European Medicines Agency
Press office

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PRESS RELEASE
Actelion withdraws its application for an extension of indication for Zavesca

The European Medicines Agency (EMEA) has been formally notified by Actelion of its decision to withdraw its application for an extension of indication for the centrally authorised medicine Zavesca (miglustat).

Zavesca was expected to be used for the treatment of neurological manifestations in patients with Niemann Pick type C disease, a rare inherited neurodegenerative disease of childhood and adolescence. Zavesca is an orphan medicinal product.

Zavesca was first authorised in the European Union on 20 November 2002. It is currently indicated for the oral treatment of mild to moderate type 1 Gaucher disease. Zavesca may be used only in the treatment of patients for whom enzyme replacement therapy is unsuitable.

The application for the extension of indication for Zavesca was submitted to the EMEA on 16 October 2006. The Agency's Committee for Medicinal Products for Human Use (CHMP) had given a negative opinion recommending the refusal of the type II variation to extend the indication on 18 October 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 is saying that the withdrawal of the application was based on its discussions with the CHMP regarding the need for additional data to be provided from patients treated with miglustat in the clinical setting. These data could be provided in order to support a resubmission in this indication in the near future.

More information about Zavesca 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.

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Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about Zavesca is available in the European Public Assessment Report (EPAR): http://www.emea.europa.eu/humandocs/Humans/EPAR/zavesca/zavesca.htm
3. 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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