

# INSMED

I N C O R P O R A T E D

March 22, 2007

Dr. Daniel Brasseur  
European Medicines Agency  
7 Westferry Circus  
Canary Warf  
London  
E14 4HB  
United Kingdom

Subject: Withdrawal of IPLEX (mecasermin rinfabate), 60 mg/ml (36 mg) solution for injection; EMEA/H/C/000754

Dear Dr. Brasseur,

I would like to inform you that, at this point in time, Insmmed Europe Ltd has taken the decision to withdraw the application for Marketing Authorization of IPLEX (mecasermin rinfabate), 60 mg/ml (36 mg) solution for injection, EMEA/H/C/000754, which was intended to be used for the treatment of primary growth hormone insensitivity (PHGI) due to molecular or genetic defects and patients with growth hormone (GH) deletion who have developed neutralizing antibodies to GH.

This withdrawal is based on a business agreement that has altered Insmmed's marketing strategy for IPLEX in the European Union. Insmmed is withdrawing the application before it has had the opportunity to respond to the 120 Day assessment, though it believes that IPLEX could have been approved for the intended indications upon successful interaction with the EMEA.

This withdrawal will not have any impact on the availability of IPLEX in the ongoing clinical study for the evaluation of safety and efficacy in the treatment of Growth Hormone Insensitivity Syndrome.

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We acknowledge our right to make further submissions at a future date in the referenced indications or other therapeutic indication(s).

On behalf of Insmmed Europe, I give consent for this letter to be published on the EMEA website.

Sincerely,

Insmmed Incorporated