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Genzyme Receives Complete Response Letter from FDA on Lumizyme Application

Company Will Host Conference Call Today at 5:00 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 outlines the remaining items that need to be addressed before the application can be approved. Lumizyme is produced at the 2000 liter (L) bioreactor scale at Genzyme's Allston Landing facility.

Specifically, Genzyme and the FDA must finalize agreement on the design of a post-approval verification study to demonstrate the clinical benefit of Lumizyme, as required under the Accelerated Approval process. In addition, Genzyme and the agency need to finalize the Risk Evaluation and Mitigation Strategy (REMS) for the product. Genzyme and the agency have been working closely and making progress toward these goals but were not able to reach them by the PDUFA date.

Genzyme also now needs to resolve issues identified in a warning letter the company received simultaneous with the complete response letter. The warning letter addresses deficiencies related to observations made during an inspection of Genzyme's Allston Landing manufacturing facility performed in September and October 2008. These issues relate to aspects of microbiological monitoring and controls, production equipment maintenance and certain process controls. Genzyme initially responded to the FDA on October 31, 2008, with a detailed plan and timeline to address all of the agency's observations. The company provided a progress update on February 23, 2009, confirming that all corrective actions had either been completed or were on schedule to be completed by the original commitment date of March 31, 2009. Given the substantial progress that Genzyme had made toward addressing the inspection observations, this warning letter was unexpected.

"We have made an enormous effort for more than two years to make this product broadly available in the United States, so we are obviously surprised and disappointed by this further delay," said Genzyme Chairman and Chief Executive Officer Henri A. Termeer. "We are confident we will be able to resolve all remaining issues with the FDA within three to six months."

Genzyme believes that all the information requested by the agency is readily at hand and that the company will be able to submit this information within approximately one month. Genzyme and the FDA are developing a work plan that will enable the agency to expedite the completion of its review once all information is received. A satisfactory resolution of the FDA's warning letter pertaining to observations at the Allston manufacturing facility is required before the agency will approve Lumizyme. Genzyme is confident that the products produced at the Allston facility continue to meet the highest quality and safety standards. To ensure that severely affected adults with Pompe disease in the United States have access to treatment, Genzyme created the Myozyme Temporary Access Program (MTAP) in collaboration with the FDA in May 2007. The company plans to continue providing Lumizyme free of charge to approximately 170 patients on a regular dosing regimen through this program until approval.

"We began the MTAP program two years ago to provide short-term access to treatment prior to approval," said Mr. Termeer. "We have made an extraordinary lifetime commitment to these 170 people living with Pompe disease. We will work with the agency to resolve the outstanding issues as quickly as possible because the only sustainable mechanism for broader access is through the commercial approval of Lumizyme."

Assuming a six-month delay, Genzyme anticipates the impact on 2009 non-GAAP earnings will be approximately \$0.12 per share. This reflects both forgone commercial sales margin and the costs of continued administration of the MTAP program. Genzyme now expects Myozyme revenue of \$370 – \$380 million in 2009, assuming a six month delay.

Genzyme currently has U.S. approval to sell Myozyme[®] (alglucosidase alfa) for the treatment of Pompe disease. This product has been reserved for infants and children because its smaller 160 L bioreactor production scale limits supply. Myozyme was approved in the United States in April 2006. Since then, the company has been seeking clearance from the FDA to market alglucosidase alfa produced at the 2000 L bioreactor scale, which will be called Lumizyme in the United States. Genzyme submitted a separate BLA for Lumizyme on May 30, 2008. On October 21, 2008, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee affirmed by a 16 to 1 vote that the Late-Onset Treatment Study established the effectiveness of Lumizyme for the treatment of Pompe disease. A majority of the committee members supported Accelerated Approval (Subpart E). While Genzyme's immediate focus is on obtaining U.S. approval of Lumizyme, the company also plans to submit a supplemental BLA filing for 4000 L-scale production to the FDA during the first half of 2009.

Myozyme produced at the 2000 L scale has already been approved for use in all patients with Pompe disease in more than 40 countries. Outside of the United States, the supply of Myozyme was significantly strengthened on February 26, 2009, by the rapid European Commission approval of 4000 L-scale production. Adult patients internationally have resumed regular infusion schedules and new patients outside of the United States are able to initiate therapy.

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.

Conference Call Information

Genzyme will host a conference call today 5:00 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 402-220-9702 and is available one hour after the call ends and is available until March 9th at midnight ET. Today's call will also be Webcast on the investor events section of www.genzyme.com.

Genzyme's press releases and other company information are available at 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 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 concerning Genzyme's future business plans and strategies, including: its estimate of the length of time it will take to submit to the FDA the information it is requesting and to resolve all issues related to securing 2000L product approval; its estimate of the financial impact of the delayed approval; its plans to seek U.S. approval of the product produced using the 4000L scale process and the timing thereof; and its assessment of the quality of the safety profile of the products produced at its Allston, MA manufacturing facility. These statements are subject to risks and uncertainties that may cause actual results to differ from those forecasted. These risks and uncertainties include, among others: that the company is not able to respond to the complete response letter or Allston warning letter in a manner satisfactory to the FDA or within the timeframes expected by the company; that the FDA does not approve the product produced using the 2000L process or does not approve it within the timeframes expected by the company; that the financial impact of the delayed

approval is larger than anticipated; that the company changes its strategy regarding filing for U.S. approval of the 4000L product; and the risks and uncertainties described in Genzyme's SEC reports filed under the Securities Exchange Act of 1934, including the factors discussed under the caption "Risk Factors" in Genzyme's Annual Report on Form 10-K for the period ended December 31, 2008. Genzyme cautions investors not to place substantial reliance on the forward-looking statements contained in this press release. These statements speak only as of today's date and Genzyme undertakes no obligation to update or revise the statements.

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