EMA/CHMP/685662/2021
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Ngenla

somatrogon

On 16 December 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ngenla,[2] intended for the treatment of growth hormone deficiency (GHD) in children and adolescents from 3 years of age. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Ngenla will be available as 24 mg/1.2 ml and 60 mg/1.2 ml solutions for injection. The active substance of Ngenla is somatrogon, a long-acting once-weekly protein known as a recombinant human growth hormone (rhGH), which is obtained through recombinant DNA technology. Somatrogon binds to the growth hormone receptor and initiates changes in growth and metabolism. The ATC code is yet to be assigned.

Ngenla demonstrated improvements of growth-related parameters, such as annualised height velocity, height standard deviation score, without excessive acceleration of bone maturation, in paediatric GHD patients who are naïve to growth hormone. Ngenla also reduced treatment burden for patients and caregivers. These effects were clinically relevant, and long-term efficacy was also demonstrated. The most common side effects were injection site reactions, headache and pyrexia.

The full indication is:

> Ngenla is indicated for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone.

Ngenla should be prescribed by physicians experienced in the treatment of paediatric patients with growth hormone deficiency (GHD).

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

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