



Fact Sheet

Bayer Schering Pharma Development Projects

Business Unit: Specialized Therapeutics

Development candidate alemtuzumab – Potential to be a new therapeutic standard in multiple sclerosis

Interim Phase II clinical study results indicate:

- Fewer relapses and slower disease progression
 - Improvement in disease status compared to the start of therapy
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Status: June 2007

<p>Project description</p> <p>The antibody alemtuzumab is currently undergoing testing in a three-year Phase II clinical study (CAMMS223) for the treatment of multiple sclerosis (MS). The patients selected for the study have active relapsing-remitting MS, which is the most common form of the disease. Interim results of the study presented in May 2007 following two years of therapy demonstrated positive results for efficacy. In contrast to the comparison substance interferon-beta-1a, which is licensed as a first-line therapy, alemtuzumab demonstrated superiority in attaining the primary endpoints: the frequency of relapses was reduced by 87% / 72% (depending on the dosage) and the progression of disability, measured using the international standard EDSS (Extended Disability Status Scale), was decreased by 66% / 88% (depending on the dosage). The interim assessment thus shows the greatest decrease in the frequency of</p>	<p>At a glance</p>
	<p>Name of the active substance</p> <p>Alemtuzumab</p>
	<p>Type of substance</p> <p>Humanized monoclonal antibody</p>
	<p>Targeted Indication</p> <p>Multiple sclerosis</p>

<p>relapses and the greatest delay in disease progression as measured by EDSS that have ever been observed over a two-year period in a clinical study of MS. Furthermore, the compound did not only delay the progression of the disease. Patients also benefited from a significant improvement in the degree of disability as assessed by EDSS in comparison to their status at the start of treatment, a parameter that was being investigated as a secondary endpoint of the study.</p> <p>In the alemtuzumab branch of the study, a total of six cases (2.8%) of idiopathic thrombocytic purpura (ITP), a disease that is characterized by a decrease in platelets (thrombocytes) and a correspondingly increased tendency to bleed, occurred. After the first three cases, and in agreement with the FDA (U.S. Food and Drug Administration), dosing of alemtuzumab was discontinued and a Patient Monitoring Program for ITP was established that includes, for example, regular blood tests and doctor and patient education. The FDA has since lifted the clinical hold.</p> <p>Currently, two phase III studies are in preparation which should start before the end of 2007.</p> <p>The medical background – multiple sclerosis Multiple sclerosis (MS) is a serious chronic disease, in which the immune system attacks the brain and spinal cord of the affected person. The disease causes a wide range of symptoms including fatigue, gait disorders, feelings of numbness, and visual disorders. In advanced stages, it can cause severe disability. The most frequent form of the disease is relapsing-remitting MS. Across the world, approximately 2.5 million patients have MS, with approximately twice as many women as men being affected. MS cannot be cured. There are many therapies for the treatment of MS, but because of their limited efficacy there is still a major need for innovative therapeutic</p>	<p>Administration form Intravenous infusion</p>
	<p>Mode of action Binding to the CD52 antigen on B- and T-cells, thus causing lysis of the cells</p>
	<p>Status Current Phase II study (CAMMS223) Completion of the study and publication of the final results planned for 2007 Start of two Phase III studies planned for 2007</p>
	<p>Collaborating partner Genzyme Corporation Cambridge, MA, USA www.genzyme.com</p>

options.

Alemtuzumab

Alemtuzumab is a humanized monoclonal antibody that binds specifically to the CD52 antigen on the surface of B- and T-cells, thus marking them as targets for destruction by the body's own immune system. The causes of multiple sclerosis have not been fully elucidated. It is assumed that autoreactive B- and T-cells play an important part in the disease-related events of this autoimmune condition.

Treatment with alemtuzumab pursues a novel approach in the therapy of MS, in that these cells are targeted and destroyed.

Bayer HealthCare and Genzyme are jointly developing alemtuzumab for use in oncology, multiple sclerosis and other indications. Bayer Schering Pharma AG holds the exclusive worldwide development and marketing rights for alemtuzumab. The antibody has been approved for the treatment of chronic lymphocytic B-cell leukemia (B-CLL) since 2001.

Phase II study CAMMS223

In the Phase II study, 334 patients with active relapsing-remitting multiple sclerosis at 49 treatment centers in Europe and the U.S. were randomized to one of three treatment groups. The patients received either alemtuzumab in one of two doses, administered by intravenous infusion on five consecutive days in year one and three consecutive days in subsequent years, or they received interferon-beta-1a, administered three times weekly according to the Product Information. In the randomized study, the safety and efficacy of alemtuzumab was compared with that of interferon-beta-1a on the basis of two primary endpoints: the risk of an MS relapse and the risk of progression of clinically relevant disability (the time to the occurrence of lasting and cumulative disability was measured after six months using the "Expanded Disability

<p>Status Score" [EDSS]). Since blinding of the patients was not possible because of the different forms of administration of the therapies, the person evaluating the patients was blinded, i.e. the therapy received by a patient was not disclosed. At the start of the study, the treatment groups were comparable with respect to all important demographic and clinical parameters.</p>	
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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 and as Bayer HealthCare Pharmaceuticals in the US and Canada. 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.

Research and Development at Bayer Schering Pharma

Bayer Schering Pharma concentrates its R&D activities on innovative treatment approaches for diseases with a high unmet medical need to improve patients' quality of life and prolong lives. In this context, Bayer Schering Pharma focuses on its core competencies and its many years of experience. Thus, Bayer Schering Pharma holds a leading position in many therapeutic fields: for example, in the treatment of hemophilia and multiple sclerosis, in contrast media and oral contraception. We are also striving for a leading position in oncology. With new approaches in cancer therapy, for cardiovascular diseases, gynaecological therapies and in molecular imaging, Bayer Schering Pharma aims to become an innovation leader in these fields. In addition, Bayer Schering Pharma further develops products already on the market in order to improve their application and/or extend their range of indications.

Contacts:

Dr. Jost Reinhard, Tel.: +49 30 468 15062

E-mail: jost.reinhard@bayerhealthcare.com

Frank Richtersmeier, Tel.: +49 30 468 17661

E-mail: frank.richtersmeier@bayerhealthcare.com

Forward-looking statements

This information contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.