Biogen Receives Positive CHMP Opinion for TYSABRI® (Natalizumab) Use in Highly Active RRMS Patients with Inadequate Response to Prior MS Therapy

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-- Opinion Supported by Nearly 10 Years of Post-Marketing Experience Highlighting TYSABRI's Proven Long-Term Efficacy and Well-Established Safety Profile --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--The Committee of Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of a variation to the marketing authorization of TYSABRI® (natalizumab), Biogen (NASDAQ: BIIB) announced today. The CHMP recommends the approval of TYSABRI for use as a disease modifying therapy (DMT) for relapsing-remitting multiple sclerosis (RRMS) patients with highly active disease activity despite a full and adequate course of treatment with at least one DMT. The positive opinion is supported by long-term real-world experience from the TYSABRI Observational Program (TOP), an ongoing observational, open-label, 10-year prospective study of RRMS patients.

"For nearly 10 years, TYSABRI has provided patients and physicians with a high efficacy therapy that has a well-established tolerability and safety profile," said Ralph Kern, senior vice president, Worldwide Medical. "This update to the European marketing authorization would allow patients with highly active disease to switch to TYSABRI regardless of the prior DMT used."

Data Supporting Positive Opinion

The CHMP opinion is based on real-world data from the TOP study. Results from TOP, recently presented at the 68th American Academy of Neurology annual meeting, showed that TYSABRI significantly reduced multiple sclerosis disease activity and demonstrated a favorable benefit-risk profile, regardless of which prior DMT was used. The incidence of reported serious adverse events was consistent with TYSABRI's known safety profile.

The opinion of the CHMP is now referred to the European Commission (EC) for final decision on approval.

This positive opinion follows April 2016 EC approvals that granted TYSABRI unlimited validity for the marketing authorization in Europe and updated the European Union product information and physician/patient education materials. The new patient management plan provides an updated risk algorithm which allows physicians to have more individualized benefit-risk discussions with their patients and provides them with clear guidelines to manage their patients appropriately.

According to the EMA, the updated risk estimates show that the risk of developing progressive multifocal leukoencephalopathy (PML) is small, and lower than previously estimated, at antibody index values of 0.9 or less, and increases substantially in patients with index values above 1.5 who have been treated with TYSABRI for longer than two years. In patients who tested negative for JC virus antibodies, the PML risk estimate remains unchanged at 0.1 per 1,000 patients. Biogen is committed to patient safety and continues to work closely with the scientific community to provide greater clarity on the minimization of risk for patients taking TYSABRI.

About TYSABRI®

TYSABRI is a disease modifying therapy (DMT) approved in more than 80 countries including the United States, the European Union, Canada, Australia and Switzerland. In the United States, TYSABRI is indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis (MS). In the European Union, it is indicated as a single DMT 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 is proven effective, with 10 years of experience in treating RRMS, and more than 149,000 people treated worldwide and 475,000 patient-years of experience.

TYSABRI is a monoclonal antibody that selectively binds to α4-integrin and is thought to interrupt the activity of inflammatory cells in MS patients by blocking the interaction between α4β1-integrin and vascular cell adhesion molecule-1. Disruption of these molecular interactions prevents transmigration of leukocytes across the endothelium into inflamed parenchymal tissue. The specific mechanism(s) by which TYSABRI exerts its effects in MS have not been fully defined.

TYSABRI has advanced the treatment of MS patients with its proven ability to slow the progression of disability, reduce relapse rates, and impact the number of MRI brain lesions with a well-characterized safety profile. Data from the Phase 3 AFFIRM trial, which was published in the New England Journal of Medicine, showed that at 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 to 54 percent (12-24-week sustained respectively, both $p<0.001$).

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), a rare opportunistic viral infection of the brain which has been associated with death or severe disability. Risk 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 and clinically significant liver injury has also been reported in the post-marketing setting. Serious, life-threatening, and sometimes fatal cases have been reported in the postmarketing setting in MS 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.

The overall benefit-risk profile of TYSABRI remains positive. For additional important safety information and the United States Prescribing Information which includes a full list of adverse events, please visit www.tysabri.com or your respective country's website.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies and

patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For more information, please visit www.biogen.com. Follow us on Twitter.

Safe Harbor
This press release includes forward-looking statements, including statements about the potential therapeutic effects and benefits of and on-going clinical use of TYSABRI. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "will," and other words and terms of similar meaning. You should not place undue reliance on these statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including uncertainty of continued successful commercialization of TYSABRI, which may be impacted by, among other things, intense competition in the MS market, the effectiveness of sales and marketing efforts, problems with the manufacturing process for TYSABRI, the occurrence of adverse safety events, difficulties in obtaining or changes in the availability of reimbursement for TYSABRI and Biogen's other MS products, failure to obtain regulatory approvals in other jurisdictions, failure to protect intellectual property and other proprietary rights, product liability claims, and the other risks and uncertainties that are described in the Risk Factors section of Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission (SEC). Any forward-looking statements speak only as of the date of this press release and Biogen assumes no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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