Biogen's Investigational Tau-Targeting Therapy BIIB080 Receives FDA Fast Track Designation for the Treatment of Alzheimer's Disease

April 2, 2025

CAMBRIDGE, Mass., April 02, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to BIIB080, an investigational antisense oligonucleotide (ASO) therapy targeting tau, for the treatment of Alzheimer's disease. Fast Track designation is intended to facilitate the development and expedite the review of investigational drugs that treat serious conditions and address unmet medical needs.

"We are encouraged by the FDA's Fast Track designation for BIIB080, which highlights the urgent need for innovative treatments targeting tau pathology in Alzheimer's disease," said Priya Singhal, M.D., M.P.H., Head of Development at Biogen. "Alzheimer's is a complex and fatal disease that we believe will require multiple therapeutic approaches to address its diverse pathologies. BIIB080, an investigational antisense therapy, is a differentiated approach to targeting tau, with promising potential for patients. We are advancing this program with urgency on behalf of people living with Alzheimer's and their families."

BIIB080 is the first tau-targeting ASO to enter clinical development for Alzheimer's disease and is currently being evaluated in the global Phase 2 CELIA study in individuals with early-stage disease. As previously announced, results from the Phase 1b study showed dose-dependent reductions in soluble tau protein in cerebrospinal fluid (CSF), decreases in aggregated tau pathology in the brain as measured by positron emission tomography (PET), and favorable trends in exploratory clinical outcomes, supporting the potential for clinical benefit. In the high-dose groups, favorable trends were observed across multiple exploratory measures of cognition and function. The Phase 2 CELIA study is now fully enrolled, with a data readout expected in 2026.

About BIIB080
BIIB080 is an investigational antisense oligonucleotide (ASO) therapy designed to target microtubule-associated protein tau (MAPT) mRNA to reduce the production of tau protein. Abnormal accumulation of tau in the brain is a hallmark of Alzheimer's disease and is associated with neurodegeneration and cognitive decline. BIIB080 is currently being evaluated in a Phase 2 clinical study (NCT05399888) in individuals with early Alzheimer's disease.

In December 2019, Biogen exercised a license option with Ionis Pharmaceuticals and obtained a worldwide, exclusive, royalty-bearing license to develop and commercialize BIIB080 (tau ASO).

About Biogen
Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements, including about the potential clinical effects of BIIB080; the potential benefits, safety and efficacy of BIIB080; potential regulatory discussions, submissions and approvals and the timing thereof; the treatment of Alzheimer's disease; the potential of Biogen's commercial business and pipeline programs, including BIIB080; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "estimate," "expect," "forecast," "goal," "guidance," "hope," "intend," "may," "objective," "plan," "possible," "potential," "predict," "project," "prospect," "should," "target," "will," "would," and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements. Given their forward-looking nature, these statements involve substantial risks and uncertainties that may be based on inaccurate assumptions and could cause actual results to differ materially from those reflected in such statements. These forward-looking statements are based on management's current beliefs and assumptions and on information currently available to management. Given their nature, we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part. We caution that these statements are subject to risks and uncertainties, many of which are outside of our control and could cause future events or results to be materially different from those stated or implied in this document, including, among others, uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans and prospects relating to product approvals, approvals of additional indications for our existing products, sales, pricing, growth, reimbursement and launch of our marketed and pipeline products; our ability to effectively implement our corporate strategy; the successful execution of our strategic and growth initiatives, including acquisitions; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements speak only as of the date of this press release and are based on information and estimates available to us at this time. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and in our subsequent reports on Form 10-Q and Form 10-K, in each case including in the sections thereof captioned "Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in our subsequent reports on Form 8-K. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements whether as a result of any new information, future events, changed circumstances or

otherwise.

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