CORRECTING and REPLACING Biogen Idec Reports Positive Data from AVONEX Dose Titration Study at 2011 Annual Meeting of the Consortium of Multiple Sclerosis Centers

June 6, 2011

-Data Show that Titrating AVONEX at Initiation of Treatment Reduced Severity of Flu-like Symptoms-

WESTON, Mass.--(BUSINESS WIRE)--The headline should read: ...AVONEX Dose Titration Study... (sted: ...AVONEX Dose Titraion Study...)

The corrected release reads:

BIOGEN IDEC REPORTS POSITIVE DATA FROM AVONEX DOSE TITRATION STUDY AT 2011 ANNUAL MEETING OF THE CONSORTIUM OF MULTIPLE SCLEROSIS CENTERS

-Data Show that Titrating AVONEX at Initiation of Treatment Reduced Severity of Flu-like Symptoms-

Biogen Idec (NASDAQ: BIIB) today announced the findings from a randomized, multicenter, dose-blinded clinical trial that evaluated the effect of AVONEX® (interferon beta-1a) dose titration, or gradual dose escalation, on flu-like symptoms associated with the therapy. The data demonstrated that dose titration with AVONEX over three weeks at the initiation of treatment resulted in a 76 percent reduction in flu-like symptom severity between pre-injection and the four–six-hour post-injection time point versus no titration ($p<0.001$). The study also showed that titration over six weeks at the initiation of treatment led to a 50 percent reduction in flu-like symptom severity between the same pre- and post-injection time point versus no titration ($p<0.001$). These data were presented at the 2011 Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting in Montreal.

“Some physicians have practiced titration in the past based on experience of improved tolerability at initiation of interferon treatment; however, there has been limited clinical evidence on the benefits of dose titration,” said Elliot Frohman, M.D., Ph.D., Professor of Neurology and Neurotherapeutics and of Ophthalmology at UT Southwestern Medical Center in Dallas, and member of the AVONEX U.S. advisory board. “We now have robust data showing that people who initially received titrated doses of AVONEX experienced a reduction in severity and incidence of flu-like symptoms.”

Flu-like symptoms (e.g., fever, chills, headache, muscle aches and pains, and fatigue) have been shown to occur with interferon treatment, and physicians currently may employ several different strategies to alleviate these symptoms. Biogen Idec conducted the AVONEX dose titration study to help characterize the impact of titration on severity and incidence of flu-like symptoms.

“AVONEX has been a leading prescribed treatment for multiple sclerosis for 15 years and continues to provide hope for patients suffering from this disease,” said Aaron Deykin, M.D., Director of Late Stage Neurology Development at Biogen Idec. “Findings from the dose titration study add to the real-world efficacy and safety data we have acquired for AVONEX, and can potentially provide the medical community with additional knowledge they can use to augment their own clinical experience to guide their approach to the initiation of AVONEX treatment.”

About the Study

An eight-week, randomized, multicenter, dose-blinded study (n=234) was conducted to evaluate the effect of dose titration on the severity and incidence of AVONEX-related flu-like symptoms, with a subsequent two-week follow-up. The primary endpoint of the study was the change in total flu-like symptoms severity score from pre-injection to the four–six-hour post-injection time point. Healthy volunteers were randomized to one of three treatment arms:

- Three-week titration, in which AVONEX was started at one-quarter of the full dose and increased in quarter-dose increments at weekly intervals over three weeks to full-dose (30 µg); then was administered at full-dose for the remaining five weeks.
- Six-week titration, in which AVONEX was started at one-quarter of the full dose and increased in quarter-dose increments at biweekly intervals over six weeks to full-dose (30 µg); then was administered at full-dose for the remaining two weeks.
- No titration, in which the full 30-µg dose was administered weekly for eight weeks.

All subjects received 650 mg of oral acetaminophen within one hour prior to each AVONEX injection, and then at four–six hours, eight–ten hours and 12–15 hours post-injection. A total flu-like symptoms score was calculated based on a 12-point scale, which was the summation of scores for four individual symptoms: fever, chills, muscle aches and pains, and fatigue. Secondary endpoints included change in total flu-like symptoms severity score from pre-injection to the 12–15-hour post-injection time point over the eight-week treatment period, and incidence (defined as the percentage of subjects with a ≥two-point increase in score between pre-injection and post-injection) of flu-like symptoms at the four–six- and 12–15-hour time points.

Results showed that over the treatment period, change in flu-like symptom severity between pre-injection and the four–six-hour post-injection time point was reduced by 76 percent with AVONEX titration over three weeks versus no titration, and by 50 percent with AVONEX titration over six weeks versus no titration. Over the same treatment period, change in flu-like symptom severity between pre-injection and the 12–15-hour post-injection time point was reduced by 37 percent with AVONEX titration over three weeks versus no titration and by 32 percent with AVONEX titration over six weeks versus no titration.

The study results also showed that dose titration reduced the incidence of post-injection flu-like symptoms. Participants in both titration arms had lower incidence of flu-like symptoms at the four–six-hour post-injection time point than subjects in the no-titration arm, with a numerically greater benefit observed with three-week titration (odds ratio [OR] 0.179; 95% confidence interval [CI] 0.075–0.429; P<0.001) than six-week titration (OR 0.414; 95% CI 0.194–0.884; P=0.023). Participants in both titration arms also had lower incidence of flu-like symptoms at the 12–15-hour post-injection time point than subjects in the no-titration arm, with a numerically greater benefit observed with three-week titration (OR 0.469; 95% CI 0.272–0.807; P=0.006)

than six-week titration (OR 0.562; 95% CI 0.338–0.936; P=0.027).

The safety profiles for both titration regimens were similar to the safety profile for the no titration AVONEX regimen. Side effects observed in the study were consistent with those outlined in the existing AVONEX product labeling.

About Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market therapies for serious diseases with a focus on neurology, immunology and hemophilia. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than $4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

About AVONEX

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide and has been approved for use in the United States for 15 years. It is used worldwide as a treatment for relapsing forms of MS to slow the progression of physical disability and reduce relapses. AVONEX is also approved for patients who have their first clinical episode and have a brain MRI scan consistent with MS.

The most common side effects associated with AVONEX MS treatment are flu-like symptoms, including myalgia, fever, fatigue, headache, chills, nausea, vomiting, pain and asthenia.

AVONEX should be used with caution in patients with depression or other mood disorders and in patients with seizure disorders. AVONEX should not be used by pregnant women. Patients with cardiac disease should be closely monitored. Patients should also be monitored for signs of hepatic injury. Routine periodic blood chemistry and hematology tests are recommended during treatment with AVONEX. Rare cases of anaphylaxis have been reported.

For information regarding the European Summary of Product Characteristics visit http://www.ema.europa.eu/ema. For the complete United States prescribing information, please visit http://www.AVONEX.com.

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