Biogen Announces Reduced Price for ADUHELM® to Improve Access for Patients with Early Alzheimer's Disease

December 20, 2021

The company to also implement cost-reduction measures.

CAMBRIDGE, Mass., Dec. 20, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that, effective January 1, 2022, it will reduce the wholesale acquisition cost (WAC) of ADUHELM® (aducanumab-avwa) 100 mg/mL injection for intravenous use in the United States by approximately 50%. For a patient of average weight (74 kg), the yearly cost at the maintenance dose (10 mg/kg) will be $28,200.

"Over the past several months, we have listened to the feedback of our stakeholders, and we are now taking important actions to improve patient access to ADUHELM," said Michel Vounatsos, Chief Executive Officer at Biogen. "Too many patients are not being offered the choice of ADUHELM due to financial considerations and are thus progressing beyond the point of benefitting from the first treatment to address an underlying pathology of Alzheimer's disease. We recognize that this challenge must be addressed in a way that is perceived to be sustainable for the U.S. healthcare system."

Biogen is taking this action with the goal of lowering out-of-pocket expenses for patients and reducing the potential financial implications for the U.S. healthcare system. ADUHELM's reduced price takes into consideration the questions raised about this first class of therapies, the potential eligible population and revised pharmaco-economic assumptions. Biogen believes with insurance coverage, and access to diagnostics and specialized centers, approximately 50,000 patients may initiate treatment with ADUHELM in 2022.

Mr. Vounatsos added, "It is a critical time for the Alzheimer's disease community as the Centers for Medicare and Medicaid Services (CMS) is considering the possibility of coverage of not only ADUHELM, but also this entire new class of Alzheimer's disease therapies. We hope our actions today will facilitate patient access to these innovative Alzheimer's treatments."

The reduced price is part of the Company's ongoing commitment to further inform treatment choice. Biogen recently presented new p-tau181 biomarker data at the Clinical Trials on Alzheimer's Disease conference (CTAD) and announced its plan to complete the Phase 4 confirmatory post marketing study of ADUHELM in an accelerated timeline of four years. ADUHELM's accelerated approval by the U.S. Food and Drug Administration has served as a catalyst for significant investment and additional research and innovation for Alzheimer's disease.

Biogen also announced that it will implement a series of cost-reduction measures in 2022 to better align its costs with its revenue base, which is expected to be impacted by the continued entry of generics in multiple sclerosis, as well as the delayed uptake of ADUHELM. The cost-reduction measures are estimated to yield approximately $500 million in annualized savings, a significant portion of which will be realized in 2022. A portion of these savings will be offset by investments in Biogen's pipeline and strategic initiatives. Further details will be finalized in the coming weeks and will be communicated in the first quarter of 2022.

Mr. Vounatsos said, "These are difficult decisions necessary to sustain our mission to develop medicines for the most devastating neurological diseases. We must bring our cost base in-line so we can continue to invest in future innovation and growth, retain and compete for outstanding talent, and provide acceptable returns to our shareholders."

About ADUHELM® (aducanumab-avwa) 100 mg/mL injection for intravenous use
ADUHELM is indicated for the treatment of Alzheimer's disease. Treatment with ADUHELM should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Aducanumab-avwa is a monoclonal antibody directed against amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. The accelerated approval of ADUHELM has been granted based on data from clinical trials showing the effect of ADUHELM on reducing amyloid beta plaques, a surrogate biomarker that is reasonably likely to predict clinical benefit, in this case a reduction in clinical decline.

ADUHELM can cause serious side effects including: Amyloid Related Imaging Abnormalities or "ARIA". ARIA is a common side effect that does not usually cause any symptoms but can be serious. Although most people do not have symptoms, some people may have symptoms such as: headache, confusion, dizziness, vision changes and nausea. The patient's healthcare provider will do magnetic resonance imaging (MRI) scans before and during treatment with ADUHELM to check for ARIA. ADUHELM can also cause serious allergic reactions. The most common side effects of ADUHELM include: swelling in areas of the brain, with or without small spots of bleeding in the brain or on the surface of the brain (ARIA); headache; and fall. Patients should call their healthcare provider for medical advice about side effects.

As of October 2017, Biogen and Eisai Co., Ltd. are collaborating on the global co-development and co-promotion of aducanumab.

Please click here for full Prescribing Information, including Medication Guide, for ADUHELM.

Cost, Coverage and Co-Pay Assistance
The WAC of ADUHELM, which is an infusion once every four weeks, will be $2,171.40 per infusion for a patient of 74 kg – the average weight of a U.S. patient with mild cognitive impairment (MCI) or mild dementia. A 170 mg vial will be $479.40 and a 300 mg vial will be $846.00. The yearly cost at the maintenance dose (10 mg/kg) would be $28,200. The cost during the first year of treatment will be $20,500 due to the titration period. WAC is a list price and not the net price or the price paid by patients with insurance. The out-of-pocket cost for patients with insurance will vary depending on their coverage.

For patients facing difficulty affording ADUHELM, financial assistance programs are available. For more information, please contact Biogen Support Services at 1-833-425-9360.

About Alzheimer's Disease
Currently, Alzheimer's disease represents a significant economic burden for patients, caregivers, and society, with more than 11 million Americans providing an estimated 15.3 billion hours[1] of unpaid care in 2020. The annual cost of care for Alzheimer's disease and other dementias in the U.S. is over $600 billion[1] and lifetime care for someone with Alzheimer's disease is estimated to cost approximately $500,000 per patient [2], which is primarily borne by patients' families as an out-of-pocket expense. It is important to note that in the U.S., nursing home costs per patient are approximately $100,000[1] per year.

About Biogen
As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing the industry's most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, $250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

The company routinely posts information that may be important to investors on its website at www.biogen.com. To learn more, please visit www.biogen.com and follow Biogen on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the potential clinical effects of ADUHELM; the potential benefits, safety and efficacy of ADUHELM; the treatment of Alzheimer's disease; the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai; clinical development programs, clinical trials and data readouts and presentations; 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 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 or the scientific data presented.

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 trials; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; risks associated with current and potential future healthcare reforms; 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 are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

References:

1. Alzheimer's Association. 2021 Alzheimer's disease facts and figures.
2. Jutkowitz E, Kane RL, Gaugler JE, MacLehose RF, Dowd B, Kuntz KM. Societal and family lifetime cost of dementia: implications for policy. J Am Geriatr Soc. 2017.

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