European Medicines Agency
Press office

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PRESS RELEASE
Supply shortage of Cerezyme – updated treatment recommendations required

The European Medicines Agency has been informed by Genzyme, the marketing authorisation holder of Cerezyme (imiglucerase), that the supply shortage of the medicine is more severe than previously expected. The Agency's Committee for Medicinal Products for Human Use (CHMP) has therefore agreed to new temporary treatment recommendations, which revise the recommendations proposed by the company in June 2009. Only patients at greatest need of treatment will receive Cerezyme, albeit at a reduced dose, until the shortage is resolved.

Cerezyme is used in the treatment of patients with Gaucher disease, a disease in which patients do not have enough of an enzyme called alglucerase.

The updated recommendations during the supply shortage are as follows:

- Infants, children and adolescents should receive Cerezyme at a reduced dose or at a reduced infusion frequency. However, no patient should be treated at a dose lower than 15 units per kilogram body weight every two weeks, or alternative treatment should be considered.
- Adult patients with severe, life-threatening disease progression should receive Cerezyme at a reduced dose or at a reduced infusion frequency. No patient should be treated at a dose lower than 15 U/kg every four weeks, or alternative treatment should be considered.
- In adult patients without severe, life-threatening disease, alternative treatment should be considered or treatment should be interrupted.
- All patients should be monitored for changes in haemoglobin, platelets and chitotriosidase levels, as appropriate, at baseline and bimonthly thereafter. Adults who demonstrate progression to severe, life-threatening disease should reinitiate the original treatment with Cerezyme.

These are temporary recommendations and do not change the currently approved Product Information for Cerezyme. It is expected that these changes will need to continue until the end of the year.

The supply shortage is caused by the shutting down of Genzyme's production site for Cerezyme and Fabrazyme (agalsidase beta) in Allston Landing, in the United States of America in June 2009, because a viral contamination (calicivirus of the type Vesivirus 2117) required sanitisation of the bioreactors. The virus is not known to cause disease in humans, but it may affect the quantity, but not the quality, of the enzymes produced in the bioreactors. An in-depth investigation of the cause of the contamination is ongoing.

As a consequence of the supply shortage caused by the interruption of manufacturing, the CHMP had issued temporary changes to the way Cerezyme and Fabrazyme are prescribed and used in June 2009. Although the manufacture of both medicines is resuming according to plan, Genzyme has now informed the European Medicines Agency that the existing stocks of Cerezyme are lower than previously communicated.

The temporary treatment recommendations for Fabrazyme issued in June 2009 remain unchanged.

-- ENDS –

Notes:
1. More information is available in a question-and-answer document.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

2. More information about the temporary recommendations from June 2009 is available in press release.
3. More information on Cerezyme, including the currently approved Product Information, is available in the European Public Assessment Report: http://www.emea.europa.eu/humandocs/Humans/EPAR/cerezyme/cerezyme.htm.
   More information on Fabrazyme, including the currently approved Product Information, is available in the European Public Assessment Report: http://www.emea.europa.eu/humandocs/Humans/EPAR/fabrazyme/fabrazyme.htm
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu