Bayer


Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

# Investor News

Therapy of multiple sclerosis

## BEYOND study:
## Results do not support regulatory filing for Betaferon® 500 mcg

- Betaferon® 250 mcg is optimal Betaferon® dose based on high efficacy and excellent tolerability
- Study unable to show superiority of Betaferon® 500 mcg compared to Betaferon 250® mcg and Copaxone®

**Leverkusen, October 29, 2007** – Bayer Schering Pharma AG, Germany, today announced top line results from the BEYOND (Betaferon Efficacy Yielding Outcomes of a New Dose) study, a large randomized trial of patients with relapsing-remitting multiple sclerosis (MS) to investigate the efficacy, tolerability and safety of a 500 mcg dose of Betaferon® (interferon beta-1b) compared to the standard 250 mcg Betaferon® dose and Copaxone® (glatiramer acetate). The overall outcome of the trial did not show a statistically significant superiority of the 500 mcg Betaferon® dose compared to the 250 mcg Betaferon® dose and Copaxone®. The risk for relapses, which was the primary end point of the trial, was similar in all three study arms. In this study, there was a very low relapse rate in the entire study population, unlike in previous trials.

Results of the BEYOND study do not support the regulatory filing for the 500 mcg dose of Betaferon®. Consequently, the intangible assets from the BEYOND project, capitalized in the course of the Schering acquisition, will be depreciated. Therefore, an impairment of -152 million Euro will be recognized in the third quarter financial reporting. Bayer Schering Pharma expects sales of Betaferon® to grow in the range of 7-9 percent in 2007 and 2008. The company's continued investment in lifecycle management programs, including enhancing the Betaferon® application system as well as ongoing long term follow-up programs will further enhance the product. The data from the Betaferon® clinical studies combined with development supporting potential new therapies, such as alemtuzumab,

demonstrate Bayer Schering Pharma's long-standing commitment to advancing the treatment of MS patients with new highly effective and safe therapies.

Patients in the study were required to exhibit clinical signs of the disease in the past year before entering the trial. When compared to the relapse rate during the year prior to study enrollment, Betaferon® 250 mcg reduced the relapse rate by 78 percent during the observational period which was up to 3.5 years (Betaferon® 500 mcg: 79 percent, Copaxone® 79 percent).

The study also provides some interesting insights into the tolerability and patient acceptance of the treatments. The drop out rate for Betaferon® 250 mcg was the lowest of the three study arms, with 13 percent for Betaferon® 250 mcg compared to 19 percent for Betaferon® 500 mcg and 17 percent for Copaxone®. Clinical experience with Betaferon® has shown that implementing dose titration, using an auto-injector and co-medication with an analgesic result in excellent patient tolerability. These methods were also used in the BEYOND study, which may have resulted in the very good tolerability seen in patients treated with Betaferon® 250 mcg.

"Results of the BEYOND study confirm the high efficacy, excellent tolerability and low drop-out rate for Betaferon®. The standard Betaferon® 250 mcg dose is the optimal Betaferon® dose for treatment-naïve patients," said Dr. Douglas S Goodin, Professor of Neurology at the University of California, San Francisco (UCSF) and member of the Steering Committee of the BEYOND study. "BEYOND is a well-conducted, comprehensive study with a wealth of data that is still to be analyzed. I look forward to identifying how additional data that will come over time might help answer some of our remaining questions about MS and its treatment."

"Betaferon® is the MS drug with the longest clinical experience of more than 16 years. The product offers both unsurpassed efficacy and long-term reliable safety in relapsing-remitting multiple sclerosis," said Darlene Jody, M.D., Senior Vice President and President of Bayer HealthCare's Specialized Therapeutics Global Business Unit. "The results from the BENEFIT study have already demonstrated that early treatment with Betaferon® reduces patients' risk of permanent disability due to MS events by 40 percent over three years compared to delayed treatment. BEYOND adds support to the BENEFIT findings in that it demonstrated that Betaferon® 250mcg is the optimal dose for the treatment-naïve patient population due to high efficacy and excellent tolerability."

**About the BEYOND study**

The BEYOND study is a phase III, randomized, multi-centered trial that compared the relative efficacy of high-dose, high-frequency Betaferon® 250 mcg every other day to a 500 mcg dose of Betaferon® every other day and to glatiramer acetate 20 mcg administered subcutaneously every day. The study enrolled 2,244 patients with relapsing-remitting MS from 198 sites in 26 countries who had not been previously treated with MS therapy, and were randomized to one of the three study arms. It is one of a number of wide-ranging clinical MS studies from Bayer Schering Pharma that seek to further improve treatment options for MS patients.

**About the BENEFIT study**

BENEFIT is a multi-center trial conducted at 98 sites in 20 countries and included patients presenting with a first clinical episode suggestive of MS and typical MRI findings. The primary outcome measures were time to diagnosis of CDMS (Clinically Definite MS), time to confirmed EDSS (Expanded Disability Status Scale) progression and patient reported Quality of Life outcomes (FAMS-TOI). A total of 468 patients were randomized to receive either 250 micrograms of interferon beta-1b (Betaferon®) every other day or placebo as a subcutaneous injection in a double-blind fashion. The placebo-controlled treatment period lasted up to 24 months or up to the time when patients experienced a second attack and were diagnosed with clinically definite MS. All study participants were then invited to participate in a follow-up study with Betaferon® to prospectively assess the impact of such early versus delayed treatment with Betaferon® on the long-term course of the disease for a total observation time of five years. The results reported in the Lancet are from a pre-planned analysis at three years.

Previous published studies in this patient population have been criticised as less scientifically rigorous, because of their retrospective nature, unblinded assessments and the high number of patients lost to follow-up. The BENEFIT study was the first study in early MS patients designed to overcome these shortcomings.

**About the 16-Year Long-Term Follow-up Study**

The 16-Year Long-Term Follow-up Study provides clinical assessment of patients who first enrolled in the Betaferon® pivotal trial between 1988 and 1990. Of the original 372 patients involved in the pivotal trial, 328 (88.2 percent) have been identified. It is a multicenter, open-label, observational study designed to evaluate the impact of Betaferon® treatment on long-term outcomes in patients with relapsing forms of MS. The study constitutes the longest follow up for any disease-modifying therapy in MS.

The Betaferon® pivotal trial was the first large, randomized, placebo-controlled study of any therapy in MS. This groundbreaking study was conducted in North America and led to the approval of Betaferon®, the first disease-modifying agent for MS, in 1993. Patients were randomly assigned to one of three study arms, Betaferon® 50mcg, Betaferon® 250mcg or placebo, with a median duration of observation of 45 months. Analysis after two years demonstrated that significantly more patients receiving Betaferon® were relapse-free, that those relapses that occurred were less frequent and less severe and that hospitalizations for MS were cut nearly in half. These results were confirmed at five years.

**About Betaferon® / Betaseron®**

Betaferon®, which is marketed in the U.S. and Canada under the trademark Betaseron®, was the first disease-modifying drug introduced for MS and is a well-established treatment around the world. In the U.S., Europe and Japan, Betaferon® has been approved for all relapsing forms of MS. Sixteen years' follow-up of people treated with Betaferon® has shown that it is safe and well tolerated.

The most commonly reported adverse reactions are lymphopenia, injection-site reaction, asthenia, flu-like symptom complex, headache and pain. Gradual dose titration and use of analgesics during treatment initiation may help reduce flu-like symptoms. Betaferon® should be used with caution in patients with depression. Injection-site necrosis has been reported in four percent of patients in controlled trials. Patients should be advised of the importance of rotating injection sites. Female patients should be warned about the potential risk to pregnancy. Cases of anaphylaxis have been reported rarely. See "Warnings", "Precautions", and "Adverse Reactions" sections of full Prescribing Information.

**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 in one or more extremities, 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 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 AG. 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 AG**

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.

Bayer AG, Investor Relations contacts:
Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Ilia Kürten (+49-214-30-35426)
Ute Menke (+49-214-30-33021)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)