European Medicines Agency
Press office

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PRESS RELEASE
Ipsen Ltd withdraws its application for an extension of indication for NutropinAq

The European Medicines Agency (EMEA) has been formally notified by Ipsen Ltd of its decision to withdraw its application for an extension of indication for the centrally authorised medicine NutropinAq (somatropin).

NutropinAq was expected to be used for the treatment of children with severe idiopathic short stature (short height not explained by growth hormone deficiency or other medical conditions) with a predicted adult height of at least 1 standard deviation score below the target height.

NutropinAq was first authorised in the European Union on 16 February 2001. It is currently indicated for use in the long-term treatment of children with growth failure due to inadequate endogenous growth hormone secretion, long-term treatment of growth failure associated with Turner syndrome, treatment of prepubertal children with growth failure associated with chronic renal insufficiency up to the time of renal transplantation, and replacement of endogenous growth hormone in adults with growth hormone deficiency of either childhood or adult-onset aetiology.

The application for the extension of indication for NutropinAq was submitted to the EMEA on 18 April 2006. The Agency's Committee for Medicinal Products for Human Use (CHMP) had given a negative opinion recommending the refusal of a marketing authorisation in 27 September 2007. The company had requested a re-examination of the negative opinion, which had not yet finished when the company withdrew.

In its official letter, the company stated that the withdrawal of the application was based on the CHMP's opinion that the data provided did not allow the Committee to recommend authorisation of the extension of the marketing authorisation in the proposed indication.

More information about NutropinAq and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website in due course.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about NutropinAq is available in the European Public Assessment Report (EPAR): http://www.emea.europa.eu/humandocs/Humans/EPAR/nutropinaq/nutropinaq.htm
3. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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