

23 October 2006 - FDA Approves Betaseron for Use After the First Event Suggestive of Multiple Sclerosis

Wayne, NJ, October 23, 2006 - Berlex, Inc., a U.S. affiliate of Schering AG, Germany (FSE: SCH; NYSE: SHR), announced today that the U.S. Food and Drug Administration (FDA) has expanded the indication of Betaseron® (interferon beta-1b) to include patients with multiple sclerosis (MS) who have experienced a first clinical episode and have MRI features consistent with MS. Betaseron is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Betaseron is the only high-dose, high-frequency interferon beta indicated for patients at the earliest stage of MS.

The new indication is based on results from the BENEFIT (BETaseron in Newly Emerging multiple sclerosis for Initial Treatment) Study of patients with a first clinical demyelinating event and MRI features suggestive of MS. The two-year study showed that treatment with Betaseron delayed the time to a second clinical event by one year compared to placebo. (1) BENEFIT is the only trial to demonstrate the efficacy of a high dose, high frequency interferon beta, Betaseron, as an effective treatment for patients with early MS. In addition to establishing efficacy in this group of patients, the study also showed that patients with early MS found Betaseron to be a safe and well-tolerated treatment, as evidenced by the findings that 93 percent of patients completed the study.

"We are very happy to offer people at the earliest stages of MS the benefit of an early start with high-dose, high-frequency Betaseron and its proven, long-term safety and efficacy profile," said Ludger Heeck, Ph.D., Vice President and General Manager, Specialized Therapeutics, Berlex. "Experts convened by the American Academy of Neurology (2) have suggested that higher doses of interferon beta, taken more frequently, appear to be more effective in fighting MS than lower doses taken less often. Betaseron is the only high-dose, high-frequency interferon beta approved in the U.S. for patients who have experienced a first clinical event suggestive of MS."

About the BENEFIT Study

Two-year data from the BENEFIT Study were recently published in *Neurology*(3). In the randomized, double-blind, placebo-controlled, multicenter trial, 468 participants were given either Betaseron 250 micrograms (mcg) subcutaneously every other day or placebo until they experienced a second clinical event or relapse, which confirms the diagnosis, or they had been followed for at least 24 months. Dose titration (increasing the dose slowly) was applied and analgesics were used prior to injection. Patients were also provided instruction on methods of self-injection.

"The BENEFIT study has taught us many things but most importantly has shown us that most patients who appear to be at high risk of developing MS do so within only two years. In the study, Betaseron cut the risk of progression to the second clinical event by nearly 50 percent compared to placebo," said Mark S. Freedman, M.D., Professor of Neurology at the University of Ottawa, Ontario, Canada, and a lead investigator of the BENEFIT Study. "We have learned from BENEFIT and other studies that early treatment is probably one of the keys to treatment success since accumulated neurological damage is often irreversible and much of this is not clinically apparent in these early phases. Betaseron is well-accepted and provides an effective first treatment option for people with relapsing MS and those with early signs of disease."

Results showed that:

- Treatment with Betaseron reduced the risk of progression to clinically definite MS by about 50 percent and to MRI-defined MS (4,5), by 46 percent, compared to placebo.
- Treatment with Betaseron delayed the time to a second clinical event by one year compared to patients in the placebo arm.
- In the placebo group, over half of the patients reached MRI-defined MS within six months and 85 percent reached MRI-defined MS in the two-year study.

The results of the BENEFIT trial also showed that the patients were willing to initiate and continue Betaseron treatment in an effort to gain control of the disease at its earliest stages:

- More than nine out of 10 patients (93 percent) treated with Betaseron completed the study, a rate similar to placebo.
- Ninety-six percent of all eligible patients opted to participate in a three-year extension of the study. To date, no other trial involving early MS patients has demonstrated such a high level of patient acceptance.
- Only 2.7 percent of patients in the trial discontinued therapy because of adverse events.

About Betaseron

Betaseron is approved for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. Betaseron has more than 17 years of clinical experience, with a well-established safety profile resulting from more than 700,000 patient years of treatment. A long-term follow-up study

demonstrated that Betaseron remains consistently safe, effective and well tolerated over the long term. Results of the study show that long-term continuous(6) use of Betaseron provided 13 years of cane-free mobility, which is, on average, six years longer than when compared to untreated patients from a natural history cohort. The study also showed that patients who continuously used Betaseron experienced a significant delay in progression to secondary progressive multiple sclerosis (SPMS) by 6.6 years compared to patients who were not on continuous Betaseron treatment.

The most commonly reported adverse reactions are lymphopenia, injection site reaction, asthenia, flu-like symptom complex, headache, and pain. Gradual dose titration and the use of analgesics during treatment initiation may help reduce flu-like symptoms. Betaseron should be used with caution in patients with depression. Injection site necrosis has been reported in five 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. Please see full Prescribing Information available at www.betaseron.com.

(1) Based on the 25th percentile

(2) Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002;58:169-178.

(3) Kappos L et al. Treatment with interferon beta-1b delays conversion to clinically definite and McDonald MS in patients with clinically isolated syndromes. *Neurology* 2006;67:1242-1249.

(4) McDonald criteria

(5) The exact relationship between MRI findings and patients' symptoms is not completely understood.

(6) Long-term continuous use is defined as > 80 percent of the study duration (>12 years).

About Berlex

Berlex, a U.S. affiliate of Schering AG, Germany (FSE: SCH; NYSE: SHR), is committed to addressing unmet medical needs through research and development in the areas of oncology, gastroenterology, women's health, diagnostics and neurology. Berlex also markets diagnostic imaging agents, innovative treatments in the areas of female health care and oncology, as well as specialized therapeutics for life-threatening and disabling diseases of the central nervous system and cardiovascular system. Berlex has business operations in New Jersey, California and Washington. For more information, please visit www.berlex.com

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