New TYSABRI® Analysis at AAN Annual Meeting Shows Improved Walking Speed in Significant Number of MS Patients

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− Additional Data Show Escalation to TYSABRI Following Relapse Improves Clinical Outcomes Compared to Remaining On or Switching Between First-Line Interferon Beta and Glatiramer Acetate −

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) today announced that a post hoc analysis of data from the AFFIRM study shows TYSABRI® (natalizumab) significantly increased the proportion of relapsing-remitting multiple sclerosis (RRMS) patients with confirmed improvement in walking speed (CIWS) relative to placebo at two years. Additional data from observational registry studies show that switching to TYSABRI after experiencing a multiple sclerosis (MS) relapse while taking interferon beta (IFNβ) or glatiramer acetate (GA) reduced the risk of future relapses and treatment discontinuation. These data were presented at the 66th American Academy of Neurology (AAN) annual meeting in Philadelphia, Pa. (April 26-May 3, 2014).

"We know that MS has a significant impact on ambulation – a key concern for many people living with this disease – which is why we analyzed data from AFFIRM to evaluate the potential impact of TYSABRI on walking speed," said Alfred Sandrock, M.D., Ph.D., group senior vice president and chief medical officer at Biogen Idec. "TYSABRI was associated with a 20 percent increase in walking speed, a clinically relevant improvement, in a significantly greater number of patients compared to placebo."

Walking Speed Impacted with TYSABRI

AFFIRM was a two-year, randomized, multi-center, placebo-controlled, double-blind study of 942 patients with RRMS that evaluated the effect of TYSABRI on the progression of physical disability and the rate of clinical relapses. A post-hoc analysis of AFFIRM assessed the impact of TYSABRI on the proportion of patients with CIWS compared to placebo. CIWS was defined as ≥20 percent increase in walking speed from baseline in the timed 25-foot walk (T25FW) confirmed 12 weeks later.

Results show that, over the course of two years, CIWS was significantly associated with improvement in patient-reported physical functioning. Treatment with TYSABRI increased the proportion of patients with CIWS at year two by 79 percent compared to placebo (TYSABRI, 12.3%; placebo 6.9%; p=0.0133). These effects were more significant and occurred earlier in patients with more advanced disability – with CIWS being increased by as much as five-fold compared to placebo at one year.

While many MS clinical trials measure disability progression, which includes a measure of ambulation by the Expanded Disability Status Scale (EDSS), these data from AFFIRM suggest that CIWS may be a more sensitive endpoint in capturing improved ambulation in RRMS patients.

These data were presented in a platform presentation on Tuesday, April 29 at 2:15 p.m. ET:

- *Natalizumab Treatment Improves Walking Speed in MS Patients: A Post Hoc Analysis of AFFIRM* (S4.006)

Efficacy Effect Observed With Switch to TYSABRI

Two additional studies used propensity-matched registry data to evaluate the effects of transitioning to TYSABRI after an on-treatment relapse while taking INFβ or GA, compared to remaining on, or switching between, INFβ and GA. Results show that switching to TYSABRI decreased the risk of future relapses, disability progression and treatment discontinuation for MS patients.

Because there are no randomized clinical trials comparing treatment options for patients with ongoing disease activity, comparisons of propensity-matched data from large observational cohorts are useful to estimate the relative risks associated with treatment decisions in a clinical setting. In these studies, researchers matched patients across three large observational clinical trials: TYSABRI Observational Program (TOP), an ongoing observational, open-label, 10-year prospective study of relapsing-remitting MS (RRMS) patients; MSBase, an ongoing, longitudinal database open to all practicing neurologists worldwide; and MSCOMET, a longitudinal MSBase registry substudy assessing the efficacy of IFNβ and GA in 1,000 patients in 14 countries.

In the first study, researchers matched 759 MS patients who participated in the MSCOMET study to the same number of patients in the TOP. They assessed time to first relapse, treatment discontinuation and disability progression over one year in those who relapsed on IFNβ or GA in the 12 months prior to study entry and either transitioned to TYSABRI or stayed on their original first-line therapy. Data show that switching to TYSABRI versus remaining on IFNβ or GA after an on-treatment relapse decreased the risk of relapse by 57 percent and reduced the risk of treatment discontinuation by 52 percent. Researchers also analyzed a smaller subset of patients (n=227 patient pairs) to assess disability progression. They found the incidence of three-month confirmed disability progression was lower in patients who transitioned to TYSABRI than in those who persisted on IFNβ or GA; however, this difference was not statistically significant, likely due to the small sample size and small number of observed progression events.

In the second study, researchers compared annual relapse rate, treatment discontinuation and disability progression over one year within two subgroups of patients who participated in MSBase and the TOP: subgroup one, patients taking IFNβ who switched to GA compared to those who switched to TYSABRI (n=578 for each cohort); and subgroup two, patients taking GA who switched to IFNβ compared to those who switched to TYSABRI (n=165 for each cohort). Results show that transitioning to TYSABRI treatment versus switching from IFNβ to GA reduced the risk of relapse by 63 percent and discontinuation risk by 62 percent. Transitioning to TYSABRI treatment versus switching from GA to IFNβ also reduced the risk of relapse by 53 percent and discontinuation risk by 48 percent. Researchers then combined the subgroups to assess three-month confirmed disability progression; results showed that transitioning to TYSABRI versus switching between IFNβ and GA reduced the risk of disability progression by 32 percent.

These data were presented as posters:

- *Comparative Efficacy of Switching to TYSABRI Versus Switching to Interferon-Beta or Glatiramer Acetate after On-Treatment MS Relapse Using Propensity-Matched Registry Data* (P3.175) was available for viewing on Tuesday, April 29 from 3:00-6:00 p.m. ET
- *Comparison of Switching to TYSABRI Versus Remaining on Interferon-Beta or Glatiramer Acetate after On-Treatment MS Relapse Using Propensity-Matched Registry Data* (P7.208) will be available for viewing on Thursday, May 1 from 3:00-6:00 p.m. ET

About TYSABRI

TYSABRI is approved in more than 65 countries. In the U.S., TYSABRI is indicated as monotherapy for the treatment of patients with relapsing forms of MS. TYSABRI increases the risk of PML. When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk. In the European Union, it is indicated as a single disease modifying therapy in highly active relapsing-remitting MS (RRMS) for adult patients who have high disease activity despite treatment with a beta interferon or glatiramer acetate or patients with rapidly evolving severe RRMS.

TYSABRI has advanced the treatment of MS patients with its established efficacy. Data from the Phase 3 AFFIRM trial, which was published in the New England Journal of Medicine, showed that after two years, TYSABRI treatment led to a 68 percent relative reduction ($p<0.001$) in the annualized relapse rate when compared with placebo and reduced the relative risk of disability progression by 42-54 percent ($p<0.001$).

TYSABRI increases the risk of PML, an opportunistic viral infection of the brain which usually leads to death or severe disability. Infection by the JC virus (JCV) is required for the development of PML and patients who are anti-JCV antibody positive have a higher risk of developing PML. Factors that increase the risk of PML are presence of anti-JCV antibodies, prior immunosuppressant use, and longer TYSABRI treatment duration. Patients who have all three risk factors have the highest risk of developing PML. TYSABRI increases the risk of developing encephalitis and meningitis caused by herpes simplex and varicella zoster viruses. Serious, life-threatening, and sometimes fatal cases have been reported in the postmarketing setting in multiple sclerosis patients receiving TYSABRI. Other serious adverse events that have occurred in TYSABRI-treated patients include hypersensitivity reactions (e.g., anaphylaxis) and infections, including opportunistic and other atypical infections. Clinically significant liver injury has also been reported in the post-marketing setting. A list of adverse events can be found in the full TYSABRI product labeling for each country where it is approved.

For additional important safety information, and the United States full prescribing information, please visit www.TYSABRI.com.

About Biogen Idec

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies. For product labeling, press releases and additional information about the Company, please visit www.biogenidec.com.

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