European Medicines Agency
*Press office*

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# PRESS RELEASE
## Neurochem withdraws its marketing authorisation application for Kiacta (eprodisate disodium)

The European Medicines Agency (EMEA) has been formally notified by Neurochem Luxco II SARL of its decision to withdraw the application for a centralised marketing authorisation for the medicine Kiacta (eprodisate disodium) capsules.

Kiacta was expected to be used for the treatment of amyloid A amyloidosis, a rare, life-threatening disease that occurs in patients with long-lasting inflammation, most commonly due to rheumatoid arthritis.

The application for marketing authorisation for Kiacta was submitted to the EMEA on 4 September 2006. The Agency's Committee for Medicinal Products for Human Use (CHMP) had given a negative opinion recommending the refusal of the marketing authorisation on 13 December 2007. The company had requested a re-examination of the negative opinion. The re-examination had not yet finished when the company withdrew.

In its official letter, the company stated that the withdrawal of Kiacta was based on the request by the CHMP for an additional placebo-controlled study, which the company is not able to provide within the timeframe allowed by the centralised procedure.

More information about Kiacta 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 EMEA website in due course.

-- ENDS --

Notes:
1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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