A Letter from Biogen's CEO on ADUHELM

June 7, 2021

Today, on behalf of my Biogen colleagues, I am incredibly humbled to share that the U.S. Food and Drug Administration (FDA) has granted accelerated approval for ADUHELM™ (aducanumab-avwa), the first-ever therapy to address a defining pathology of Alzheimer's disease—amyloid beta plaque.

We come to this historic moment with thanks for the inspiring contributions of thousands of Alzheimer's patients and caregivers who participated in our clinical trials, for the pioneering work of scientists and researchers inside and outside Biogen, and for the relentless dedication of our employees globally. We are also very appreciative of our collaboration partners Eisai and Neurimmune.

For nearly two decades, the medical and scientific communities have searched for a new treatment for Alzheimer's disease. And millions of people with this dreaded condition—along with tens of millions more of their family, friends and caregivers—have watched helplessly, with little hope, as they confronted this devastating condition. In my own experience, I too have seen how this disease robs patients of their cognitive abilities, of their capacity to enjoy their lives and interact with loved ones.

The approval of ADUHELM represents a crucial inflection point in our collective battle against Alzheimer's disease. By addressing a defining pathology of the disease, this novel therapy has the potential to help fundamentally change the way patients are diagnosed and treated.

I have hoped for years that we would reach a moment like this. We all know the staggering numbers: there have been at least 100 drug development programs discontinued since 2003—the last time a new Alzheimer's drug was approved. What it tells us is that the path for innovation is not straightforward, especially for something as complex as Alzheimer's research. The journey during Biogen's many years of research and development has been humbling, but we have learned from industry's past research efforts and been determined to follow the science, always driven to address patients' unmet needs.

ADUHELM is a first-in-class approved therapy: I believe it will be the catalyst to a new era of innovation for Alzheimer's disease, and the first of many new treatments available to patients. More resources will be drawn into research that can help patients through the disease continuum, explore new pathways, and find potential therapy combinations.

Our industry has been the source of similar types of transformative innovation before. This is exactly how HIV/AIDS and many forms of cancer were changed from untreatable diseases into conditions with viable treatment options. Multiple sclerosis provides a good example. The first therapy introduced in 1993 via accelerated approval set in motion a cycle of innovation that resulted in now more than 20 treatments approved, including six developed by Biogen.

We are committed to sharing our future insights about ADUHELM with the scientific community as we collect more data from the real-world use of this treatment. In addition, as part of our accelerated approval, Biogen will conduct a confirmatory trial to verify the clinical benefit of ADUHELM.

Until now, patients had no treatment option directed at a defining pathology of the disease. Now that a new treatment studied in the early stage of the disease is available, we must collectively shift our focus to early detection, diagnosis and access.

Price and access are sensitive matters for all groundbreaking innovations. We have engaged extensively with health economists, public health experts, and payers about ADUHELM – and we have examined other recent biologic drug innovations. Consistent with our pricing principles, we have established a price for ADUHELM that reflects the overall value this treatment brings to patients, caregivers and society – and one that will enable continuous innovation.

Our commitment goes even further—from not increasing ADUHELM's price for the next four years to entering into value-based agreements with payers and insurers. Our agreement with the Veterans Health Administration and another with Cigna will be important steps to making the treatment available to eligible patients, and we look forward to continued engagement with the Centers for Medicare and Medicaid Services and insurance companies. As Biogen generates data in the real world and better understands ADUHELM's place in the Alzheimer's treatment landscape, we will continue these engagements with the aim of ensuring ADUHELM continues to be accessible in a way that is sustainable.

While we launch ADUHELM, we are also investing in more than 30 clinical programs currently under development. These include our investigations into several possible additional treatments for Alzheimer's disease, as well as other debilitating neurological conditions such as Parkinson's disease, ALS and stroke. We have spent more than $28 billion in research and development since 2003.

The approval of ADUHELM lays the foundation for creating a new treatment paradigm around Alzheimer's disease, but what's needed is far bigger than what any one medicine or any single company can achieve on its own. Today's milestone is a major step forward in changing Alzheimer's disease from a disease often perceived as an inevitable consequence of aging to a condition with a new treatment option.

We are working toward the goal of creating an environment where detection of the disease is as early, widespread and routine as mammograms and colonoscopies. Biogen and Eisai have also launched a range of innovative programs and services in the U.S. to help patients and families navigate the diagnostic and treatment journey.

Of particular importance are our multiple initiatives that aim to address the health disparities and inequities experienced by Alzheimer's patients and caregivers in underserved communities. We are proud to have joined forces with CVS Health and the National Association of Free and Charitable Clinics (NAFC) to reach the most vulnerable. And we stand ready to cooperate with more stakeholder groups to support broad access to treatment, now and into the future.

Today, incredibly inspirational for all of us at Biogen, marks the beginning of a new era for patients, caregivers, and the scientific community engaged in Alzheimer's research. At Biogen, we are committed more than ever to neuroscience and brain health, to pioneering science and working fearlessly to change patients' lives. Our focus remains, as always, on their unmet need.

Sincerely,
Michel Vounatsos
Chief Executive Officer

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 I 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. Your healthcare provider will do magnetic resonance imaging (MRI) scans before and during your treatment with ADUHELM to check you for ARIA.
Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the symptoms listed above.

Before receiving ADUHELM, tell your healthcare provider about all of your medical conditions, including if you: are pregnant or plan to become pregnant. It is not known if ADUHELM will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with ADUHELM. Or if you are breastfeeding or plan to breastfeed. It is not known if aducanumab-avwa (the active ingredient in ADUHELM) passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while receiving ADUHELM.
Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of ADUHELM? ADUHELM can cause serious side effects, including:
See above "What is the most important information I should know about ADUHELM?"
Serious allergic reactions. Swelling of the face, lips, mouth, or tongue and hives have happened during an ADUHELM infusion. **Tell your healthcare provider if you have any of the symptoms of a serious allergic reaction during or after 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. Call your doctor for medical advice about side effects. You 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.

Biogen Safe Harbor

This document 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 and access to ADUHELM; the identification and 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 ADUHLEM; the clinical development program, data readouts and presentations for aducanumab; 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; 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 document. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.