

Genzyme Announces FDA Enforcement Action Regarding Allston Plant

March 24, 2010

Company Will Hold Conference Call Today at 11:00 a.m. Eastern

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme Corporation (NASDAQ: GENZ) announced today that the FDA notified the company yesterday afternoon that, while the agency recognizes Genzyme's efforts, it intends to take enforcement action to ensure that products manufactured at the plant are made in compliance with good manufacturing practice regulations. The FDA enforcement action will likely result in a consent decree, under which a third party would inspect and review the plant's operation for an extended period and certify compliance with FDA regulations. Under a consent decree, Genzyme also would be required to make payments to the government and could incur other costs.

Based on its initial communication with the agency and the medical need for patients, Genzyme expects that shipments of Cerezyme[®] (imiglucerase for injection) and Fabrazyme[®] (agalsidase beta), which are manufactured in Allston, will continue uninterrupted during the period of the enforcement action. In addition, Genzyme expects that shipments of Myozyme[®] (alglucosidase alfa) produced at the 160-L scale, which is filled and finished in Allston, will continue uninterrupted. Genzyme also fills and finishes Thyrogen[®] (thyrotropin alfa for injection) at the Allston plant and intends to discuss with the agency the company's view that there is also a patient need for uninterrupted supply of this product. The discussions with the FDA are expected to occur over the next several weeks.

Genzyme will work cooperatively with the FDA to restore the agency's confidence in its ability to operate the Allston plant at the highest standards, building on the progress it has made over the past year to address the manufacturing deficiencies at the Allston plant. This progress includes:

- Retaining a leading quality assurance advisory firm to help develop a comprehensive strategy and risk mitigation plan. More than 30 expert consultants from this firm are currently working at the Allston plant or at other Genzyme manufacturing facilities.
- Naming a new site head and reorganizing and strengthening the management team at the facility.
- Hiring two highly regarded industry veterans to serve as President of Global Manufacturing and Corporate Operations and Senior Vice President of Global Product Quality.

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 12,000 employees in locations spanning the globe and 2009 revenues of \$4.5 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 forwarding-looking statements regarding the potential FDA enforcement action, including that an action will result in a consent decree and that shipments of Cerezyme® (imiglucerase for injection), Fabrazyme® (agalsidase beta), and Myozyme® (alglucosidase alfa) produced at the 160-L scale will continue uninterrupted, and the timing of discussions with the FDA. These statements are subject to risks and uncertainties that may cause actual results to differ materially. These risks and uncertainties include, among others, that Genzyme may be unable to reach agreement with the FDA on the terms of a consent decree and that the terms of such a consent decree may differ from Genzyme's current expectations, as well as 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 Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial Condition and Results of Operations in Part II, Item 7 of Genzyme's Annual Report on Form 10-K. 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 release, and Genzyme undertakes no obligation to update or revise them.

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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.

Conference Call Information

Genzyme will host a conference call today at 11 a.m. Eastern. To participate in the call, please dial 773-799-3828 and refer to pass code "Genzyme." A replay of this call will be available by dialing 203-369-0637. This call will also be Webcast live on the investor events section of www.genzyme.com. A replay of the Webcast will be available.

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