# EISAI and Biogen Inc. Announce U.S. FDA Grants Breakthrough Therapy Designation for LECANEMAB (BAN2401), an Anti-Amyloid Beta Protofibril Antibody for the Treatment of Alzheimer's Disease

June 23, 2021

TOKYO and CAMBRIDGE, Mass, – Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and Biogen Inc. (Nasdaq: BIIB, Corporate headquarters: Cambridge, Massachusetts, CEO: Michel Vounatsos, “Biogen”) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for lecanemab (BAN2401), an investigational anti-amyloid beta (Aβ) protofibril antibody for the treatment of Alzheimer’s disease (AD).

Breakthrough Therapy designation is an FDA program intended to expedite the development and review of medicines for serious or life-threatening conditions. The benefits of a Breakthrough Therapy designation include more intensive guidance on an efficient development program as well as eligibility for rolling review and potentially priority review.

The FDA’s Breakthrough Therapy designation for lecanemab is based on the recently published results of a Phase 2b clinical trial (Study 201) of 856 patients with mild cognitive impairment (MCI) due to AD and mild AD with confirmed presence of amyloid pathology.1 The proof-of-concept Study 201 explored the impact of treatment with lecanemab on reducing brain amyloid beta (Aβ) and clinical decline. In this study, pre-specified analysis showed consistent reduction of clinical decline across several clinical and biomarker endpoints at the highest doses.
In March 2021 Eisai and Biogen completed enrollment of 1,795 patients with early AD in the Clarity AD study. The study’s primary endpoint is expected to be completed by the end of September 2022. Additionally, the Phase 3 clinical study, AHEAD 3-45, is currently exploring lecanemab in individuals with preclinical AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains. Open label extension data from Study 201 confirmed time-dependent reduction of brain Aβ in individuals newly treated with lecanemab and was presented at the 2021 Alzheimer’s Disease and Parkinson’s Disease Conference.

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical development or gain health authority approval.

**Biogen Safe Harbor Statement**
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 the potential clinical effects of lecanemab; the potential benefits, safety and efficacy of lecanemab; potential regulatory discussions, submissions and approvals and the timing thereof; the expected data readout for the Clarity AD study; 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 lecanemab; 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 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; 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 lecanemab; actual timing and content of submissions to and decisions made by the regulatory authorities regarding lecanemab; uncertainty of success in the development and potential commercialization of lecanemab; 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:

Eisai Co., Ltd.

Public Relations Department

TEL: +81-(0)3-3817-5120

Eisai Inc.

Public Relations Department

TEL: +1-201-753-1945

MEDIA CONTACT:

Biogen Inc.

Allison Parks

public.affairs@biogen.com

INVESTOR CONTACT:

Biogen Inc.

Mike Hencke

libby_holman@eisai.com

+1-781-464-2442

IR@biogen.com

INVESTOR CONTACT:

Eisai Co., Ltd.

Investor Relations Department

TEL: +81-(0)3-3817-5121

**[Notes to editors]**

**About Lecanemab (BAN2401)**
Lecanemab is an investigational humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab selectively binds to neutralize and eliminate soluble, toxic amyloid-beta (Aβ) aggregates (protofibril) that are thought to contribute to the neurodegenerative process in AD. As such, lecanemab may have the potential to have an effect on disease pathology and to slow down the progression of the disease. Eisai obtained the global rights to study, develop, manufacture and market lecanemab for the treatment of AD pursuant to an agreement concluded with BioArctic in December 2007. In March 2014 Eisai and Biogen entered into a joint development and commercialization agreement for lecanemab and the parties amended that agreement in October 2017. Currently, lecanemab is being studied in a pivotal Phase 3 clinical study in symptomatic early AD (Clarity-AD), following the outcome of the Phase 2 clinical study (Study 201). In July 2020 the Phase 3 clinical study (AHEAD 3-45) for individuals with preclinical AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, was initiated. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium, funded by the National Institute on Aging, part of the National Institutes of Health, and Eisai.

**About the Collaboration between Eisai and Biogen for Alzheimer's Disease**
Eisai and Biogen are collaborating on the joint development and commercialization of AD treatments. Eisai serves as the lead in the co-development of lecanemab.

**About the Collaboration between Eisai and BioArctic for Alzheimer's Disease**
Since 2005, BioArctic has had a long-term collaboration with Eisai regarding the development and commercialization of drugs for the treatment of AD. The commercialization agreement on the lecanemab antibody was signed in December 2007, and the development and commercialization agreement on the antibody lecanemab back-up for AD, which was signed in May 2015. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for AD. BioArctic has no development costs for lecanemab in AD.

**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.

**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.

Reference
1: Alzheimer's Research & Therapy volume 13, Article number: 80 (2021)
https://alzres.biomedcentral.com/articles/10.1186/s13195-021-00813-8