Biogen Announces Peer-Reviewed Publication of ADUHELM® Phase 3 EMERGE and ENGAGE Data in The Journal of Prevention of Alzheimer's Disease

March 16, 2022

CAMBRIDGE, Mass., March 16, 2022 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced that *The Journal of Prevention of Alzheimer's Disease (JPAD)* today published a peer-reviewed manuscript detailing data from the pivotal Phase 3 EMERGE and ENGAGE trials for ADUHELM® (aducanumab-avwa) 100 mg/mL injection for intravenous use in early Alzheimer's disease. The publication includes results from the primary, secondary and tertiary endpoints in the trials, as well as safety data and biomarker sub-studies.

In June 2021, the U.S. Food and Drug Administration (FDA) granted accelerated approval for ADUHELM as the first Alzheimer's disease treatment to address a defining pathology of the disease. 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).

"We are pleased that the peer-reviewed manuscript is now available to provide physicians with a greater understanding of the appropriate use of ADUHELM," said Samantha Budd Haeberlein, Ph.D., SVP, Head of Neurodegeneration Development at Biogen. "We will continue to provide physicians with efficacy and safety data to help them make the best treatment decisions for patients as we learn from our ongoing trials and real-world evidence."

"The peer reviewed publication of these data is a testament to the importance of the findings for the scientific and Alzheimer's disease communities," said Dr. Paul Aisen, MD., Alzheimer Therapeutic Research Institute, University of Southern California, San Diego. "Alzheimer's disease is an incredibly complex condition, and this dataset is critical to advancing the understanding of the Phase 3 results."

The publication may be accessed here.

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).

ADUHELM 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.

From 2017 to March 13, 2022, Biogen and Eisai jointly collaborated on the development, commercialization and manufacturing of ADUHELM. Effective March 14, 2022, Biogen has sole decision-making authority over the development, commercialization and manufacturing of ADUHELM. In 2022 the parties will continue in a global profit/loss sharing arrangement subject to a cap on Eisai's expenses for 2022. Eisai will be entitled to a tiered royalty on net sales of ADUHELM as of January 1, 2023.

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

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 a 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.

MEDIA CONTACT(S):
Biogen
Ashleigh Koss
+ 1 908 205 2572
public.affairs@biogen.com

INVESTOR CONTACT(S):
Biogen
Mike Hencke
+1 781 464 2442
IR@biogen.com