Biogen and Eisai Update for the Alzheimer's Disease Community

June 23, 2021

CAMBRIDGE, Mass. and WOODCLIFF LAKE, N.J., June 23, 2021 – Biogen (Nasdaq: BIIB) and Eisai Inc., U.S. subsidiary of Eisai Co., Ltd. today issued the following statement:

On June 7, 2021, ADUHELM™ (aducanumab-avwa) 100 mg/mL solution for injection was granted accelerated approval by the U.S. Food and Drug Administration (FDA). We are committed to responding to questions from the Alzheimer's disease community and providing more details about our plans.

About ADUHELM treatment and the confirmatory trial

- ADUHELM is indicated for the treatment of Alzheimer's disease. 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).
- 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. ADUHELM can cause serious allergic reactions. The most common side effects include ARIA, headache and fall. Please see Important Safety Information below.
- We are working with urgency and putting resources and plans in place towards the goal of completing the confirmatory trial ahead of the nine-year timeframe, with a focus on high quality data. We are advancing the design of the protocol and plan to engage with regulators, investigators and other stakeholders including CMS (Centers for Medicare and Medicaid Services) as we work to complete the necessary steps and start patient enrollment.

About the Patient Population

- In the United States, physicians can already prescribe the treatment for appropriate patients based on the information included in the product label. It is very important to note that ADUHELM has been studied in patients with early symptomatic stages of Alzheimer's disease (mild cognitive impairment and mild Alzheimer's disease dementia) with confirmed presence of amyloid pathology.
- We do not have data on the more advanced Alzheimer's patients and our engagement with health professionals will be focused on patients in the early symptomatic stage of the disease.
- Based on the entry criteria of the clinical trials conducted with ADUHELM, we estimate the appropriate patient population for ADUHELM to be approximately 1-2 million. These are patients who have been clinically diagnosed with mild cognitive impairment or mild dementia suspected to be due to Alzheimer's disease who would have confirmed amyloid beta pathology, if tested.
- It is important to note that we do not expect all of these patients will be treated with ADUHELM, for a variety of reasons, including appropriate patient selection criteria, a complex diagnostic and care pathway and limited capacity of specialists, who we believe will be the primary prescribers of ADUHELM. As a result of these factors, we anticipate that patient uptake will be gradual over a number of years.

About the price of ADUHELM, impact on healthcare budget and patient access

- We have determined the launch price of ADUHELM based on our belief in the impact of treatment as well as the size of the appropriate patient population based on the entry criteria of our clinical trials. In the event that our fundamental assumptions on population size and rate of adoption are significantly different than expected, we stand ready to work with public and private payers to address pricing in order to achieve both patient access and support budget sustainability.
- We have been engaging directly with public and private payers and health systems to ensure coverage policies support access for appropriate patients. For example, we have already announced our intention to enter into innovative access agreements with CIGNA Corporation and the Veterans Health Administration. We believe these will serve to stimulate further discussions with other payers on creating solutions to ensure access.
- We are committed to engaging with CMS on innovative price and access agreements, including but not limited to,

volume-based agreements that would help support continued sustainability of Medicare budgets.

- As part of our commitment to budget sustainability, Biogen will not be increasing the price of ADUHELM in the first four years following launch.
- We are committed to providing access to ADUHELM for patients across a spectrum of financial situations. We operate within the existing health insurance and legal system that limits the company's ability to subsidize out of pocket expenses for Medicare patients while generally allowing such assistance for commercially insured patients.
    - We estimate that 40% of patients will have an out-of-pocket exposure of approximately $200 or less a year.
    - We believe a further 50% of patients will have a cap on out-of-pocket expenses, either because they are covered through a Medicare Advantage plan with a Maximum Out-of-Pocket (MOOP) or because they have a form of secondary coverage (e.g., employee retiree coverage).
    - We also acknowledge that an estimated 10% of patients, those who do not have supplemental Medicare coverage, will potentially have an out-of-pocket exposure of ~20% of the costs. For patients facing difficulty affording ADUHELM, financial assistance programs are available that may help eligible patients. For more information, please contact Biogen Support Services at 1-833-425-9360.
- We stand ready to work with payers, including CMS, to create innovative agreements which could lower patient co-payment shares or out-of-pocket expense for patients treated with ADUHELM. We believe in the need to reform patient insurance benefit structures to reflect innovation.

About Health Equity

- Biogen and Eisai's commitment to health equity is rooted in efforts that are focused on providing culturally competent resources and care, offering cognitive testing, engaging with community health centers and, when possible, mitigating out-of-pocket costs for patients and families.
- 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.
- To start, we have signed agreements with CVS Health and NAFC (National Association of Free and Charitable Clinics) focused on addressing health disparities and access. CVS Health and NAFC have a large network of clinics across the country with teams that will provide appropriate information and education about Alzheimer's disease and support cognitive screening.
- We will continue to prioritize health equity in our programs moving forward including collecting more data from underserved and underrepresented populations.

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION
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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 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 statement contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: Biogen's strategy and plans; potential of, and expectations for, Biogen's commercial business, including ADUHELM; the potential clinical effects of ADUHELM; the potential benefits, safety and efficacy of ADUHELM; access to and reimbursement for ADUHELM; the treatment of Alzheimer's disease; the anticipated benefits and potential of our collaboration arrangements with Eisai; the clinical development program and future clinical trial(s) for ADUHELM; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "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: 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 our drug candidates, including ADUHELM; unexpected concerns that may arise from additional data or analysis obtained during clinical trials; actual timing and content of submissions to and decisions made by the regulatory authorities regarding ADUHELM; the occurrence of adverse safety events, restrictions on use or product liability claims; risks of unexpected costs or delays; the risk of other unexpected hurdles; 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; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition; and any other risks and uncertainties that are described 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 statement. 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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