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Press Office

Press release

Dyax s.a. withdraws its marketing authorisation application for Kalbitor (ecallantide)

The European Medicines Agency has been formally notified by Dyax s.a. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Kalbitor (ecallantide), 10 mg/ml solution for injection. Kalbitor 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.

The application for the marketing authorisation for Kalbitor was submitted to the Agency on 1 June 2010. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that they decided to withdraw the application because they were unable to provide sufficient information to address the outstanding clinical issues identified during the evaluation of their application.

More information about Kalbitor and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the CHMP meeting on 14-17 November 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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