Genzyme Begins Enrollment in Post-Marketing Study to Evaluate Use of Low Dose Fabrazyme Treatment for Fabry Disease

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme Corporation (Nasdaq: GENZ) announced today that the company has begun enrollment in a world-wide post-marketing clinical trial evaluating the efficacy and safety of treating pediatric male patients with mild Fabry disease symptoms with a low-dose regimen of Fabrazyme® (agalsidase beta). Data from the “Fabrazyme: Intervening Early at a Lower Dose (FIELD)” study may support supplemental submissions to regulatory agencies seeking additional dosing options that facilitate early treatment for Fabry disease.

“This treatment regimen might be more adapted for those patients with milder symptoms of the disease, providing them flexibility in their treatment options. The ability to provide a lower or less frequent dose of Fabrazyme for pediatric patients with milder symptoms may translate to some patients receiving the treatment early,” said Dr. Uma Ramaswami, metabolic pediatrician at Addenbrooke's Hospital in Cambridge, UK, and co-principal investigator for the FIELD study.

Up to 20 institutions across Europe, the U.S., Canada and Latin America are expected to participate in the study. The trial will examine the efficacy and safety of two lower-dose regimens of Fabrazyme in male patients aged 5 to 18 years over the course of five years. Patients will receive either half the recommended dose of Fabrazyme every two weeks (0.5mg/kg of body weight) or a dose of 1mg/kg every four weeks. Fabrazyme at the recommended dose of 1mg/kg every two weeks has been approved in more than 40 countries, including the U.S. and Canada, as well as throughout the European Union, for the treatment of Fabry disease.

“We are very excited to be a part of this important study,” said Dr. Paul Fernhoff from the Emory University School of Medicine and one of the clinicians conducting FIELD in the U.S. “We know that Fabry disease is a progressive disorder in which irreversible damage occurs, sometimes very early in life, and feel that intervention prior to this damage may be vital to improved patient outcomes.”

About Fabry Disease

Fabry disease is one of a group of rare diseases called lysosomal storage disorders. It is characterized by excessive accumulation of the lipid GL-3 in various organs and tissues, which over time can cause renal, cardiac and cerebrovascular events. As a result, patients with Fabry disease typically have a shortened life span, and children must often cope with significant pain and disability. Fabry disease is an inherited and life threatening disease linked to the X chromosome which affects approximately 5,000 patients in the world.

Important Safety Information about Fabrazyme

Fabrazyme is indicated for use in patients with Fabry disease. Fabrazyme reduces GL-3 deposition in the capillary endothelium of the kidney and certain other cell types. The reduction of GL-3 inclusions suggests that Fabrazyme may ameliorate disease expression: however, the relationship of GL-3 inclusion reduction to specific clinical manifestations of Fabry disease has not been established.

The most serious and most common adverse reactions reported with Fabrazyme are infusion reactions. Serious and/or frequently occurring related adverse reactions consisted of one or more of the following events: chills, pyrexia, feeling hot or cold, dyspnea, nausea, flushing, headache, vomiting, paresthesia, fatigue, pruritus, pain in extremity, myalgia, back pain, pallor, bradycardia, urticaria, hypotension, face edema, rash, and somnolence. The occurrence of somnolence can be attributed to clinical trial specified pre-treatment with antihistamines. Patients should be given antipyretics prior to infusion. Infusion reactions occurred in some patients after receiving pre-treatment with antipyretics, antihistamines, and oral steroids. Full prescribing information can be found at www.fabrazyme.com

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 2007 revenues of $3.8 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 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 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.

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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