Biogen Idec Receives Conditional Approval in the European Union for FAMPYRA® to Improve Walking in Adults with Multiple Sclerosis

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--Novel oral therapy provides clinically meaningful improvement in walking--

ZUG, Switzerland--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) announced today it has received conditional approval from the European Commission for FAMPYRA® (prolonged-release fampridine tablets) to improve walking in adult patients with multiple sclerosis (MS) who have walking disability (Expanded Disability Status Scale 4-7).

FAMPYRA is the first treatment that addresses this unmet medical need with demonstrated efficacy in people with all types of MS.[1] FAMPYRA can be used alone or in combination with disease modifying therapies, including immunomodulatory drugs.

“With its approval by the European Commission, FAMPYRA has the potential to make a real difference for thousands of people across Europe with both relapsing remitting and progressive forms of MS,” explained Prof. Dr. Bernd C. Kieseier, Department of Neurology, University Hospital Duesseldorf. “Functional impairment in MS presents many challenges for patients and walking impairment is one of the most physically and emotionally disruptive aspects. Until now, no approved treatment has existed to address this issue and FAMPYRA should provide patients and clinicians with a welcome new option.”

People with MS consistently rate walking as the most important function throughout the course of their condition[2]. Walking impairment is directly associated with loss of independence, restrictions on a patient’s ability to work and a reduction in overall levels of household income [3,4].

“Walking disability is one of the most devastating consequences of MS and one of the symptoms MS patients are most concerned about. It can significantly impact quality of life as well as social participation,” explained Douglas E. Williams, Ph.D., Executive Vice President, Research and Development at Biogen Idec. “Patients worldwide are benefitting from Biogen Idec’s therapies, and FAMPYRA is the third product Biogen Idec is bringing to the MS community in Europe. We are excited to offer patients this novel oral therapy that has been shown to improve walking ability.”

FAMPYRA was developed and is being commercialized in the United States by Acorda Therapeutics, Inc. (NASDAQ: ACOR) under the trade name AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg. Biogen Idec licensed the rights from Acorda to develop and commercialize fampridine in all markets outside the United States.

“Studies have shown that even small degrees of walking impairment can have a major negative impact on the patient. The European approval of FAMPYRA allows people with MS in the European Union to have access to a novel therapy that has been shown to improve walking ability across a wide range of impairment, from mild to severe,” said Ron Cohen, M.D., Acorda’s President and CEO. “Since its launch in the United States in 2010, this medication has been prescribed for tens of thousands of people with MS. We will continue to work with our partner Biogen Idec to make it available in other markets around the world.”

FAMPYRA enhances neurologic function by improving impulse conduction across demyelinated neurons. In clinical trials, patients responding to FAMPYRA had an average increase in walking speed of 25 percent [1,5,6] and FAMPRYA was shown to provide a clinically meaningful improvement in walking.[5,6,7]

FAMPYRA will be available in Europe, on a country-by-country basis, beginning with Germany in September 2011, with other countries following.

About Conditional Marketing Authorization

A conditional marketing authorization 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 authorization is renewable annually. As part of the conditions of the conditional marketing authorization for FAMPYRA, the Committee is recommending that Biogen Idec 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 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 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. (NASDAQ: ACOR) under the trade name AMPYRA (dalfampridine) Extended Release Tablets, 10 mg. Biogen Idec licensed rights from Acorda to develop and commercialize fampridine in all markets outside the United States.

The highest incidence of adverse reactions identified from placebo-controlled trials in MS patients with FAMPYRA, given at the recommended dose, are reported as urinary tract infections (in approximately 12% of patients), although infection was often not proven by culture. Adverse drug reactions identified are mostly neurological and include seizure, insomnia, anxiety, balance disorder, dizziness, paraesthesia, tremor, headache and asthenia. This is consistent with fampridine’s pharmacological activity. FAMPYRA® was developed using Elan's Matrix Drug Absorption System (MXDAS™) technology and is manufactured by Elan.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, unpredictable and progressive disease of the central nervous system (CNS) that causes inflammation and destruction of the myelin sheath – the protective layer that surrounds the body's nerve fibers. This destruction may result in cognitive impairment, physical disability and fatigue. According to the National MS Society, MS affects about 400,000 people in the U.S. and more than 2.5 million people worldwide.

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 the occurrence of adverse safety events, the availability of reimbursement for our products, 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.

References:

1. FAMPYRA Summary of Product Characteristics July 2011.
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