EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2012
EMA/431454/2012
Press Office

Press release

Ferrer Internacional, S.A. withdraws its marketing authorisation application for Egrifta (tesamorelin)

The European Medicines Agency has been formally notified by Ferrer Internacional, S.A. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Egrifta (tesamorelin), 2 mg, powder for solution for injection. Egrifta was intended to be used for the treatment of excess visceral adipose tissue (VAT), defined as a level greater than 130 cm^2 by imaging procedures, in treatment-experienced HIV-infected patients.

The application for the marketing authorisation for Egrifta was submitted to the Agency on 31 May 2011. 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 the CHMP considers that the provided data do not allow it to conclude on a positive benefit-risk balance.

More information about Egrifta 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 of 16-19 July 2012.

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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