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Investor News

Genzyme Files for Expanded Label for Campath® as First-Line Treatment for B-CLL Patients

Berlin, Germany and Cambridge, MA, USA / April 4, 2007 – Bayer HealthCare and Genzyme Corp. (Nasdaq: GENZ) announced today that a supplemental biologics license application (sBLA) for Campath® (alemtuzumab) has been submitted to the U.S. Food and Drug Administration (FDA) to expand the current product label to include first-line treatment of B-cell chronic lymphocytic leukemia (B-CLL). Campath® is currently approved for the treatment of B-CLL patients who have been previously treated with an alkylating agent and have failed fludarabine therapy. Genzyme intends to make a similar filing in Europe within the next couple of weeks to support this label expansion.

The product is marketed outside the United States as MabCampath®, by Bayer Schering Pharma AG, Germany and in the U.S. by the company's US affiliate, Bayer HealthCare Pharmaceuticals, as Campath®. A label expansion to include first-line therapy would significantly increase the number of potential patients for whom Campath® would be indicated.

“In addition to the filing to expand the product’s label, we will continue focusing our efforts on further exploring the full potential of Campath® in high risk CLL, combination and consolidation therapy, and in seeking approval for treatment via subcutaneous administration,” stated Gunnar Riemann, PhD, Member of the Board Management of Bayer Schering Pharma AG, Germany.

“Submission of this sBLA is based on positive data from a phase III clinical trial, which showed first-line treatment of B-CLL with Campath® resulted in significantly better efficacy with a manageable safety profile as compared to chlorambucil,” stated Mark Enyedy, senior vice-president and general manager of Genzyme’s oncology business unit. “We are very excited about the potential use of Campath® in treating

patients earlier in the course of their disease, and about making a very important difference in battling leukemia."

The phase III study was an international, randomized, controlled clinical trial conducted to satisfy a post-approval commitment to the FDA to demonstrate clinical benefit of Campath® in B-CLL, and to complete the conversion to regular approval. This confirmatory study was completed in accordance with timelines committed to the FDA by Genzyme.

Chronic Lymphocytic Leukemia
CLL is the most prevalent form of adult leukemia, affecting approximately 120,000 people in Europe and the United States. The disease is most commonly diagnosed among people age 50 or older. CLL is characterized by the accumulation of functionally immature white blood cells (lymphocytes) in the bone marrow, blood, lymph tissue, and other organs. Two types of lymphocytes are present in the blood, B cells and T cells. About 95 percent of CLL cases involve cancerous B cells. Because these B cells have a longer than normal life span, they begin to build up and "crowd out" the normal, healthy blood cells. The accumulation of functionally immature cells in the bone marrow inhibits the generation of healthy cells and can become fatal. Symptoms include fatigue, bone pain, night sweats, fevers, and decreased appetite and weight loss. Bone marrow infiltration leads to a lack of healthy blood cells, thus leading to fatigue, susceptibility to bleedings and weakening of the immune system, exposing the patient to a higher risk of infection.

Campath®
Campath® received accelerated approval in 2001 and this first-line, randomized study was the primary post-approval commitment study designed to support regular approval. Campath® is currently indicated for the treatment of B-CLL in patients who have been treated with alkylating agents and who have failed fludarabine therapy. Determination of the effectiveness of Campath® is based on overall response rates. Comparative, randomized trials demonstrating increased survival or clinical benefit such as improvement in disease-related symptoms have not yet been conducted.

The most commonly reported infusion-related adverse events were rigors, drug-related fever, nausea, vomiting, and hypotension. Hematologic toxicities included pancytopenia/marrow hypoplasia, anemia, thrombocytopenia, neutropenia, and profound lymphopenia, and should be monitored. Infections reported included sepsis,

pneumonia, and opportunistic infections such as CMV, candidiasis, aspergillosis, and mucormycosis.

Genzyme and Bayer HealthCare are co-developing Campath® in oncology and other indications.

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 9,000 employees in locations spanning the globe and 2006 revenues of $3.2 billion. Genzyme has been selected by FORTUNE as one of the "100 Best Companies to Work for" in the United States.

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 diseases, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as immune disease, infectious disease, 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 1-703-797-1866 outside the United States.

Bayer HealthCare
Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide.

Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life.

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