European Medicines Agency
Press office

London, 25 June 2009
Doc. Ref. EMEA/389995/2009

PRESS RELEASE
Supply shortages of Cerezyme and Fabrazyme - priority access for patients most in need of treatment recommended

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) has recommended that patients who are in greatest need of treatment are given priority access to Cerezyme (imiglucerase) and Fabrazyme (agalsidase beta) during the expected supply shortage of these two medicines over the next few months.

Cerezyme and Fabrazyme are both used to treat rare, inherited enzyme-deficiency disorders. Cerezyme is used in patients with Gaucher disease, a disease in which patients do not have enough of an enzyme called alglucerase. Fabrazyme is used in patients with Fabry disease, a disease in which patients do not have enough of an enzyme called alpha-galactosidase A.

The supply shortage is caused by the shutting down of Genzyme's production site in Allston Landing, in the United States of America, where both medicines are produced. The company found a viral contamination (calicivirus of the type Vesivirus 2117) and has shut down the production facility for a sanitization 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.

While the facility is shut down, no new stocks of Cerezyme and Fabrazyme can be produced. All batches manufactured prior to the detection of the contamination were tested and the Agency confirmed that they are suitable for release. To ensure that existing stocks last as long as possible until new batches can be produced, the European Medicines Agency has agreed to some temporary changes to the way these medicines are prescribed proposed by the company. These changes should be implemented immediately.

- For Cerezyme, priority is given to infants, children and adolescents, and adults with active disease progression. These patients can continue to receive Cerezyme at the standard dosage schedule of one infusion every two weeks. However, adult patients without clinical evidence of active disease progression should receive Cerezyme at a reduced dose (half a dose once every two weeks) or at a reduced infusion frequency (once a month at their current dose).

- For Fabrazyme, priority is given to children and adolescents, and adult male patients, who should continue to receive Fabrazyme as one infusion every two weeks. However, adult female patients, in whom the disease is less severe, may receive Fabrazyme at a reduced dose.

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

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Notes:

1. More information is available in a question-and-answer document.
2. 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
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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