Genzyme Receives FDA Complete Response Letter for Clolar

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme Corporation (Nasdaq: GENZ) announced today that the FDA provided a complete response letter regarding the company's supplemental New Drug Application for Clolar® (clofarabine) in previously untreated older adult patients with acute myeloid leukemia (AML) and at least one unfavorable baseline prognostic factor. The agency recommended a randomized, controlled clinical study be conducted for label expansion of Clolar in this indication.

In September, the FDA Oncologic Drugs Advisory Committee voted 9 to 3 that data from a randomized, controlled trial was necessary to establish the efficacy and safety of Clolar in the proposed adult AML indication. Genzyme had sought approval to expand the indication based on the findings from a single-arm trial in an adult AML population.

Genzyme intends to request a meeting with the FDA to discuss the optimal path forward, including what additional or ongoing studies may satisfy regulatory requirements.

Genzyme is conducting a randomized, placebo-controlled Phase 3 trial (CLASSIC I) comparing clofarabine in combination with cytarabine to cytarabine alone in relapsed and refractory adult AML patients 55 years old or older. The trial continues to exceed patient accrual expectations, and results are expected in 2011. Clofarabine, which is an approved agent in the treatment of relapsed or refractory pediatric acute lymphoblastic leukemia (ALL) after at least two prior regimens, is also being investigated in clinical trials by many of the leading AML experts and major cooperative leukemia investigation groups in the United States and Europe.

About Clolar
Clolar is currently approved for pediatric ALL patients who have relapsed or have refractory disease after at least two prior regimens. Clolar has Orphan Drug designation for AML and pediatric ALL, and seven years of market exclusivity in the United States for relapsed/refractory pediatric ALL. The FDA also granted six months of extended market exclusivity to Clolar under the Best Pharmaceuticals for Children Act. For more information about Clolar, please call 1-800-RX CLOLAR or visit www.CLOLAR.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 11,000 employees in locations spanning the globe and 2008 revenues of $4.6 billion.

With many established products and services helping patients in nearly 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 without limitation its expectations for discussions with the FDA and the availability of data from the company's phase 3 study for Clolar. These risks and uncertainties include, among others: the FDA's decisions regarding a path forward for the possible approval of Clolar to treat older adult patients with acute myeloid leukemia; the actual safety and efficacy of Clolar for the indications in which it is being tested; 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 Quarterly Report on Form 10Q for the quarter ended June 30, 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 today's date and Genzyme undertakes no obligation to update or revise the statements.

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