Bayer

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Investor News

New top-line efficacy data presented from phase II trial of Alemtuzumab in multiple sclerosis:

Three-year analysis demonstrates continued robust treatment effect of Alemtuzumab compared to Rebif®

Berlin, October 15, 2007 – Bayer Schering Pharma AG, Germany, today announced that top-line, three-year data from the CAMMS223 Phase II clinical trial comparing alemtuzumab with Rebif® (interferon beta-1a) for the treatment of multiple sclerosis were presented this weekend at the 23rd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Prague. The results come from an analysis conducted at 36 months following treatment of 334 patients in the three-year trial.

Overall efficacy results demonstrated that two once-yearly cycle of alemtuzumab therapy provided a significant treatment effect that has been found to last at least three years among patients in the study. Analysis of the first co-primary endpoint showed that patients taking alemtuzumab experienced at least a 73 percent reduction in the risk for relapse after three years of follow up when compared to patients treated with interferon beta-1a. This difference was highly statistically significant in favor of the alemtuzumab patients with a p-value less than the pre-specified value (p=0.00396) assigned for the three-year analysis.

Analysis of the other co-primary endpoint showed that patients taking alemtuzumab experienced at least a 70 percent reduction in the risk for progression of clinically significant disability when compared to patients treated with interferon beta-1a. This difference was statistically significant in favor of the alemtuzumab

patients with a p-value less than the pre-specified value (p=0.01646) assigned for the three-year analysis.

“We are very pleased that these three-year results of the Phase II trial confirmed all trends of the one-year and two-year analyses, especially the positive impact on disability," said Kemal Malik, Member of the Board of Bayer Schering Pharma AG, responsible for Global Development. "These unprecedented results suggest that two once-yearly courses of alemtuzumab therapy provide a durable response in the treatment of multiple sclerosis. We look forward to the ongoing Phase III program to further validate these promising results as we strive to continue to advance therapy for MS patients."

Results of the primary outcomes from this trial were presented by Alastair Compston, Professor of Neurology and the head of the Department of Clinical Neurosciences at the University of Cambridge, United Kingdom, during the prestigious Charcot Award lecture at ECTRIMS. Results for the secondary endpoints support the findings seen in the co-primary endpoints. Full, detailed efficacy and safety data from the study are expected to be presented at the 60th Annual Meeting of the American Academy of Neurology next spring.

Two Phase III studies have recently begun examining the safety and efficacy of alemtuzumab for the treatment of multiple sclerosis. Bayer Schering Pharma AG, Germany and co-development partner Genzyme announced last month the start of the CARE-MS I trial (Comparison of Alemtuzumab and Rebif® Efficacy in Multiple Sclerosis), a randomized, rater-blinded study that will compare alemtuzumab to Rebif® as first-line therapy for patients with relapsing-remitting multiple sclerosis (MS). The second Phase III study, CARE-MS II, also has begun and will enroll patients who have continued to experience relapse episodes while on currently available disease-modifying therapies.
Alemtuzumab is an investigational drug for the treatment of MS and must not be used outside of a formal clinical trial setting in MS patients. Physicians or patients seeking additional information about the recently-initiated CARE-MS I Phase 3 trial

should contact Genzyme Medical Information at 1-800-745-4447, option 2 in the United States, + 31 35 6991499 in Europe, or visit www.clinicaltrials.gov.

A total of six alemtuzumab-treated patients in the CAMS223 trial have been diagnosed with idiopathic thrombocytopenic purpura (ITP), a disorder characterized by a low platelet count and corresponding increased risk of uncontrolled bleeding. There have been no new cases of ITP reported in the past year in this study. Though potentially serious, ITP can be detected and monitored through blood tests, and is usually treatable with several drugs, notably prednisone and other immunomodulatory therapy, though some refractory patients may require splenectomy. Common non-serious adverse events included infusion reactions in the alemtuzumab patients and flu-like symptoms in patients using interferon beta-1a. Severe infections were infrequent in the alemtuzumab patients and were resolved with or without an intervention. The incidence of all thyroid adverse events, including Graves' disease, was less than expected compared to early reports in the literature on the use of alemtuzumab in MS.

The phase II trial randomized 334 patients with active relapsing-remitting multiple sclerosis at 49 medical centers in Europe and the United States. Patients in the trial were treated with alemtuzumab at one of two doses (12 or 24/mg per day intravenously for five days at initial treatment, and three days of re-treatment after 12 months with an option to treat again at 24 months), or interferon beta-1a (44 mcg administered by subcutaneous injection three times per week, as indicated in its product label). The randomized trial compared the efficacy of alemtuzumab with interferon beta-1a using two primary endpoints: the rate of relapse of MS symptoms, and the time to Sustained Accumulation of Disability over six months as measured by Expanded Disability Status Scale [EDSS]. Efficacy assessments were made by independent neurologists blinded to therapy.

About Multiple Sclerosis

MS is a chronic, progressive disease of the central nervous system and the likelihood of disability increases the longer someone has MS. Symptoms of MS vary from person to person and can be unpredictable. They may include: Fatigue or

tiredness, dimness of vision in one or both eyes, weakness of one or both legs, numbness and tingling in the face, arms, legs and trunk of the body, spasticity (muscle stiffness), dizziness, double vision, slurred speech and loss of bladder control.

About Alemtuzumab

Alemtuzumab is licensed in the United States as a single agent for the treatment of B-cell chronic lymphocytic leukemia (B-CLL), and outside of the U.S. for the treatment of B-CLL in patients who have been treated with alkylating agents and who have failed fludarabine therapy. The product was launched in its oncology indication in 2001 in the US, where it is marketed by Bayer HealthCare Pharmaceuticals Inc. as Campath®, and in Europe, where it is named MabCampath®. Alemtuzumab 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.

Genzyme and Bayer Schering Pharma AG, Germany, are co-developing alemtuzumab in oncology, multiple sclerosis and other indications. Bayer Schering Pharma AG, Germany, holds exclusive worldwide marketing and distribution rights to alemtuzumab.

About Bayer HealthCare

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.

About 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. Find more information at www.bayerscheringpharma.de.

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