

For Immediate Release December 13, 2007

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## Genzyme Study of Myozyme<sup>®</sup> for Late-Onset Pompe Patients Meets Co-Primary Efficacy Endpoints

CAMBRIDGE, Mass. – Genzyme Corp. (Nasdaq: GENZ) announced today that its Late Onset Treatment Study (LOTS) of Myozyme<sup>®</sup> (alglucosidase alfa) met its coprimary efficacy endpoints. The study was undertaken to evaluate the safety and efficacy of Myozyme in juvenile and adult patients with Pompe disease. Myozyme was first approved in 2006, and the product is now registered in 36 countries.

The randomized, double-blind, placebo-controlled study enrolled 90 patients at eight primary sites in the United States and Europe. Participants received either Myozyme or a placebo every other week for 18 months. The average age of study participants was 44 years. The primary efficacy endpoints of the study sought to determine the effect of Myozyme on functional endurance as measured by the six-minute walk test and to determine the effect of Myozyme on pulmonary function as measured by percent predicted forced vital capacity.

The results showed that, at 18 months, patients treated with Myozyme increased their distance walked in six minutes by an average of approximately 30 meters as compared with the placebo group (P=0.0283; Wilcoxon test). The placebo group did not show any improvement from baseline. The average baseline distance walked in six minutes in both groups was approximately 325 meters.

Percent predicted forced vital capacity in the group of patients treated with Myozyme increased by 1 percent at 18 months. In contrast, it declined by approximately 3 percent in the placebo group (P=0.0026; Wilcoxon test). The average baseline percent predicted forced vital capacity in both groups was approximately 53 percent.

The results for both efficacy endpoints were consistent across various prospectively defined subgroups.

"These exciting findings build on our pivotal study results and underscore the benefit of Myozyme to all patients with Pompe disease, said Richard A. Moscicki, senior vice president and chief medical officer for Genzyme. "The preservation of pulmonary function is extremely important because respiratory failure is the major cause of mortality in this progressive and life-threatening neuromuscular disease. This trial has broader implications, in that it is one of the first large randomized trials to show benefit in a degenerative neuromuscular disease. On behalf of Genzyme, I want to thank the patients and physicians who participated in this study, whose commitment to ensuring its successful completion was a service to the entire Pompe community."

The safety of Myozyme was similar to placebo in the LOTS study. The number of patients with serious and treatment-emergent non-serious adverse events was similar in the Myozyme and placebo groups. Approximately 25 percent of patients in each group experienced infusion-associated reactions. There was one death in the Myozyme group unrelated to treatment.

Genzyme is completing an analysis of the study results and will apply in the second half of next year for potential inclusion of the results in the product labeling.

Detailed results will be presented at medical congresses throughout the world by the study investigators and submitted for publication in a peer-reviewed journal.

Myozyme used in the LOTS study was produced at Genzyme's Allston Landing facility using the larger scale manufacturing process (2000L) that is currently approved by 35 countries. The FDA is currently reviewing Genzyme's application for approval of this larger scale process.

"This is a real breakthrough for the treatment of Pompe patients, as for the first time it has been demonstrated in a large placebo-controlled trial that Myozyme elicits a positive effect in adults with Pompe disease," said Ans van der Ploeg, M.D., Ph.D., of Erasmus Medical Center in Rotterdam, one of the study's principle investigators.

"This confirms previous benefits reported in individual patients by our group, as well as others, and extends the proven benefits across the spectrum of the disease."

## About Pompe Disease

Pompe disease 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.

## About Myozyme

Myozyme (alglucosidase alfa) is indicated for use in patients with Pompe disease (GAA deficiency). The U.S. product label includes a boxed warning with information on the potential risk of hypersensitivity reaction. Life-threatening anaphylactic reactions, including anaphylactic shock, have been observed in patients during Myozyme infusion. Because of the potential for severe infusion reactions, appropriate medical support measures should be readily available when Myozyme is administered. Full prescribing information for the product, including a complete list of the most common adverse reactions, is available on Genzyme's website:

http://www.genzyme.com/components/highlights/mz\_pi.pdf

## 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 10,000 employees in locations spanning the globe and 2006 revenues of \$3.2 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. In 2006 and 2007, Genzyme was selected by FORTUNE as one of the "100 Best Companies to Work for" in the United States.

With many established products and services helping patients in nearly 90 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 diagnostic testing. Genzyme's commitment to innovation continues today with a

substantial development program focused on these fields, as well as immune disease, infectious disease, and other areas of unmet medical need.

This press release contains forward-looking statements, including statements regarding anticipated regulatory submissions, the potential inclusion of study data in product labeling and plans to present and publish study results. These risks and uncertainties include, among others, the actual timing of the completion of the analysis of study results; the timing and content of submissions to and decisions by regulatory authorities related the product labeling for Myozyme; and the risks and uncertainties described in reports filed by Genzyme with the U.S. Securities and Exchange

Commission, including without limitation the factors discussed under the caption "Risk Factors" in Genzyme's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007. We caution investors not to place undue reliance on the forward-looking statements contained in this press release. These statements speak only as of the date of this press release, and we undertake no obligation to update or revise the statements.

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