Bayer

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Investor News

First-of-its-Kind Data Show:

Immediate Treatment of Early MS Patients with Betaferon® Significantly Delayed Permanent Disability

Risk to confirmed EDSS progression reduced by 40 percent compared to delayed treatment

Berlin / May 1 – Bayer Schering Pharma AG, Germany, announced today new data, which show that immediate initiation of Betaferon® (interferon beta-1b) treatment in patients with a first event suggestive of multiple sclerosis (MS) can significantly reduce the risk of permanent neurological impairment as measured by the Expanded Disability Status Scale (EDSS) by 40 percent over three years compared to delayed treatment. These findings from the BENEFIT (BEtaferon in Newly Emerging multiple sclerosis For Initial Treatment) studies* were presented today at the American Academy of Neurology's 59th Annual Meeting in Boston, Massachusetts.

"Some patients have already developed significant neurological damage when they first present with signs of MS, which can lead to accumulated disability later in life. The BENEFIT results clearly show that immediate treatment with Betaferon® initiated after the first clinical event can significantly reduce that damage, which could translate into a greater delay in the time it takes for patients to suffer from the debilitating consequences of MS," said Dr. Mark S. Freedman, Professor of Neurology at the University of Ottawa and investigator of the study. "This is a truly novel finding that has not yet been demonstrated for any other immunomodulatory MS treatment, and underscores the urgent need to treat patients early rather than waiting for further signs of MS to develop. Physicians and patients should consider these unprecedented findings when making treatment decisions."

“Immediate treatment” refers to treatment initiated after the first clinical event; “delayed treatment” is initiated after the second clinical event or after 2 years, whatever comes first.

“We are delighted that the BENEFIT study continues to deliver ground-breaking results,” said Darlene Jody, M.D., President of Bayer HealthCare’s Specialized Therapeutics Global Business Unit. “In the past year, Betaferon® has received approval around the world for use in patients with the earliest signs of MS. We intend to submit this novel data for inclusion in our label. Regulatory approval would further differentiate Betaferon® from other products in the market place and strengthen our position.”

About BENEFIT

BENEFIT is a multi-center trial conducted at 98 sites in 20 countries and included patients presenting with a single clinical episode suggestive of MS. A total of 468 patients with a first clinical demyelinating event suggestive of MS and typical MRI findings 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 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 immediate versus delayed treatment with Betaferon® on the long-term course of the disease for a total observation time of five years.

Results from a prospectively planned analysis of patients three years after the first event suggestive of MS showed that immediate treatment with Betaferon® after the first event suggestive of MS reduced the risk for confirmed EDSS progression by 40 percent over three years compared to delayed treatment. At three years, patients who initiated Betaferon® treatment immediately were 41 percent less likely to progress to clinically definite MS versus patients who began treatment later. These results confirm the findings of the placebo-controlled BENEFIT study.

At the end of three years, 73 percent of patients were on Betaferon® treatment after the first event suggestive of MS.

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. It is able to reduce the number of MS episodes by one-third, and the frequency of moderate to severe episodes by as much as 50 percent. Sixteen years' follow up of people treated with Betaferon® has shown that it is safe and well tolerated.

References

*Mark S. Freedman, et al: Betaseron in Newly Emerging Multiple Sclerosis for Initial Treatment (BENEFIT): Effects of Immediate vs. Early Onset of Interferon Beta-1b Treatment, American Academy of Neurology, 59th Annual Meeting

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.

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Forward-looking statements
This news release 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 our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.