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Genzyme Submits All Information Requested by FDA for Lumizyme

CAMBRIDGE, Mass. – Genzyme Corporation (Nasdaq: GENZ) announced today that it has submitted the final documentation to address all items in the FDA's complete response letter for Lumizyme™ (alglucosidase alfa), produced at the 2,000 L bioreactor scale.

The submission included clinical data requested by the FDA from Genzyme's Pompe Registry. The FDA has agreed that these data can fulfill the requirements for a verification study to demonstrate the clinical benefit of Lumizyme. Also included in the submission were the Risk Evaluation and Mitigation Strategy (REMS) and the final label for the product.

Because the submission will include clinical data, Genzyme anticipates that its filing will be designated as a class 2 resubmission with a six-month PDUFA goal. However, given the ongoing dialogue between Genzyme and the FDA, the company expects that the agency will expedite the review process.

Genzyme has also completed all of the measures required to respond to the FDA warning letter regarding the company's Allston manufacturing facility. The FDA has begun the inspection process at the plant to determine if the deficiencies cited in its warning letter have been satisfactorily addressed. When the FDA issues its formal findings, Genzyme will provide an update.

Genzyme and the FDA are also in active discussion regarding the submission of an sBLA for the 4,000 L-scale manufacturing process. The company and the FDA are working collaboratively to determine the most expeditious path toward approval. Genzyme anticipates filing its submission later this quarter.

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.

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.

This press release contains forward looking statements regarding Genzyme's business plans and strategies, including: its expectation that its Lumizyme marketing application will be designated a class 2 resubmission and have an associated 6 month PDUFA goal; its expectation that the FDA will expedite its review of its Lumizyme application; and its plans to submit for FDA approval of the 4,000L product and the timing thereof. These statements are subject to risks and uncertainties that may cause Genzyme's actual results to differ materially. Those risks and uncertainties include: that the FDA does not expedite its review of the Lumizyme filing; that the FDA inspects the Allston facility and finds deficiencies that delay receipt of approval of Lumizyme; that the Company is unable to file for approval of the 4,000L product within its expected timeframes due to a failure to get FDA agreement as to strategy or any other reason; and the risks and uncertainties described in the Company's reports filed with the SEC under the Securities Exchange Act of 1934, including in the section titled "Risk Factors" in the Company's quarterly report on Form 10-Q for the period ended March 31, 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 the statements.

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.

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