Biogen Idec Receives Approval for FAMPYRA in Australia to Improve Walking Ability in Adult Patients with MS

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ZUG, Switzerland--(BUSINESS WIRE)--The Australian Therapeutic Goods Administration (TGA) has granted approval for FAMPYRA ™, (fampridine) 10 mg Modified Release (MR) tablet, for the symptomatic improvement of walking ability in adult patients with multiple sclerosis (MS) who have shown improvement after eight weeks of treatment. FAMPYRA demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). FAMPYRA can be used alone or with existing MS therapies, including immunomodulator drugs.

Biogen Idec (Nasdaq: BIIB) is presently taking steps to obtain Pharmaceutical Benefit Scheme (PBS) reimbursement approval for FAMPYRA, an outcome which will benefit the MS community in Australia. While Biogen Idec follows this reimbursement procedure, FAMPYRA is expected to be available to patients with a private prescription beginning in October 2011.

“We are very pleased with the TGA's decision to approve FAMPYRA in Australia for people with MS. Studies have shown FAMPYRA can increase walking speed by 25%, independent of the type of MS, and that this increase is associated with clinically meaningful improvements in overall walking ability” said Norman Putzki, Director Development at Biogen Idec.

FAMPYRA is an oral potassium channel blocker which is thought to work by stopping potassium leaving the nerve cells which have been damaged by MS. This enables signals to pass down the nerve more regularly, which may allow patients to walk better.

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.

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 placebo-treated patients.

The majority of the study participants in these trials were also taking 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 questionnaire measuring the impact of walking impairment on a patient’s ability to perform everyday activities.

Important Safety Information

The use of FAMPYRA is contraindicated in patients: with hypersensitivity to fampridine or the tablet ingredients; with moderate or severe renal impairment; with a history of seizure or medically assessed as at high risk of seizure, and currently on treatment with other forms of fampridine / 4-aminopyridine.

FAMPYRA should not be administered at doses higher than the recommended dose of 10 mg, twice daily, 12 hours apart.

Renal Impairment: FAMPYRA should be used with caution, and monitoring of renal function considered in patients with mild renal impairment. Particular caution is required when FAMPYRA is prescribed concurrently with drugs or medicinal products that can significantly impact renal function

Seizures: FAMPYRA can cause seizures. The risk of seizures increases with increasing FAMPYRA doses. Discontinue FAMPYRA use if seizure occurs.

The most common adverse events (*incidence ≥ 2% and at a rate greater than the placebo rate*) for FAMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.

There are no adequate and well-controlled studies of FAMPYRA in pregnant women. FAMPYRA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

About FAMPYRA

FAMPYRA is a modified-release (prolonged-release) tablet formulation of the drug fampridine (4-aminopyridine, 4-AP or dalfampridine).

FAMPYRA is an oral potassium channel blocker which is thought to work by stopping potassium leaving the nerve cells which have been damaged by MS. This enables signals to pass down the nerve more normally, which may allow patients to walk better.

This prolonged-release formulation was developed and is being commercialized 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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