European Medicines Agency's Committee for Medicinal Products for Human Use Issues Positive Opinion on Marketing Authorisation Application for FAMPYRA

May 20, 2011

ZUG, Switzerland--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) announced today that FAMPYRA® (prolonged-release fampridine tablets) has been granted a positive opinion for conditional approval from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP). Based on the CHMP recommendation, Biogen Idec expects that a marketing authorisation for FAMPYRA should be granted within 67 days.

"We are very pleased by the CHMP decision. Walking disability is a common symptom in multiple sclerosis patients and we are excited to offer an oral therapy in Europe to address this high unmet medical need," said Dr. Norman Putzki, Director of Development at Biogen Idec. "FAMPYRA will offer patients, regardless of their type of MS, a novel therapeutic option to improve their walking. A conditional approval will allow us to bring this treatment to patients in European markets this summer."

The CHMP recommended the conditional marketing authorisation of FAMPYRA to improve walking ability in adult patients with multiple sclerosis (MS) who have walking disabilities (Expanded Disability Status Scale of 4 to 7). FAMPYRA demonstrated efficacy in people with all types of MS, both relapsing remitting and progressive forms. FAMPYRA can be used alone or with existing MS therapies, including immunomodulatory drugs.

"Walking impairment is a primary concern for patients with MS," said Prof. Dr. Bernd C. Kieseier, Neurological Hospital, Dusseldorf University in Germany. "FAMPYRA will enhance the ability to improve patient's walking and subsequently be expected to help in their daily life activities."

In the two Phase III clinical trials, a significantly greater portion ($p<0.001$) of FAMPYRA 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 in the FAMPYRA group was observed across all types of MS included in the studies.

FAMPYRA treated patients 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 placebo group.

In the two studies, 31.7 percent and 34.5 percent of FAMPYRA treated patients showed 20 percent improvement compared to 11.1 percent and 15.3 percent, respectively, for the 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.

Patients confirmed the clinical meaningfulness of improved walking using the 12-item Multiple Sclerosis Walking Scale (MSWS-12), a patient-based assessment that measures the impact of walking impairment on the patient's ability to perform everyday activities.

Fampridine was developed by Acorda Therapeutics, Inc., which markets the drug in the United States under the trade name AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg. As of December 31, 2010, approximately 40,000 people with MS had filled a prescription for prolonged-release fampridine tablets in the United States. Biogen Idec plans to commercialize and further develop the product outside of the U.S. under a licensing agreement with Acorda.

"Thousands of patients in the United States have experienced improvement in their walking since initiating therapy with this medication, and we are pleased that the CHMP decision is expected to soon make FAMPYRA available to patients in Europe, as well," said Dr. Andrew R. Blight, Chief Scientific Officer of Acorda Therapeutics, Inc. "We are also pleased with the high caliber of the collaboration between Acorda and Biogen Idec, which has expanded the number of people with MS who may benefit from this important medication."

Last week, FAMPYRA was also approved in Australia for the improvement in walking ability in adult patients with MS.

About Conditional Marketing Authorisation

A conditional marketing authorisation is granted to a medicinal product with a positive benefit/risk assessment that fulfills an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorisation is renewable annually. As part of the conditions of the conditional marketing authorisation for FAMPYRA, the CHMP is recommending Biogen Idec to carry out a further study to find out more about the medicine's benefits and safety in the long term. In particular, the study will provide information on the medicine's benefits beyond its effects on walking speed. These requirements are consistent with already planned post-approval development activities.

About FAMPYRA

FAMPYRA is a prolonged-release (sustained release) tablet formulation of the drug fampridine (4-aminopyridine, 4-AP or dalfampridine). FAMPYRA has been developed to improve walking in adult patients with MS. In MS, damaged myelin exposes channels in the membrane of axons allowing potassium ions to leak, weakening the electrical current sent through nerves. Studies have shown that fampridine can increase conduction along damaged nerves, which may result in improved walking ability. This prolonged-release formulation was developed and is being commercialised in the U.S. by Acorda Therapeutics, Inc. under the trade name AMPYRA (dalfampridine) Extended Release Tablets, 10 mg. Biogen Idec plans to commercialize and further develop the product outside of the U.S. under a licensing agreement with Acorda.

FAMPYRA was developed using Elan's Matrix Drug Absorption System (MXDAS ™) technology and is manufactured by Elan.

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

Safe Harbor

This press release includes forward-looking statements, including statements about the development and commercialization of FAMPYRA®. 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 meeting endpoints in clinical trials, obtaining regulatory approval, the occurrence of adverse safety events, product competition, the availability of reimbursement for our products, adverse market and economic conditions, problems with our manufacturing processes and our reliance on third parties, failure to comply with government regulation and possible adverse impact of changes in such regulation, our ability to protect our intellectual property rights and the cost of doing so, and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the SEC. These statements are based on our current beliefs and expectations and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

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