

Barcelona, 21 June 2012

CHMP Chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of EGRIFTA (Tesamorelin), 2 mg, powder for solution for injection
EMEA/H/C/2427

Dear CHMP Chairman,

For the withdrawal of initial marketing authorisation application

I would like to inform you that, at this point of time, Ferrer Internacional, S.A. has taken the decision to withdraw the application for Marketing Authorisation of EGRIFTA (Tesamorelin), 2 mg, powder for solution for injection, which was intended to be used for the treatment of excess visceral adipose tissue (VAT), defined as a level greater than 130 cm² by imaging procedures, in treatment-experienced adult HIV-infected patients.

This withdrawal is based on the following reason:

The CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

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