Bayer

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Investor News

B-cell chronic lymphocytic leukemia:

FDA Approves Expanded Labeling for Campath® to Include First-line Treatment for Leading Form of Adult Leukemia

Study data demonstrated improved progression-free survival with Campath

Leverkusen, September 20, 2007 – Bayer Schering Pharma AG, Germany, and Genzyme Corp., USA, today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) for Campath® (alemtuzumab) and granted regular approval for single-agent Campath for the treatment of B-cell chronic lymphocytic leukemia (B-CLL). Campath was initially approved in 2001 under accelerated approval regulations for the treatment of B-CLL in patients who have been treated with alkylating agents and who have failed fludarabine therapy. The FDA has determined that the study results submitted in the sBLA fulfill the post-marketing commitment to verify clinical benefit. A label expansion to include first-line treatment is under consideration in Europe.

“Campath is clearly an important single agent for the first-line treatment of CLL,” said Peter Hillmen, MB, ChB, of the Leeds General Infirmary, Leeds, United Kingdom, and the lead investigator of the pivotal study comparing Campath against chlorambucil. “We are excited to be entering an era where our improved understanding of CLL, coupled with more advanced laboratory tests and targeted therapy options like Campath, have dramatically changed the first-line treatment approach for this type of leukemia.”

Campath works in an entirely different way than chemotherapy, and is the first and only monoclonal antibody approved by the FDA for the treatment of B-CLL.

"We are excited that Campath can now be used to treat patients in the U.S. earlier in the course of their disease", said Gunnar Riemann, Ph.D., member of the Board of Management of Bayer Schering Pharma AG. "The ability to now provide Campath as a first-line treatment of the disease will make an important difference in battling B-CLL. It may help patients by offering a potentially more effective treatment approach that can extend progression-free survival."

Presented at the 48th Annual Meeting of the American Society of Hematology (ASH) conference last year, data supporting the sBLA were part of an international Phase III clinical trial comparing Campath with chlorambucil in previously untreated patients with B-CLL. The study met its primary endpoint by demonstrating longer progression free survival (PFS) in patients treated with Campath versus chlorambucil with Campath reducing the risk of disease progression or death by 42 percent (p=0.0001).

Patients receiving Campath exhibited higher overall and complete response rates that were statistically significant in comparison to patients who were treated with chlorambucil. Campath also exhibited a manageable safety profile among study patients.

"The data that supported this label expansion add to a growing body of evidence about the effectiveness of Campath across the entire CLL treatment pathway," stated Mark Enyedy, president of Genzyme's oncology business unit. "A broader range of patients is now eligible for Campath treatment, regardless of whether they have received prior therapy. The approval also marks an important step in a long-term development plan that is exploring the full potential of Campath in high-risk CLL, combination and consolidation therapy."

Bayer Schering Pharma AG, Germany, and Genzyme are developing Campath in oncology, multiple sclerosis and other indications. Bayer Schering Pharma AG, Germany, holds exclusive worldwide marketing and distribution rights. Campath is marketed outside the United States as MabCampath® by Bayer Schering Pharma AG, Germany, and in the U.S. by Bayer HealthCare Pharmaceuticals Inc., as Campath.

About B-Cell Chronic Lymphocytic Leukemia

According to the Leukemia and Lymphoma Society, approximately 15,000 new cases of B-cell chronic lymphocytic leukemia (B-CLL) are diagnosed in the U.S. each year. It is the largest subset of chronic lymphocytic leukemia (CLL), the most common form of adult leukemia in the western world. B-CLL is characterized by the accumulation of functionally immature cells in the bone marrow, blood, lymph tissue and other organs. Because these cancerous B cells have a longer than normal life span, they begin to build up and “crowd out” normal, healthy blood 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 causing susceptibility to bleedings and weakening of the immune system, exposing the patient to a higher risk of infection.

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 9,500 employees in locations spanning the globe and 2006 revenues of $3.2 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. In 2006 and 2007, Genzyme was 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 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.

About Bayer Schering Pharma

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. 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. Find more information at www.bayerhealthcare.com.

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. Find more information at www.bayerscheringpharma.de.

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