

**For Immediate Release**  
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## **Genzyme Receives Complete Response Letter on Lumizyme Application**

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Company will host conference call today at 12:00 P.M. Eastern**

CAMBRIDGE, Mass. – Genzyme Corporation (Nasdaq: GENZ) announced today that it has received a complete response letter from the FDA regarding its application to market Lumizyme™ (alglucosidase alfa) for the treatment of Pompe disease. In its letter, the agency stated that satisfactory resolution of deficiencies related to the Allston Landing manufacturing plant are required before the Lumizyme application can be approved. Genzyme believes the other elements of the Lumizyme review, such as the Risk Evaluation and Mitigation Strategy (REMS), the product label, and post-marketing requirements, have been satisfactorily addressed.

The FDA completed its five-week inspection of the Allston plant on Friday, and provided Genzyme with a Form-483 outlining remaining deficiencies, which were mainly related to the fill/finish capabilities at the facility. The FDA has indicated a willingness to work with Genzyme to resolve these issues and to ensure continued product supply. Genzyme's plan to address these deficiencies includes establishing additional internal controls and updating fill/finish capabilities in Allston, transferring additional filling activities to existing Genzyme contract manufacturers, and utilizing excess capacity at Genzyme's manufacturing facility in Waterford, Ireland. The state-of-the-art Waterford facility is undergoing a major expansion, with engineering runs scheduled to begin in early next year. This expansion will increase Genzyme's internal filling capacity by four fold. Cerezyme® (imiglucerase for injection) 400-unit vials, which supply over 80 percent of patients worldwide, will be filled exclusively in Waterford moving forward.

Alglucosidase alfa 2000 L scale (Lumizyme) is no longer produced at the Allston facility and Genzyme is transitioning all patients worldwide to the product produced at a larger scale in the company's facility in Geel, Belgium. Production of alglucosidase alfa at the larger 4000 liter bioreactor scale is required to fulfill global demand. Genzyme will be requesting a meeting with FDA to discuss the most expeditious path forward toward U.S. approval of the product produced at this larger scale in Belgium.

"We have made significant progress in bringing the Allston plant back in operation, and we will continue to work closely with the FDA to resolve these issues," said Genzyme Chairman and Chief Executive Officer Henri Termeer.

### Supply Update

Genzyme has successfully processed material to final product stage for both Cerezyme and Fabrazyme® (agalsidase beta). A second set of Fabrazyme runs has been initiated. Genzyme continues to anticipate making a Cerezyme shipment later this month that will enable patients currently receiving product to continue to be treated. Cerezyme shipments in December will

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allow all patients access to treatment at the end of the month. Genzyme plans to communicate more specific details around the dose and timing of Cerezyme re-supply in the next ten days. Genzyme continues to anticipate making a Fabrazyme shipment at the end of December, which will allow patients to continue therapy at current levels. The company is currently evaluating the impact of changes to its fill/finish operations on Fabrazyme, and Genzyme expects to communicate timelines and further details regarding Fabrazyme resupply by early December.

#### Conference Call Information

Genzyme will host a conference call today 12:00 P.M. Eastern. To participate in the call, please dial 1-773-799-3828 and use passcode “Genzyme.” The replay number for the call is 203-369-0687 and is available one hour after the call ends and is available until November 23 at midnight ET. Today’s call will also be Webcast on the investor events section of [www.genzyme.com](http://www.genzyme.com). Genzyme’s press releases and other company information are available at [www.genzyme.com](http://www.genzyme.com) and by calling Genzyme’s investor information line at 1-800-905-4369 within the United States or 1-678-999-4572 outside the United States.

#### About Pompe Disease

Pompe disease is a progressively debilitating disease that manifests as a broad spectrum of clinical symptoms. All patients typically experience progressive muscle weakness and breathing difficulty, but the rate of disease progression can vary widely depending on the age of onset and the extent of organ involvement. When symptoms appear within a few months of birth, babies frequently display a markedly enlarged heart and die within the first year of life. When symptoms appear during childhood, adolescence or adulthood, patients may experience steadily progressive debilitation and premature mortality due to respiratory failure. They often require mechanical ventilation to assist with breathing and wheelchairs to assist with mobility.

To ensure that severely affected adults with Pompe disease in the United States have access to treatment prior to commercial approval, Genzyme created the Alglucosidase Alfa Temporary Access Program (ATAP) in collaboration with the FDA in May 2007. Since then, the company has provided therapy free of charge to approximately 170 patients. Genzyme continues to produce Myozyme<sup>®</sup> (alglucosidase alfa) at the 160 L scale which is reserved for patients 17 years and younger.

#### About Genzyme

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with more than 11,000 employees in locations spanning the globe and 2008 revenues of \$4.6 billion. In 2007, Genzyme was chosen to receive the National Medal of Technology, the highest honor awarded by the President of the United States for technological innovation.

With many established products and services helping patients in approximately 100 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant and immune disease, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as cardiovascular disease, neurodegenerative diseases, and other areas of unmet medical need.

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This press release contains forward looking statements regarding Genzyme's future business plans and strategies, including: its estimates of when newly produced Fabrazyme and Cerezyme will be available for shipment; its assessment of the outstanding issues related to securing approval of Lumizyme; its strategy to address the deficiencies cited by the FDA in the 483 and complete response letter; its timeline for communicating additional information concerning Fabrazyme and Cerezyme resupply; and its expectations regarding the capacity and timing of the Waterford fill finish expansion. These forward looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those forecasted. These risks and uncertainties include: that Genzyme is unable to successfully implement its initial strategy or successfully develop and implement long-term solutions to address the manufacturing issues and fill/finish deficiencies at its Allston plant; that the further production or supply of Fabrazyme and/or Cerezyme does not occur as planned due to any reason, including bacterial or viral contamination, mechanical failures, cell growth at lower than expected levels, fill/finish inefficiencies, and regulatory issues; that Genzyme is unable to reach agreement with the FDA on a path forward for approval of the 2000 L and/or 4000 L alglucosidase alfa product on anticipated timelines or at all; and the risks and uncertainties described in reports filed by Genzyme with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, including without limitation the information under the heading "Risk Factors" in Genzyme's Quarterly Report on Form 10-Q for the quarter ending September 30, 2009. Genzyme cautions investors not to place substantial reliance on the forward-looking statements contained in this press release. These statements speak only as of the date of this press release, and Genzyme undertakes no obligation to update or revise these statements.

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