26 February 2026
EMA/22216/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Palsonify

paltusotine

On 26 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Palsonify[2], intended for the treatment of adults with acromegaly.

The applicant for this medicinal product is Crinetics Pharmaceuticals Europe GmbH.

Palsonify will be available as 20 mg and 30 mg film-coated tablets. The active substance of Palsonify is paltusotine, a pituitary and hypothalamic hormone analogue (ATC code: H01CB06). Paltusotine is very similar to the natural hormone somatostatin, suppressing the secretion of growth hormone (GH) and, as a result, insulin-like growth factor-1 (IGF-1). This leads to lower, and in many cases normalised, GH and IGF-1 levels in patients with acromegaly.

The benefit of Palsonify is its ability to achieve and maintain normal IGF-1 levels in most patients. As shown in one phase 3 randomised, double-blind, parallel group, placebo-controlled clinical study in patients who were not receiving medical treatment and were biochemically uncontrolled, in patients not treated with acromegaly medical therapy at least 4 months at screening and in patients biochemically controlled on stable dose of injectable long-acting octreotide or lanreotide monotherapy for at least 3 months after a washout of up to 12-16 weeks at randomization (PATHFNDR-2), 55.7% (30 out of 54) of patients treated with Palsonify achieved biochemical control (IGF-1 level ≤ 1.0×ULN) at week 24 compared with 5.3% (3 out of 57) of patients given placebo (p-value < 0.0001).

In another phase 3 randomised, double-blind, parallel group, placebo-controlled clinical study in patients who were biochemically controlled on injectable long-acting octreotide or lanreotide monotherapy (PATHFNDR-1), 25/30 (83.3%) of patients treated with Palsonify maintained the biochemical control (IGF- 1 level ≤ 1.0×ULN) at week 36 compared to (1/28) 3.6% of placebo-treated patients(p-value < 0.0001).

The most common side effects are diarrhoea, abdominal pain, nausea and abdominal discomfort.

[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

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The full indication is:

Palsonify is indicated for the medical treatment of adult patients with acromegaly.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.