



Myozyme Supply Update January 2009

We would like to take this opportunity to provide an important update to the global Pompe Community.

Background

In the early stages of development of Myozyme[®] (alglucosidase alfa), Genzyme initiated manufacturing at a small scale, and has since scaled-up the process to produce larger quantities of product for commercial use worldwide. The bioreactors in which alglucosidase alfa has been produced over the course of time have steadily grown in size to the 2000 liter (L) scale that currently produces Myozyme for worldwide use. This incremental scale-up is standard manufacturing practice for any biological drug development process. Due to the rapidly growing number of patients with Pompe disease receiving treatment, worldwide demand for Myozyme has continuously increased since it was launched in April 2006. Anticipating a higher long-term demand, Genzyme started to develop an even larger production facility of 4000 L bioreactors for Myozyme approximately five years ago at a manufacturing facility located in Belgium. Genzyme has submitted an application seeking approval to produce Myozyme at the 4000 L scale to the European Medicines Agency (EMA), the regulatory authority that assesses whether a drug is efficacious and safe in the European Union. Under the standard 60-day review process we would expect approval in April 2009 at the earliest. Genzyme has requested an expedited review of its application from the EMA Committee for Medicinal Products for Human Use (CHMP). Ultimately, Genzyme plans to apply for 4000 L approval with regulatory agencies throughout the world to be the main supply source of Myozyme in its effort to assure a sustainable supply for the Pompe Community.

Update

As Genzyme previously stated in July and again in October 2008, due to greater than expected adoption and rapidly increasing global demand, Myozyme supply will be particularly tight until 4000 L production is approved in the European Union. Beginning in January inventory levels are expected to be so tight that there is a risk of delays in order fulfillment that could result in potential interruptions to therapy. To responsibly manage through this temporary supply constraint and best support those currently receiving Myozyme, and in particular to safeguard supply for infants and children, the company has taken a number of steps to ensure optimal management of the existing supply until the 4000 L manufacturing scale is approved by the EMA.

Genzyme will continue to work collaboratively with the EMA to expedite the review of the 4000 L process. Also, Genzyme is exploring the potential for providing Pompe patients with access to Myozyme produced at the 4000 L scale prior to approval in the European Union, should this become necessary.



In addition, Genzyme has collaborated with a group of stakeholders from the global Pompe Community, the Myozyme Stakeholders Working Group (MSWG) composed of leading physicians from several countries and patient community representatives from the International Pompe Association, to develop a guidance document to help with clinical decision making with respect to product usage during this finite period of supply constraint. Genzyme is working with regulatory authorities to ensure the acceptability and the communication of this guidance. Physicians involved in the treatment of Pompe patients with Myozyme therapy and patients receiving Myozyme therapy are strongly encouraged to follow these recommendations.

The following recommended guidelines will be in effect as of January 13, 2009:

- Infants and children should continue to receive their prescribed treatment without any interruptions, and all newly diagnosed infants and children should start therapy as recommended by their physician.
- All adults (ages 19 and older) receiving Myozyme through commercial, charitable, or temporary access channels should receive monthly infusions beginning in January until Myozyme inventory levels return to normal. This means adults should immediately cancel their infusion between January 15th and January 31st and cancel one infusion each month until further information becomes available from Genzyme.
- No new adult patients should initiate therapy until Myozyme inventory levels return to normal.
- Physicians should contact Genzyme Medical Information if they have concerns with following these recommendations for severely affected adults.

In Europe, the CHMP has issued similar advice to physicians. For more information, please visit the EMEA website at www.emea.europa.eu.

A high degree of compliance to these recommendations is necessary to ensure that infants and children can continue their treatment without interruption and to ensure that the impact of monthly infusions is shared equally across the adult Pompe Community. Working together will allow us to manage through this period of tight supply in the best way possible.

Genzyme will continue to provide frequent updates to the community as new information becomes available. Anyone requiring immediate assistance and who cannot reach their local Genzyme representative is encouraged to contact Genzyme Medical Information. In the meantime, we fully appreciate the impact of this situation on both families and physicians. Please know that we remain committed to resolving the constrained Myozyme supply as quickly as possible.