Biogen to Realign Resources for Alzheimer's Disease Franchise

January 31, 2024

- Company to reprioritize resources allocated to ADUHELM® (aducanumab-avwa) to advance LEQEMBI® (lecanemab-irmb) and to develop new treatment modalities
- Biogen committed to building a leading Alzheimer's disease franchise to address patient needs

CAMBRIDGE, Mass., Jan. 31, 2024 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced plans to reprioritize its resources in Alzheimer's disease (AD), a strategic therapeutic area expected to drive near and long-term growth. The company will continue to advance LEQEMBI® (lecanemab-irmb), the first anti-amyloid beta treatment with FDA traditional approval in the United States, and will accelerate development of potential new treatment modalities, including its ASO targeting tau (BIIB080) and an oral small molecule inhibitor of tau aggregation (BIIB113). The company will discontinue the development and commercialization of ADUHELM® (aducanumab-avwa) 100 mg/mL injection for intravenous use and will terminate the ENVISION clinical study. This decision is not related to any safety or efficacy concerns. A large portion of the resources released resulting from termination of the ADUHELM program will be redeployed in Biogen's AD franchise.

"As a pioneer in Alzheimer's disease, Biogen is reprioritizing resources to build a leading franchise to address the multiple pathologies of the disease and patient needs. We plan to further advance the launch of LEQEMBI, together with Eisai, and continue to bolster innovation with the development of the other assets in our pipeline," said Christopher A. Viehbacher, President and Chief Executive Officer of Biogen. "When searching for new medicines, one breakthrough can be the foundation that triggers future medicines to be developed. ADUHELM was that groundbreaking discovery that paved the way for a new class of drugs and reinvigorated investments in the field."

In January 2023, Biogen began a strategic review of its research and development efforts, including seeking potential partners or external financing for ADUHELM, as part of a focus on prioritizing the company's portfolio. During this process, Biogen considered the time and investment required for the post-marketing confirmatory ENVISION study and the likely advancements in the field by the time of potential ADUHELM FDA traditional approval. Despite an extensive process, the company did not identify potential strategic partners or external financing.

Biogen has recorded a one-time charge of approximately $60 million related to close out costs for the program in the fourth quarter of 2023. Biogen licensed aducanumab from Neurimmune and has terminated that license. The rights to aducanumab will revert to Neurimmune.

"We have gained significant insight from the development of ADUHELM and will carry this forward as we continue our pioneering work in Alzheimer's disease," said Priya Singhal, M.D., M.P.H., Head of Development at Biogen. "We'd like to sincerely thank the trial investigators, healthcare providers, advocates, patients and families involved in the development of ADUHELM. We are grateful to Neurimmune for its scientific contributions and collaboration over many years."

ADUHELM received accelerated approval from the U.S. Food and Drug Administration in June 2021. The Phase 4 post-marketing confirmatory ENVISION study was a requirement of FDA accelerated approval of ADUHELM.

Eisai serves as the lead of LEQEMBI development and regulatory submissions globally with both Eisai and Biogen commercializing and co-promoting the product and Eisai having final decision-making authority.

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About Biogen
Founded in 1978, Biogen is a leading global biotechnology company that has pioneered multiple breakthrough innovations including a broad portfolio of medicines to treat multiple sclerosis, the first approved treatment for spinal muscular atrophy, two co-developed treatments to address a defining pathology of Alzheimer's disease, the first treatment to target a genetic form of ALS, the first oral treatment approved for postpartum depression, and the first approved treatment for Friedreich's ataxia. Biogen is advancing a pipeline of potential novel therapies across neurology, neuropsychiatry, specialized immunology and rare diseases and remains acutely focused on its purpose of serving humanity through science while advancing a healthier, more sustainable and equitable world.

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.

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This news release contains forward-looking statements, about the potential benefits from the discontinuation of development of ADUHELM and the termination of the ENVISION study and the allocation of the resources from the discontinuation of development of ADUHELM and the termination of the ENVISION study into our Alzheimer's franchise; the potential benefits, safety and efficacy of LEQEMBI; the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai; the potential of Biogen's commercial business and pipeline programs, including LEQEMBI, BIIB080 and BIIB113; and risks and uncertainties associated with drug development and commercialization. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "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 studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. 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 without limitation unexpected concerns that may arise from additional data, analysis or results obtained during clinical studies; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including LEQEMBI; actual timing and content of submissions to and decisions made by the regulatory authorities regarding LEQEMBI; uncertainty of success in the development and potential commercialization of LEQEMBI; failure to protect and enforce

Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's 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 speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

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