Biogen Idec Submits Application in Europe for the Approval of Fampridine-PR Tablets to Improve Walking Ability in People with Multiple Sclerosis

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-- Application for approval also submitted to Health Canada --

ZUG, Switzerland--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) announced today the submission of a marketing authorization application (MAA) to the European Medicines Agency for Fampridine Prolonged Release (Fampridine-PR) tablets, a novel oral therapy for the improvement of walking ability in adult patients with multiple sclerosis (MS). The company also has filed a New Drug Submission (NDS) to Health Canada.

"Walking impairment has a significant impact on the lives of many people living with MS," said Alfred Sandrock, MD, PhD, Senior Vice President, Neurology Research and Development, Biogen Idec. "Fampridine-PR tablets may offer a novel approach to address this debilitating aspect of the disease by improving the walking ability of MS patients. We look forward to working with regulators to make this therapy available to people with MS in Europe and Canada."

The MAA submission and Canadian NDS are based on a comprehensive development program including results from two Phase III, randomized, double-blind, placebo-controlled studies. These studies demonstrated the efficacy of Fampridine-PR tablets in improving walking ability in patients with relapsing remitting, secondary progressive, progressive relapsing, and primary progressive MS.

In the two Phase III clinical trials, a significantly greater portion ($p<0.001$) of Fampridine-PR-treated patients had a consistent improvement in walking speed when compared to placebo (34.8 percent vs. 8.3 percent and 42.9 percent vs. 9.3 percent, respectively). The increased response rate of the Fampridine-PR group was observed across all types of MS included in the studies.

The Fampridine-PR treated subjects who had consistent improvement in the two studies experienced an average increase in walking speed of 25.2 percent and 24.7 percent compared to 4.7 percent and 7.7 percent, respectively, for the entire placebo group.

The majority of the study participants in these trials were using immunomodulatory drugs, including interferons, glatiramer acetate, and natalizumab; however the magnitude of improvement in walking ability was independent of concomitant therapy.

About Fampridine-PR

Fampridine-PR is a prolonged release (sustained release) tablet formulation of the investigational drug fampridine (4-aminopyridine or 4-AP). Fampridine-PR tablets act by blocking the potassium channels in demyelinated nerves, which reduces the leakage of current from the axons, restoring neuronal conduction, and action potential formation.

This tablet formulation, called Fampridine-SR in the United States (U.S.), was developed and will be commercialized in the U.S. by Acorda Therapeutics, Inc. (Nasdaq: ACOR). The U.S. Food and Drug Administration (FDA) has accepted a New Drug Application (NDA) for Fampridine-SR and assigned it a Prescription Drug User Fee Act (PDUFA) date of January 22, 2010. The PDUFA date is the target date for the FDA to complete its review of the Fampridine-SR NDA. Biogen Idec will commercialize Fampridine-PR in markets outside of the U.S.

**Note to editors - In Canada, Fampridine-PR is referred to as Fampridine-SR.*

About Multiple Sclerosis

MS is a chronic disease of the central nervous system that affects millions of people worldwide. It is a disease that affects more women than men, with onset typically occurring between 20 and 50 years of age. MS is caused by damage to myelin, the protective sheath surrounding nerve fibers in the central nervous system, which interferes with messages from the brain to the body. Symptoms of MS may include difficulty walking, loss of balance, numbness, vision problems, and paralysis.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing and commercialization of innovative therapies. Patients in more than 90 countries benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

Safe Harbor

This press release contains forward-looking statements, including statements about the anticipated timing of regulatory filings. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those that we expect, including the uncertainty of obtaining regulatory approval, the occurrence of adverse safety events with our products, our dependence on collaborations over which we may not always have full control, and the other risks and uncertainties that are described in Item 1.A.

Risk Factors in our annual report on Form 10-K and in other reports we file with the SEC. These forward-looking statements speak only as of the date of this press release, and we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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