17 January 2011
EMA/40297/2011
Press Office

Press release

Abbott Laboratories Limited withdraws its marketing authorisation application for Ozespa (briakinumab)

The European Medicines Agency has been formally notified by Abbott Laboratories Limited of its decision to withdraw its application for a centralised marketing authorisation for the medicine Ozespa (briakinumab), 100 mg solution for injection.

This medicine 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 application for the marketing authorisation for Ozespa was submitted to the Agency on 2 September 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 its decision to withdraw the application was based on the views of the rapporteurs in their day 80 assessment reports that additional new data and analyses would be required for a favourable opinion, but those could not be generated within the timeframe allowed in the centralised procedure.

More information about Ozespa 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 next CHMP meeting on 17 – 20 January 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. The withdrawal of the application has no impact on the ongoing clinical trials. The company will continue to make Ozespa available for patients enrolled in the trials.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu