo-controlled study in adult patients with hypoparathyrodism. The most common side effects are injection site reactions, headache, and paraesthesia. Hypercalcaemia may occur, especially when starting Yorvipath or when increasing the dose, and patients should be monitored for signs and symptoms of hypercalcaemia.

The full indication is:

> Yorvipath is a parathyroid hormone (PTH) replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism.

Yorvipath should be initiated and monitored by physicians experienced in the diagnosis and treatment of patients with hypoparathyroidism.

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] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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