GENZYME EUROPE BV
GOOIMEER 10
1411 DD NAARDEN
NETHERLANDS
Tel: +31-35-699-1200
Fax: +31-35-694-3214

Direct Healthcare Professional Communication on the supply of Cerezyme® (imiglucerase)
Further extension of the delay in the normal supply

22-April-2010

Dear Healthcare Professional,

Following the recent communication in February 2010 announcing that the supply of Cerezyme would return to normal levels by 16 April 2010, Genzyme wishes to inform you about a **further extension of Cerezyme shortage**.

- Genzyme detected an equipment defect at the Allston manufacturing site leading to a continuation of the Cerezyme supply shortage on the European market. **This means that Genzyme has currently only sufficient Cerezyme to supply 50% of global demand.**

- **Genzyme is hereby extending the period of the temporary recommendations until at least the end of July 2010** to try to ensure that patients with life-threatening Gaucher disease continue to receive Cerezyme. **The treatment recommendations as communicated in the previous DHPC (October 2009) are to remain in place.**

- All patients, especially those receiving Cerezyme at a lower dose or at a reduced frequency should be closely monitored for changes in haemoglobin, platelets and chitotriosidase levels, as appropriate, at baseline and once every two months thereafter. **Adults who demonstrate exacerbation of disease while on dose reduction/dose interruption are at risk for the development of progressive disease or complications and should reinitiate the original treatment with Cerezyme, or alternative treatment should be considered.**

- Adverse events for Cerezyme should continue to be reported as usual and physicians are reminded to document batch numbers in the patient record.

These are temporary recommendations and do not change the currently approved Product Information for Cerezyme. The recommendations only apply until the supply problems have been resolved.

Should you require any further information, please contact Genzyme local entity via e-mail ukmedinfo@genzyme.com or telephone 01865 405 283.

Yours sincerely,

genzyme

Carlo Incerti, MD.
Head of R&D Europe

Annex: Cerezyme treatment recommendation, October 2009

genzyme

European Medicines Agency

London, 22 October 2009
Doc. Ref. EMEA/665112/2009

Updated temporary treatment recommendations for Cerezyme

The temporary treatment recommendations on which patients should receive Cerezyme (imiglucerase) as a priority during the shortage are as follows:

- When medically possible infants, children and adolescents should receive Cerezyme at a reduced dose or at a reduced infusion frequency, because these 'early-onset patients' may have the most rapid disease progression and are at risk of serious long-term problems. 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 at high risk for the development of severe, life-threatening disease progression or pregnant women with symptomatic Gaucher disease should also receive Cerezyme at a reduced dose or at a reduced infusion frequency. Patients with such high risk include patients with one or more of the following criteria: platelet count less than 20,000 per microlitre, thrombocytopenia and bleeding, symptomatic anaemia, severe co-morbidity requiring imiglucerase treatment, such as a condition that puts a patient at risk for bleeding (for example cirrhosis, major surgery), a need for chemotherapy, lung disease caused by Gaucher cell infiltration, or new acute bone event during the last 12 months. No patient should be treated at a dose lower than 15 U/kg every two weeks, or alternative treatment should be considered.
- In patients without a high-risk for severe, life-threatening disease progression, an 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 exacerbation of disease while on dose reduction/dose interruption are at high risk for the development of progressive disease or complications and should reinitiate the original treatment with Cerezyme, or alternative treatment should be considered.

Reporting of side effects will continue as normal, with doctors recording the batch numbers of the medicines in each patient's records. These are temporary recommendations and do not change the currently approved product information for this medicine. The shortage is expected to last until end of 2009.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu