



Biogen Idec Receives Negative Opinion from the CHMP on FAMPYRA

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The Company intends to appeal the negative CHMP opinion

ZUG, Switzerland--(BUSINESS WIRE)--[Biogen Idec](#) (NASDAQ: BIIB) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a negative opinion recommending against approval of FAMPYRA[®] (prolonged-release fampridine 10 mg tablets) to improve walking ability in adult patients with multiple sclerosis (MS) in the European Union. Biogen Idec intends to appeal this opinion and request a re-examination of the decision by the CHMP.

"About two-thirds of MS patients report difficulty in walking due to their disease^{1,2}, and currently there is no therapy approved in Europe to address this high unmet medical need," said Alfred Sandrock, M.D., Ph.D., Head of Neurology Research & Development at Biogen Idec. "Tens of thousands of people with MS have already received the therapy in the United States, where it is approved, and many have reported important benefits. We will work closely with the CHMP during the appeal process to address the Committee's concerns, with the goal of making this important medication available to MS patients in Europe."

As a leader in MS with two MS medications on the market and six potential MS therapies in the pipeline, Biogen Idec has significant scientific expertise in MS and is committed to improving the lives of patients living with this disease.

As of the end of September 2010, approximately 6300 prescribers had initiated approximately 31,000 MS patients on prolonged-release fampridine tablets treatment in the United States (U.S.), where the drug is commercialized by its developer, Acorda Therapeutics, Inc., under the trade name AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg. AMPYRA was approved by the U.S. Food and Drug Administration on January 22, 2010.

For further details about the CHMP opinion on FAMPYRA, please visit the EMA website www.ema.europa.eu/ema.

About FAMPYRA

FAMPYRA 10 mg tablets is a prolonged-release (sustained release) tablet formulation of the drug fampridine (4-aminopyridine or 4-AP). FAMPYRA has been developed to improve walking in adult patients with multiple sclerosis (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 FAMPYRA can increase conduction along damaged nerves, which may result in improved walking ability. This prolonged-release formulation was developed and is being commercialized in the U.S. by Acorda Therapeutics, Inc. It has been approved in the U.S. 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.

In two Phase III clinical trials, a significantly greater portion ($p < 0.001$) of patients treated with FAMPYRA 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.

The 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 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.

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.

About Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market biological products for the treatment of serious diseases with a focus on neurological disorders. 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 interactions with regulatory agencies, the anticipated development and timing of programs in our clinical pipeline, and new commercial launches. 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 our dependence on our three principal products, [AVONEX](#)[®], [RITUXAN](#)[®] and [TYSABRI](#)[®], the importance of TYSABRI's sales growth, product competition, uncertainty of success in commercializing other products, the occurrence of adverse safety events with our products, changes in the availability of reimbursement for our products, market and economic conditions, our dependence on collaborations over which we may not always have full control, failure to execute our growth initiatives, failure to comply with government regulation and possible adverse impact of changes in such regulation, charges and other costs relating to our properties, problems with our manufacturing processes and our reliance on third parties, fluctuations in our effective tax rate, our ability to attract and retain qualified personnel, the risks of doing business internationally, our ability to protect

our intellectual property rights and the cost of doing so, representation of activist shareholders on our board of directors, product liability claims, fluctuations in our operating results, the market, interest and credit risks associated with our portfolio of marketable securities, our level of indebtedness, environmental risks, aspects of our corporate governance, and collaborations 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.

¹ Harris Interactive. Experiences with Multiple Sclerosis (MS): Perspectives of People with MS and MS Care Partners (poll). March 25, 2008

² Scheinberg L. et al. NY State J Med 1980; 80: 1395 -1400

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