



ACTELION

Creative Science for Advanced Medicine

Global DRA Project Manager

19 February 2008

Dr E. Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Dear Dr Abadie,

RE: Withdrawal of (EMEA/H/C/435/II/21),

We would like to inform you that, at this point of time, Actelion has taken the decision to withdraw the application for an extension of a new indication, Niemann Pick type C disease, a type II change to the marketing authorisation, for Zavesca® (miglustat) in the treatment of neurological manifestations of Niemann Pick Type C disease.

This withdrawal is based on the following reason:

Upon discussions with the CHMP, it was concluded that relevant additional data from patients treated with miglustat in the clinical setting could be provided in order to support a resubmission in this indication in the near future.

There will be no consequences of the withdrawal for patients in ongoing clinical trials or in special access programs.

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

We agree for this letter to be published on the EMEA website.

Yours sincerely,

Global DRA Project Manager

Head, Strategic Clinical Development