Biogen's FAMPYRA® Granted Standard Marketing Authorization in European Union for Improvement of Walking in People with MS

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New Phase 3 Data Confirm Positive and Significant Effects in Walking Improvement and Enhanced Quality of Life

ZUG, Switzerland--(BUSINESS WIRE)--The European Commission (EC) has granted a standard marketing authorization for FAMPYRA (prolonged-release fampridine tablets) for walking improvement in people with multiple sclerosis (MS), Biogen (NASDAQ: BIIB) announced today. The approval is based on the results of the Phase 3 ENHANCE study, which confirm the clinically meaningful benefits and safety of FAMPYRA over the long term in people with both relapsing and progressive forms of MS. The ENHANCE study was conducted following the EC's conditional marketing authorization for FAMPYRA in 2011. FAMPYRA can be used alone or with existing MS therapies, including immunomodulatory drugs.

"Approximately 80 percent of people with MS experience walking impairment, one of the most common issues with the disease. We frequently hear from people living with MS that these walking challenges affect their independence, restrict their ability to work and negatively impact their overall quality of life," said Jeremy Hobart, Ph.D., consultant neurologist at Plymouth Hospitals NHS Trust and professor of Clinical Neurology and Health Measurement at the Plymouth University Peninsula Schools of Medicine and Dentistry. "Results from the ENHANCE study provided additional evidence that FAMPYRA is an effective treatment for MS and echo what I and other clinicians have observed in treating people with MS: FAMPYRA provides a clinically significant improvement in walking ability as well as on broader aspects of quality of life."

ENHANCE Results Reaffirm Clinically Meaningful Benefits of FAMPYRA
Biogen initiated ENHANCE, the third Phase 3 study for FAMPYRA, to evaluate the long-term safety and efficacy of the therapy in walking improvement in people with MS who have walking disabilities (as measured by Expanded Disability Status Scores [EDSS] of 4.0 – 7.0). ENHANCE, the largest and longest randomized trial of FAMPYRA, included patients with primary-progressive, secondary-progressive, progressive-relapsing and relapsing-remitting MS. Results, first reported in 2016, show that over 24 weeks:

- Significantly more FAMPYRA patients achieved a clinically meaningful improvement in walking ability compared to patients taking placebo (43.2% vs. 33.6%, respectively; p=0.006), as measured by the self-reported 12-Item MS Walking Scale (MSWS-12), the primary endpoint.
- Significantly more FAMPYRA patients experienced improved mobility compared to those taking placebo, as measured by a mean improvement in the clinician-reported timed up and go (TUG) speed from baseline (43.4% vs. 34.7%, respectively; p=0.03).
- FAMPYRA patients demonstrated greater improvements in the Multiple Sclerosis Impact Scale-29 (MSIS-29) physical score, a self-reported measure of the physical impact of MS, than those treated with placebo (-8.00 vs. -4.68, respectively; p<0.001).
- The positive effects of FAMPYRA on improving balance and upper limb dexterity compared to placebo were also observed; however, these results were not statistically significant.
- The benefit-risk profile of FAMPYRA remains positive.

"FAMPYRA is a valued medication among MS patients and physicians that addresses one of the most prevalent and disruptive symptoms of the disease. For the past several years, Biogen has been focused on ensuring that FAMPYRA is available to MS patients in Europe who experience walking disability," said Ferenc Tracik, M.D., vice president, EU+ Medical Affairs. "The approval of the standard marketing authorization for FAMPYRA is validation of the substantial difference this therapy has made on the lives of people with MS, and speaks to our deep, long-standing commitment to the MS community."

About FAMPYRA ®
FAMPYRA® (prolonged-release fampridine tablets) is a treatment indicated to improve walking in adult patients with MS. Biogen has a license from Acorda Therapeutics, Inc. to develop and commercialise FAMPYRA in all markets outside the United States.

FAMPYRA is the first treatment to both address the unmet medical need of walking improvement in adults living with MS, and demonstrate clinical efficacy in adults with MS. FAMPYRA can be used alone or in combination with disease modifying therapies, including immunomodulatory drugs. In clinical trials, patients responding to FAMPYRA had an average increase in walking speed of 25 percent and FAMPYRA was shown to provide a clinically meaningful improvement in walking.

The highest incidence of adverse reactions identified from placebo-controlled trials in MS patients with FAMPYRA, given at the recommended dose, was urinary tract infection (in approximately 12% of patients), although infection was often not proven by culture. Adverse drug reactions identified were mainly divided between neurological disorders (such as insomnia, balance disorder, dizziness, paraesthesia, headache, anxiety and tremor) and gastrointestinal disorders (including nausea, vomiting, dyspepsia and constipation). Other common adverse drug reactions reported were asthenia, back pain, pharyngolaryngeal pain and dyspnea. In post-marketing experience, there have been reports of seizures, hypersensitivity reactions (including anaphylaxis) and exacerbations of trigeminal neuralgia (TN) in patients with a history of TN. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

For further information on FAMPYRA in your country please click here.

U.S. residents: For information, please visit Acorda Therapeutics.

About Biogen
Through cutting-edge science and medicine, Biogen discovers, develops and delivers innovative therapies worldwide for people living with serious neurological and neurodegenerative diseases. Founded in 1978, Biogen is a pioneer in biotechnology and today the Company has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first and only approved treatment for spinal muscular atrophy, and is at the forefront of neurology research for conditions including Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis. Biogen also manufactures and commercializes biosimilars of advanced biologics. For more information, please visit www.biogen.com. Follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Safe Harbor
This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements relating to the potential benefits, safety and efficacy of FAMPYRA and the results of certain real-world data. These forward-looking statements may be accompanied by words such as "anticipate," "believe," "could," "estimate," "except," "forecast," "intend," "may," "plan," "potential," "possible," "will" and other words and terms of similar meaning. You should not place undue reliance on these statements or the scientific data presented. Drug development and commercialization involve a high degree of risk. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation: unexpected concerns that may arise from additional data or analysis; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of Biogen's drug candidates or expansion of product labeling; or Biogen may encounter other unexpected hurdles which may be impacted by, among other things, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect intellectual property and other proprietary rights, product liability claims or third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. 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, whether as a result of new information, future developments or otherwise.

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