

24th January 2008

Dr. Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB

Dear Dr Abadie,

Re: Withdrawal of EMEA/H/000315/II/024

We would like to inform you that, at this point in time, Ipsen Ltd has taken the decision to withdraw the application for a new indication for NutropinAq, in the treatment of children with severe idiopathic short stature.

This withdrawal is based on the CHMP's consideration that the data provided does not allow them to recommend authorisation of the extension of the marketing authorisation with the proposed indication.

NutropinAq continues to be available in the currently approved indications.

Ipsen wishes to point out there are no ongoing clinical trials with NutropinAq in this indication in Europe. NutropinAq is approved in the USA for "the long-term treatment of idiopathic short stature, also called non-growth hormone-deficient short stature, defined by height SDS ≤ -2.25 , and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means."

Ipsen remains committed to the field of growth hormone research and to gaining necessary scientific advice on plans for future developments in this or similar patient populations.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

We agree for this letter to be published on the EMEA website.

Yours sincerely,

Regulatory Affairs Officer

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