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March 15, 2011

To: Dr. Abadie
CHMP Chair
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB

Ref: Epostim – 2265; Withdrawal of application EMEA/H/C/002265/0000

Cc Dr. Pierre Demolis (Rapporteur); Dr. Sol Ruiz (Co-Rapporteur); H. Boix (EMA PTL)

Dear Dr. Abadie,

We would like to inform you that, at this point in time, Reliance GeneMedix plc would like to withdraw our application for the Market Authorisation of Epostim: 2000IU/0.5ml; 4000IU/0.4ml; and 10000IU/ml solution for injection in pre-filled syringes.

Based on its initial assessment of the application, the EMA has asked for additional data to be provided by the Company which is expected to take more time than permitted by the EMA prescribed schedule.

As a consequence, the Company has decided to withdraw its application to EMA for the time being and is evaluating EMA's comments before developing a plan to generate that data by doing certain additional studies and to resubmit the application in due course.

We understand that this withdrawal decision does not impact any ongoing or future clinical trials with Epostim. We reserve the right to make further submissions at a future date for this or other therapeutic indications

Thank you for your support through this process.

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

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