Biogen and Eisai launch multiple initiatives to help patients with Alzheimer's disease access ADUHELM™

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Programs now available to support patients and families with their treatment journey

Collaborations with Veterans Health Administration, CVS Health and NAFC focused on health disparities in underserved communities

Value-based agreements in progress with Cigna and other payers

CAMBRIDGE, Mass. and WOODCLIFF LAKE, N.J., June 07, 2021 (GLOBE NEWSWIRE) -- Following today's U.S. Food and Drug Administration's (FDA) accelerated approval of ADUHELM™ (aducanumab-avwa) as the first and only Alzheimer's disease treatment to address a defining pathology of the disease by reducing amyloid beta plaques in the brain, Biogen (Nasdaq: BIIB) and Eisai Inc., U.S. subsidiary of Eisai Co., Ltd., announced a range of programs intended to support access for all qualified patients, including traditionally underserved populations. These initiatives aim to help patients and their families understand the disease, navigate the diagnostic journey, secure culturally competent care and afford treatment.

"We feel a great sense of purpose and responsibility to turn the hope of today's FDA approval of ADUHELM into a reality for people living with Alzheimer's disease and their families," said Alisha Alaimo, President of Biogen U.S. "We are committed to access and health equity as top priorities and will continue working with multiple stakeholders with the goal of helping patients who may benefit from treatment obtain care as quickly as possible."

"ADUHELM is the first new treatment for Alzheimer's disease to be approved in the U.S. in nearly 20 years, bringing long-awaited hope for patients and families living with this neurodegenerative disease," said Ivan Cheung, Chairman of Eisai Inc. and President, Neurology Business Group, Eisai Co., Ltd. "It is critically important for Eisai and Biogen to not only establish these access programs but to champion their reach, especially in underserved patient communities."

Patient Services Now Available

Personal Biogen Support Service Coordinators are now available to patients and their families to provide one-on-one support. The service coordinators can answer questions about Alzheimer's disease and ADUHELM treatment, assess financial assistance options for eligible patients, and locate healthcare providers and infusion sites, among other topics. Biogen Support Service Coordinators can be reached at 1-833-425-9360.

Biogen and Eisai have also established a program with Labcorp and Mayo Clinic Laboratories to help physicians and patients access cerebrospinal fluid (CSF) diagnostic laboratory testing to aid in the diagnosis of Alzheimer's disease.

Multiple Collaborations to Address Health Equity

Biogen and Eisai are committed to addressing health equity for underserved and underrepresented populations that are at higher risk for Alzheimer's disease. Black/African Americans and Latinx people are disproportionally more likely to develop Alzheimer's disease as well as more likely to have missed diagnoses compared to non-Hispanic white Americans. The ethnically diverse population of U.S. veterans also faces increased risk for the disease as a result of their service, including conditions such as post-traumatic stress disorder, traumatic brain injury, and other factors.

With the Veterans Health Administration (VHA), Biogen is working to finalize a multi-year agreement in order to support access for veterans throughout the VHA system. The VHA is the largest integrated health system in the U.S., with nine million enrolled veterans, approximately 48 percent of which are over the age of 65.

Biogen has also entered into an initiative with CVS Health focused on the importance of brain health, screening and disease education. As part of this effort, cognitive screenings will be available through CVS Health's Project Health, a longstanding health services program helping address care disparities for uninsured and underinsured Americans, particularly in racially and ethnically diverse communities. Patients or their caregivers will be able to consult with onsite healthcare providers about their personalized screening results. The program is scheduled to begin in September in the following cities: Atlanta, Boston/Providence, Charlotte, Charleston/Columbia, Chicago, Dallas/Fort Worth, Detroit, Houston, Jackson/Memphis, Los Angeles, Miami, New York City, Philadelphia, and Washington DC.

"We all recognize that the optimal delivery of healthcare requires multiple stakeholders working together," said Sree Chaguturu, M.D., Chief Medical Officer, CVS Caremark. "We are committed to addressing systemic health disparities in our country, and this novel initiative is an example of how we can use our enterprise assets and capabilities to make a real difference."

In addition, Biogen is working with The National Association of Free and Charitable Clinics (NAFC), a nationwide network of 1,400 clinics that focuses on ensuring the medically underserved have access to affordable quality healthcare. Together, the organizations intend to develop a program that supports brain health and culturally competent Alzheimer's disease education for patients and healthcare providers within the NAFC member clinic network.

"Brain health is a vital part of overall health and wellbeing, but so many people across the United States don't have the information or access they need to prevent them from falling through the cracks of the healthcare system," said Nicole Lamoureux, President and Chief Executive Officer of the National Association of Free and Charitable Clinics. "As a trusted source for vulnerable communities nationwide, we are proud to work with Biogen to support NAFC's clinics with Alzheimer's disease education and resources."

Cost, Coverage, Co-Pay Assistance and Value-Based Contract with Cigna

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 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 and lifetime care for someone with Alzheimer's disease is estimated to cost approximately $500,000 per patient, which is primarily

borne by patients' families as an out-of-pocket expense.

Biogen has established the price of ADUHELM based on the overall value this treatment is expected to bring to patients, caregivers, and society, while reflecting key principles such as innovation, access and sustainability. The wholesale acquisition cost (WAC) of ADUHELM, which is an infusion once every four weeks, is $4,312 per infusion for a patient of 74 kg–the average weight of a U.S. patient with mild cognitive impairment (MCI) or mild dementia. The yearly cost at the maintenance dose (10 mg/kg) would be $56,000. The cost during the first year of treatment will be lower 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.

Biogen and Eisai are committed to providing access to ADUHELM for patients across a spectrum of financial situations. For qualified, commercially insured ADUHELM patients, co-pay and infusion cost assistance programs may reduce out-of-pocket costs to as low as $0. Patients who are covered by Medicare through a Medicare Advantage plan have a maximum annual out-of-pocket cap. Most traditional fee-for-service Medicare enrollees also have secondary coverage (e.g., Medicaid or a supplemental Medigap plan) that limit out-of-pocket expenses. Medicaid patients have nominal co-pays.

ADUHELM has been studied in patients with early stages of Alzheimer's disease - MCI and mild dementia - with confirmed presence of amyloid pathology. Biogen and Eisai estimate that approximately one to two million people in the U.S. who have been clinically diagnosed with MCI or mild dementia suspected to be due to Alzheimer's disease would have confirmed amyloid beta pathology if tested.

The companies have been working closely with payers to prepare them for the launch of ADUHELM and support patient access. In that regard, Biogen and Cigna Corporation, a global health service company, intend to enter into a value-based contract to ensure that there is a streamlined path to access treatment for patients consistent with the population in which ADUHELM was studied. The parties will also be tracking performance towards certain outcome metrics for patients.

"Alzheimer's disease imposes a tremendous burden on patients, caregivers and society as a whole," said Dr. Steve Miller, Executive Vice President and Chief Clinical Officer at Cigna. "Given the known infrastructure challenges in the U.S., we are working to ensure that the patients who will benefit most from this new treatment have a clear path to access it."

Biogen and Eisai have committed to not increasing the price of ADUHELM for the next four years.

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

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION
ADUHELM is a prescription medicine used to treat people with Alzheimer's disease.

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 ADUHELM (aducanumab-avwa)

ADUHELM (aducanumab-avwa), a human monoclonal antibody, is the first and only Alzheimer's disease treatment to address a defining pathology of the disease by reducing amyloid beta plaques in the brain. ADUHELM is indicated for the treatment of Alzheimer's disease. This indication is granted under accelerated approval based on reduction in amyloid beta plaques in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Biogen licensed ADUHELM from Neurimmune in 2007 under a collaborative development and license agreement. Since October 2017, Biogen and Eisai have collaborated on the development and commercialization of ADUHELM globally.

Full Prescribing Information is available here and at www.ADUHELM.com.

About Alzheimer's Disease

Alzheimer's disease is a progressive neurological condition that impairs thinking, memory and independence, leading to premature death. The disease is a growing global health crisis, affecting those living with the disease and their families. According to the World Health Organization (WHO), more than 30 million people worldwide live with Alzheimer's disease, and the number will grow in the years ahead, outpacing the healthcare resources needed to manage it and costing billions of dollars.

Alzheimer's disease is characterized by changes in the brain, including the abnormal accumulation of toxic amyloid beta plaques, which begins approximately 20 years before patients exhibit symptoms of the disease. Mild cognitive impairment due to Alzheimer's disease is one of the earliest

symptomatic stages of the disease when symptoms start to be more visible and can be detected and diagnosed.

For more information about Alzheimer's disease, visit www.ItsTimeWeKnow.com.

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 Inc.

At Eisai Inc., human health care (hhc) is our goal. We give our first thoughts to patients and their families, and helping to increase the benefits health care provides. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., we have a passionate commitment to patient care that is the driving force behind our efforts to discover and develop innovative therapies to help address unmet medical needs. Eisai is a fully integrated pharmaceutical business that operates in two global business groups: oncology and neurology (dementia-related diseases and neurodegenerative diseases). Our U.S. headquarters, commercial and clinical development organizations are located in New Jersey; our discovery labs are in Massachusetts and Pennsylvania; and our global demand chain organization resides in Maryland and North Carolina. To learn more about Eisai Inc., please visit us at www.eisai.com/US and follow us on Twitter and LinkedIn.

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, the potential clinical effects of ADUHELM; the potential benefits, safety and efficacy of ADUHELM; 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; anticipated manufacturing, distribution, and supply of ADUHELM; the treatment of Alzheimer's disease; the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai; the potential of Biogen's commercial business and pipeline programs, including ADUHELM; 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; unexpected concerns that may arise from additional data or analysis obtained during clinical trials; the occurrence of adverse safety events, restrictions on use, or product liability claims; 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; risks of unexpected costs or delays; the risk of other unexpected hurdles; risks relating to investment in our manufacturing capacity; problems with our manufacturing processes; failure to protect and enforce our data, intellectual property, and other proprietary rights and uncertainties relating to intellectual property claims and challenges; third party collaboration risks; risks associated with current and potential future healthcare reforms; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our 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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