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United Kingdom

[redacted]

Date: 14th January 2011

Dr. Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of the original application for OZESPA, briakinumab, 100 mg solution for injection -EMEA/H/C/002019/0000

Dear Dr. Abadie

We would like to inform you that, at this point of time, Abbott Laboratories Limited has taken the decision to withdraw the application for Marketing Authorisation of OZESPA (briakinumab) 100 mg solution for injection, which was intended to be used for the treatment of moderate to severe chronic plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and PUVA.

The decision was taken by Abbott Laboratories Limited based on the preliminary comments from the Rapporteur and Co-Rapporteur in their day 80 draft assessment reports. These indicate that in order to conclude a favourable approval decision additional new data and/or analyses may be necessary. These could not reasonably be generated within the timeframe allowed in the Centralised Procedure.

The withdrawal of the application for Marketing Authorisation has no impact on the ongoing clinical trials and Abbott Laboratories Limited will continue to make OZESPA available to patients enrolled in these trials.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

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

Yours sincerely,

[redacted]

Associate Director

[redacted]

cc: Dr. Hudson (Rapporteur), Dr. Kallio (Co-Rapporteur),

[redacted]