Genzyme’s Campath Meets Primary Endpoint in Phase 3 Combination Therapy Trial for Chronic Lymphocytic Leukemia

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Significant Improvement in Progression Free Survival Seen in Relapsed or Refractory Patients

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genzyme Corporation (Nasdaq: GENZ) announced today that its randomized Phase 3 clinical trial investigating Campath® (alemtuzumab) in combination with Fludara® (fludarabine phosphate) in relapsed or refractory chronic lymphocytic leukemia (CLL) patients met its primary endpoint by demonstrating a significant improvement in progression free survival (PFS). The trial's independent data safety monitoring board, in a pre-planned interim analysis, determined that the study achieved its primary endpoint (p<0.0173) and recommended early closure of the trial. Patients in the international, multi-center study treated with Campath in combination with Fludara (FluCAM) experienced a significant increase in the amount of time they lived without the disease progressing compared to patients treated with Fludara alone. The trial was designed to detect at least a 50 percent overall improvement in progression free survival in the FluCAM arm in comparison to the Fludara arm. Study results from this interim analysis are expected to be submitted to the American Society of Hematology meeting held in December.

"The standard of care for patients with chronic lymphocytic leukemia is evolving, as active single agents are studied in combination," said Cyndi Sirard, MD, Medical Director, Genzyme Transplant and Oncology. "Campath has proven to be a highly active single agent therapy across the spectrum of this disease, and Fludara is considered a backbone of CLL therapy. These trial results are anticipated to provide clinically meaningful data supporting Campath use in combination with Fludara in patients with relapsed or refractory CLL."

"There is no cure for CLL, and it's important that we continue to develop new approaches to treat this significant unmet medical need," said Doug Burcz, Genzyme Vice President and General Manager, Campath, Fludara, Leukine. "Pending approval, the FluCAM dosing regimen used in the Phase 3 trial will extend the use of Campath by giving physicians an important alternative treatment regimen for their patients with progressive disease."

In the CAM314 trial, patients in the FluCAM arm had lower total exposure to Campath and Fludara when dosed in combination, as compared to the labeled, single-agent dosing regimen of each drug for the treatment of CLL.

Based on the study's positive findings, Genzyme intends to seek regulatory approval in the United States, European Union, and other countries to further broaden the Campath label to include the use of this combination regimen. If the expanded label is granted, Campath, marketed as MabCampath® in Europe, would be the first humanized monoclonal antibody approved as both a single agent and in combination therapy for the treatment of CLL.

Chronic lymphocytic leukemia is the most common type of leukemia in adults, accounting for approximately 25-30 percent of all forms of leukemia. The median age of patients diagnosed with CLL is 72 years. While CLL is generally considered a disease that is slow to progress, a significant proportion of patients have rapidly progressing forms of the disease.

Genzyme has established a leading position in therapies to manage hematological malignancies. The company recently expanded its commercial presence in the field by acquiring the sales and marketing rights to Campath, Fludara and Leukine® (sargramostim). Genzyme also markets Clofarabine® (clofarabine injection), known as Evoltra® in Europe, and Mozobil® (plerixafor injection), two important therapies for patients managing blood cancers.

About the CAM314 Phase 3 Study

The CAM314 Phase 3 study was a multicenter, international, open-label, randomized study that included 335 patients with progressive Rai stage I-IV chronic lymphocytic leukemia, as defined by the 1996 National Cancer Institute Working Group criteria. The study investigated whether treatment of patients with relapsed or refractory CLL with Campath in combination with Fludara (FluCAM) was more beneficial than treatment with Fludara alone. Patients in the trial received one prior therapy, and excluded patients who were refractory to Fludara or Campath. FluCAM patients received Campath in escalating doses of 3, 10, 30 mg IV (days 1-3 up to 14 days). The patients then received Fludara at 30 mg/m2 IV (days 1-3) followed by Campath 30 mg IV (days 1-3) every 28 days for up to 6 cycles. Patients in the Fludara arm received Fludara at 25 mg/m2 IV daily for 5 consecutive days (days 1-5) every 28 days for up to 6 cycles. The primary endpoint was progression-free survival. Secondary
endpoints were overall response, complete response, safety, and overall and three year survival. Genzyme will continue to assess overall survival in patients treated with this combination regimen in this study.

About Campath (alemtuzumab)

Campath (alemtuzumab) is licensed in the United States as a single agent for the treatment of B-CLL, and in the E.U., where it is marketed as MabCampath, for the treatment of patients with B-CLL for whom fludarabine combination chemotherapy is not appropriate. The product was originally launched in its oncology indication in 2001.

Alemzumab is a humanized monoclonal antibody that binds to a specific target, CD52, on cell surfaces and directs the body’s immune system to destroy those cells. It is the first and only monoclonal antibody approved by the FDA for the treatment of patients with B-CLL.

Campath for B-CLL has a boxed warning that includes information on cytopenias, infusion reactions, and infections. The most commonly reported adverse reactions in patients with B-CLL were infusion reactions (fever, chills, hypotension, urticaria, nausea, rash, tachycardia, dyspnea), cytopenias (neutropenia, lymphopenia, thrombocytopenia, anemia), and infections (CMV viremia, CMV infection, other infections). Other commonly reported adverse reactions include vomiting, abdominal pain, insomnia and anxiety. The most commonly reported serious adverse reactions are cytopenias, infusion reactions, and immunosuppression/infections.

About Fludara (fludarabine phosphate)

Fludara, a purine nucleotide analog, inhibits the synthesis of new DNA, thus preventing leukemia cells from multiplying. The intravenous (i.v.) formulation of Fludara was first approved in 1991 and is available in 98 countries worldwide as a second-line therapy for B-CLL patients who have failed previous treatment with alkylating agents. In addition, Fludara i.v. has been approved as a first-line therapy of B-CLL in 62 countries. In 29 countries, Fludara i.v. is also approved for the second-line treatment of low grade non-Hodgkin's Lymphoma (lg-NHL). The oral formulation has the same effect as the i.v. formulation and was approved in Europe in 2001.

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 future plans and business strategies, including: its expectations about when data will be presented on the CAM314 study, and Genzyme’s plans to seek regulatory approval for Campath in combination use. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected in these forward-looking statements, including: that the timing required to present the data on the CAM314 study; the timing and outcome of discussions with the regulatory agencies regarding approval of Campath for combination use with Fludara; and the risks and uncertainties described in reports filed by Genzyme with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, including without limitation the information under the heading "Risk Factors" in Genzyme’s Quarterly Report on Form 10-Q for the quarter ending 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 the date of this press release, and Genzyme undertakes no obligation to update or revise these statements.

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