FDA Approves Updated ADUHELM™ Prescribing Information to Emphasize Population Studied in Clinical Trials

July 8, 2021

ADUHELM should be initiated in patients with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia

CAMBRIDGE, Mass. and TOKYO, July 08, 2021 (GLOBE NEWSWIRE) -- Biogen (Nasdaq: BIIB) and Eisai Co., Ltd. (Tokyo, Japan) today announced the U.S. Food and Drug Administration (FDA) has approved an updated label for ADUHELM™ (aducanumab-avwa) injection 100 mg/mL solution.

The update includes an addition to the Indications and Usage section of the label (Section 1) to emphasize the disease stages studied in the clinical trials, as seen below (*italics* to note updated language).

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).

Alfred Sandrock, Jr., M.D., Ph.D., Head of Research and Development at Biogen, said, "Based on our ongoing conversations with prescribing physicians, FDA and patient advocates, we submitted this label update with the goal to further clarify the patient population that was studied across the three ADUHELM clinical trials that supported approval. We are committed to continue to listen to the community's needs as clinical practice adapts to this important, first-in-class treatment option."

The update clarifies the indication by emphasizing information about the disease stages studied in the ADUHELM clinical trials. Information about the population studied has been previously communicated by Biogen and Eisai, including in the companies' statement of June 23, 2021.

Please see the full **Prescribing Information**.

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

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).

IMPORTANT SAFETY INFORMATION

What is the most important information a patient should know about ADUHELM?

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.** It is most commonly seen as temporary swelling in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain with the swelling. Although most people with swelling in areas of the brain 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. **Patients should call their healthcare provider or go to the nearest hospital emergency room right away if they have any of the symptoms listed above.**

Before receiving ADUHELM, patients should tell their healthcare provider about all of their medical conditions, including if: they are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed. It is not known if ADUHELM will harm their unborn baby or if aducanumab-avwa (the active ingredient in ADUHELM) passes into breast milk.

What are the possible side effects of ADUHELM? ADUHELM can cause serious side effects, including: See above "What is the most important information a patient should know about ADUHELM?"

Serious allergic reactions. Swelling of the face, lips, mouth, or tongue and hives have happened during an ADUHELM infusion. Patients should tell their healthcare provider if they have any of the symptoms of a serious allergic reaction during or after an ADUHELM infusion.

The most common side effects of ADUHELM include: swelling in areas of the brain, with or without small spots of bleeding in or on the surface of the brain (ARIA); headache and fall. Patients should call their healthcare provider for medical advice about side effects. Patients may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information including Medication Guide.

About Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative 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, 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, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and

neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

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

About Eisai Co., Ltd.

Eisai Co., Ltd. is a leading global pharmaceutical company headquartered in Japan. Eisai's corporate philosophy is based on the *human health care (hhc)* concept, which is to give first thought to patients and their families, and to increase the benefits that health care provides to them. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our hhc philosophy by delivering innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

Leveraging the experience gained from the development and marketing of a treatment for Alzheimer's disease, Eisai aims to establish the "Eisai Dementia Platform." Through this platform, Eisai plans to deliver novel benefits to those living with dementia and their families through constructing a "Dementia Ecosystem," by collaborating with partners such as medical organizations, diagnostic development companies, research organizations, and bio-ventures in addition to private insurance agencies, finance industries, fitness clubs, automobile makers, retailers, and care facilities. For more information about Eisai Co., Ltd., please visit https://www.eisai.com.

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 Biogen's strategy and plans; potential of, and expectations for, Biogen's commercial business and pipeline programs, including ADUHELM; planning and timing for the commercial launch of, and access to, ADUHELM; 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 uncertainty of success in the development and commercialization of ADUHELM; risks relating to the launch of ADUHELM, including preparedness of healthcare providers to treat patients, the ability to obtain and maintain adequate reimbursement for ADUHELM and other unexpected difficulties or 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 ADUHELM; 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.

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