Initiation of New Phase III Clinical Study (AHEAD 3-45) of BAN2401 Preclinical (Asymptomatic) Alzheimer's Disease

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The Alzheimer's Clinical Trials Consortium (ACTC), Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai"), and Biogen Inc. (Nasdaq: BIIB, Headquarters: Cambridge, Massachusetts, United States, CEO: Michel Vounatsos, "Biogen") announced today that a new Phase III clinical study （AHEAD 3-45) of BAN2401, an anti-amyloid beta (Aβ) protofibril antibody, has been initiated in the United States of America for individuals with preclinical Alzheimer's disease (AD), meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains. Currently, BAN2401 is being studied in a pivotal Phase III clinical study in symptomatic early AD (Clarity AD), following the outcome of the Phase II clinical study (Study 201). The AHEAD 3-45 will be conducted in the US, Japan, Canada, Australia, Singapore, and Europe.

AHEAD 3-45 is a Phase III clinical study, conducted as a public-private partnership between the ACTC, funded by the National Institute on Aging, part of the National Institutes of Health, and Eisai. After a common screening period in AHEAD 3-45, participants will be enrolled into one of two randomized, double-blind, placebo controlled trials based on the level of amyloid in the brain: the A45 trial and the A3 trial. A total of 1400 participants will be enrolled in the study and treated with BAN2401 for 216 weeks. The A45 trial will enroll cognitively unimpaired participants who have elevated levels of amyloid in the brain, and aims to prevent cognitive decline and suppress the progression of brain AD pathology with BAN2401 administration. The primary endpoint for A45 is the change from baseline in the Preclinical Alzheimer Cognitive Composite 5 (PACC5) at 216 weeks of treatment. Secondary endpoints are changes from baseline in brain amyloid levels as measured by amyloid positron emission tomography (PET) and in brain tau levels as measured by tau PET and Cognitive Function Index, a participant and study partner reported outcome. The A3 trial will enroll cognitively unimpaired participants who have an intermediate amount of amyloid in the brain, and who are at high risk for further Aβ accumulation. The primary endpoint for A3 is change from baseline in brain amyloid levels as measured by amyloid PET. The secondary endpoint is change from baseline in brain tau levels as measured by tau PET. Both trials include additional clinical assessment scales, imaging, blood biomarkers and cerebrospinal fluid (CSF) in a subset, as exploratory endpoints. An ATN (Amyloid, Tau, Neurodegeneration) biomarker panel of imaging and biofluid, especially CSF, markers including Aβ 1-42, Aβ 1-40, t-tau, p-tau, neurogranin, neurofilament light chain, will be used to evaluate therapeutic effects on the progression of AD pathophysiologic changes.

"It is hoped that initiating treatment much earlier in the disease process may be advantageous in preventing future cognitive decline. The AHEAD 3-45 should provide critically important answers about the optimal time to intervene with anti-amyloid therapy" said Dr. Reisa Sperling, Director, Center for Alzheimer Research and Treatment at Brigham and Women's Hospital and co-Principal Investigator, ACTC.

Dr. Aisen, Director of the University of Southern California Alzheimer's Therapeutic Research Institute, which serves as the coordinating center for the ACTC, noted, "The mission of the ACTC includes the development of public-private partnerships to conduct trials of promising candidate therapies. AHEAD 3-45 is the type of collaboration we need in the fight against Alzheimer's disease."

"The initiation of AHEAD 3-45 with BAN2401, focused on therapies for the earliest stages of the AD continuum through our collaboration with the ACTC group, marks an exciting time for us," says Lynn Kramer, M.D., Chief Clinical Officer, Neurology Business Group, Eisai. "This represents a next step in developing precision therapies for AD using biomarker panels as part of our *human health care* mission; we are committed to making a difference for patients, their families, and health care professionals across the globe."

For additional information please visit: https://www.a3a45.org/

BAN2401 is a humanized, monoclonal, anti- Aβ soluble aggregate (protofibril) antibody obtained through collaboration research between Eisai and BioArctic AB (Sweden). BAN2401 selectively binds to neutralize and eliminate toxic Aβ protofibrils that are thought to be a causative factor for AD. This suggests that BAN2401 may have the potential to have an effect on disease pathology and to slow the progression of AD. Study 201 demonstrated a statistically significant slowing of disease progression and decreasing of brain Aβ accumulation as the first late-stage large scale clinical study for early AD, and successfully showed potential disease-modifying effects. It is being conducted along with the 201 Open-Label Extension (OLE) study (Open-label continuous administration study) and one pivotal clinical study (Clarity AD). Eisai and Biogen Inc. have entered into a collaboration to develop and commercialize BAN2401.

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 the potential clinical effects of BAN2401; the potential benefits, safety, and efficacy of BAN2401; the clinical development program for BAN2401, including the AHEAD 3-45 study and the Clarity AD study; the results of the Phase II study of BAN2401; the identification and treatment of AD; the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai; the potential of Biogen's commercial business and pipeline programs, including BAN2401; 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; the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected; risks of unexpected costs or delays; the risk of other unexpected 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.

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[Notes to editors]

1. About The Alzheimer's Clinical Trials Consortium (ACTC)

The ACTC, funded by the National Institute on Aging at the National Institutes of Health (grant number U24AG057437), provides the infrastructure for academic clinical trials in Alzheimer's Disease and related dementias. The consortium, based at the University of Southern California, Harvard University and the Mayo Clinic, includes expert units to support clinical trials design, biostatistics, informatics, medical safety, regulatory oversight, recruitment, clinical operations, data management, site monitoring, a biomarker laboratory and repository, and neuroimaging. The ACTC includes 35 primary clinical sites across the United States.

2. 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 Aricept®, a treatment for Alzheimer's disease and dementia with Lewy bodies, 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, fitness clubs, automobile makers, retailers, and care facilities. For more information about Eisai Co., Ltd., please visit https://www.eisai.com.

3. 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, immunology, neurocognitive disorders, acute neurology and pain.

We routinely post information that may be important to investors on our website at https://www.biogen.com. Follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

4. About the National Institutes of Health (NIH), National Institute of Aging (NIA)

NIA, one of the 27 Institutes and Centers of NIH, leads a broad scientific effort to understand the nature of aging and to extend the healthy, active years of life. NIA is the primary Federal agency supporting and conducting Alzheimer's disease research. The National Institutes of Health, National Institute of Aging are providing funding for the A45 Study (grant number R01AG061848) and A3 Study (grant number R01AG054029)

5. About the Preclinical AD Cognitive Composite 5 (PACC5)

The PACC5 is a composite score for evaluating the severity of cognitive decline to enable highly-sensitive detection of changes in clinical functions in the preclinical AD stage.

6. About the Cognitive Function Index (CFI)

The Cognitive Function Index is an evaluation index that assesses the ability to perform advanced functional tasks in daily life and general cognitive function.