NOVARTIS

Dr Silvia Pfaff
DRA EU Regional Head

Novartis Pharma AG
DRA BF IID
WSJ-157.5.14.2
Lichstrasse 35
CH-4056 Basel
Tel: +41 61 324 1627
Fax: +41 61 324 0812
E-mail: silvia.pfaff@novartis.com

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

16th April 2010

Cc: Prof. Lechat (Rapporteur), Dr. Ljungberg (Co-Rapporteur), R. Turner (EMA PTL)

Subject: Withdrawal of original application for JOULFERON®, albinterferon alfa-2b, 900 micrograms powder and solvent for solution for injection in pre-filled pen and vials - EMEA/H/C/002166/0000

Dear Dr. Abadie,

We would like to inform you, at this point of time, Novartis Europharm Limited has taken the decision to withdraw the application for the Marketing Authorisation of JOULFERON (albinterferon alfa-2b) 900 micrograms powder and solvent for solution for injection in pre-filled pen and vials, which was intended to be used in combination with ribavirin for the treatment of adults with chronic hepatitis C (CHC) virus infection who have compensated liver disease and have not been previously treated with interferon alpha (IFNα).

The decision was taken by Novartis Europharm Limited on the basis of preliminary comments from the Rapporteur and Co-Rapporteur in the day 80 draft assessment reports. These indicate that in order to conclude a favourable approval decision, additional new data would be requested, which could not reasonably be generated within the timeframe allowed in the Centralised Procedure.

This withdrawal has no impact on the ongoing clinical trials, Novartis Europharm Limited will continue to make JOULFERON available to patients enrolled in those trials.

Novartis Europharm Limited reserves the right to make further submissions at a future date in this or other therapeutic indications.

Novartis Europharm Limited agrees for this letter to be published on the EMA website.

Yours Sincerely,