[redacted]

20-Dec-2024

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: **Withdrawal Letter – Ngenla (somatrogon) Procedure EMEA/H/C/005633/II/0016**

Type II variation (C.I.6.a) application to update the product information with a new indication for Ngenla.

Dear Professor Sepodes,

I would like to inform you that Pfizer Europe MA EEIG has taken the decision to withdraw the application to add a new indication for Ngenla in the treatment of adult growth hormone deficiency (procedure EMEA/H/C/005633/II/0016).

This withdrawal at this time is to allow conduct of additional analyses related to the use of Ngenla in the targeted population.

This withdrawal does not have any impact on any ongoing clinical studies.

Pfizer reserves the right to make further submissions to CHMP at a future date for the proposed indication or other associated therapeutic indications.

Pfizer would like to sincerely thank the Rapporteurs, EMA, PRAC and CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.

Yours sincerely,

[redacted]