



European Medicines Agency
Press office

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PRESS RELEASE

Insmed withdraws its marketing authorisation application for IPLEX

The European Medicines Agency (EMA) has been formally notified by Insmed Incorporated of its decision to withdraw the application for a centralised marketing authorisation for the medicinal product IPLEX (mecasermin rinfabate), 60 mg/ml (36 mg) solution for injection.

IPLEX was expected to be used for the treatment of primary growth hormone insensitivity, a rare genetic disorder, caused by the body's inability to use the growth hormone it produces, and for the treatment of patients with growth hormone gene¹ deletion who have developed neutralising antibodies to growth hormone. Mecasermin rinfabate was designated as an orphan medicinal product for the treatment of these conditions on 20 June 2006.

The application for marketing authorisation for IPLEX was submitted to the EMA on 1 June 2006. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of IPLEX was due to a business agreement that has altered Insmed's strategy for IPLEX in the European Union.

More information about IPLEX and the current 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 EMA website after the next meeting of the CHMP on 23-26 April 2007.

--ENDS--

NOTES

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information about the work of the EMA, can be found on the EMA website: <http://www.emea.europa.eu>

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel: (44-20) 74 18 84 27, E-mail: press@emea.europa.eu

¹ Correction: inclusion of the word 'gene'