Biogen and Eisai Announce FDA's 3-Month Extension of Review Period for the Biologics License Application for Aducanumab

January 29, 2021

The new Prescription Drug User Fee Act (PDUFA) action date set by the FDA is June 7, 2021

CAMBRIDGE, Mass. and TOKYO, Jan. 29, 2021 (GLOBE NEWSWIRE) -- Biogen (Nasdaq: BIIB) and Eisai Co., Ltd. (Tokyo, Japan) today announced that the U.S. Food and Drug Administration (FDA) has extended the review period by three months for the Biologics License Application (BLA) for aducanumab, an investigational treatment for Alzheimer's disease. The updated Prescription Drug User Fee Act (PDUFA) action date is June 7, 2021.

As part of the ongoing review, Biogen submitted a response to an information request by the FDA, including additional analyses and clinical data, which the FDA considered a Major Amendment to the application that will require additional time for review.

"We are committed to working with the FDA as it completes its review of the aducanumab application," said Michel Vounatsos, Chief Executive Offer at Biogen. "We want to thank the FDA for its continued diligence during the review."

Biogen submitted the aducanumab BLA to the FDA in July 2020. The FDA accepted the BLA in August 2020 and granted Priority Review.

About Aducanumab

Aducanumab (BIIB037) is an investigational human monoclonal antibody studied for the treatment of Alzheimer's disease. Based on clinical data from patients with Mild Cognitive Impairment due to Alzheimer's disease and mild Alzheimer's disease, aducanumab has the potential to impact underlying disease pathophysiology, slow cognitive and functional decline and provide benefits on patients' ability to perform activities of daily living, including conducting personal finances, performing household chores, such as cleaning, shopping and doing laundry, and independently traveling out of the home. If approved, aducanumab would be the first treatment to meaningfully change the course of the disease for individuals living with Alzheimer's disease.

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

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), tens of millions of 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 plaque, 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 stages of the disease when symptoms start to be more visible and can be detected and diagnosed. Current research efforts are focused on catching and treating patients as early as possible for the best chance of slowing or stopping the progression of Alzheimer's disease.

For more information about Alzheimer's disease, visit www.CatchItEarly.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 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 potential regulatory discussions, submissions and approvals and the timing thereof; the potential clinical effects of aducanumab; the potential benefits, safety and efficacy of aducanumab; 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 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 actual timing and content of submissions to and decisions made by the regulatory authorities regarding aducanumab; 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 aducanumab; 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; uncertainty of success in the development and potential commercialization of aducanumab; risks relating to the potential launch of aducanumab, including preparedness of healthcare providers to treat patients, the ability to obtain and maintain adequate reimbursement for aducanumab and other unexpected difficulties or hurdles; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; 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.

Contacts

MEDIA CONTACT:

Biogen Inc.
David Caouette
+ 617 679 4945
public.affairs@biogen.com

MEDIA CONTACT:

Eisai Co., Ltd.
Public Relations Department
TEL: +81-(0)3-3817-5120

Eisai Inc.
Public Relations Department
TEL: +1-201-753-1945

INVESTOR CONTACT:

Biogen Inc.
Mike Hencke
+781 464 2442
IR@biogen.com

INVESTOR CONTACT:

Eisai Co., Ltd.
Investor Relations Department
TEL: +81-(0)3-3817-5327