Dyax Corp.

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Dyax

11 November 2011

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

Subject: **Withdrawal of Kalbitor, (ecallantide), 10 mg/ml, solution for injection**
EMEA/H/C/002200

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Dyax s.a. has taken the decision to withdraw the application for Marketing Authorisation of Kalbitor (ecallantide), 10 mg/ml solution for injection, which was intended to be used for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults and adolescents 16 years of age and older.

This withdrawal is based on the following reason: The applicant is unable to address to the satisfaction of the CHMP the remaining clinical issues raised in the Joint Assessment Report by the Rapporteurs on Day 181, such that the submitted information is deemed not sufficient to demonstrate a positive benefit-risk balance. The clinical issues involve the rate of clinical reactivity and the proposed dosage in heavy weight patients.

This decision will not have consequences for patients enrolled in any ongoing Dyax sponsored clinical trials. We reserve the right to make further submissions at a future date in this or other therapeutic indication.

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

Yours sincerely,

[redacted]
Vice President, Regulatory Affairs and Operations
On behalf of Dyax s.a.

cc: Dr Ian Hudson, Medicines and Healthcare products Regulatory Agency (Rapporteur)
Dr Barbara van Zweiten-Boot, Medicines Evaluation Board (Co-Rapporteur)
[redacted], European Medicines Agency Product Team Leader