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Eisai Co., Ltd.

INITIATION OF PHASE III CLINICAL TRIAL OF BAN2401 IN EARLY ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced that a global Phase III clinical study (Clarity AD/Study 301) of BAN2401, an anti-amyloid beta protofibril antibody, in patients with early Alzheimer's disease has been initiated. BAN2401 is being jointly developed by Eisai and Biogen Inc. (Headquarters: Cambridge, Massachusetts, United States, "Biogen").

Clarity AD is a global placebo-controlled, double-blind, parallel-group, randomized study in 1,566 patients with mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's disease dementia (collectively known as early AD) with confirmed amyloid pathology in the brain. After discussion with regulatory agencies based on the results of a Phase II clinical study (Study 201), a single Phase III clinical study is being initiated to support a filing for BAN2401. The treatment group will be administered a dosage of 10 mg/kg bi-weekly of BAN2401, with patients allocated in a 1:1 ratio to receive either placebo or the treatment group. The primary endpoint is the change from baseline in the Clinical Dementia Rating–Sum of Boxes (CDR-SB) at 18 months of treatment. Respective changes from baseline to 18 months of treatment in the AD composite score (ADCOMS), AD Assessment Scale–Cognitive Subscale (ADAS-cog), and brain amyloid levels as measured by amyloid positron emission tomography (PET) have been set as key secondary endpoints.

Eisai aims to create innovative medicines for Alzheimer's disease as soon as possible in order to further contribute to addressing the unmet medical needs of, as well as potentially increasing the benefits provided to, patients and their families.

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[Notes to editors]

1. About BAN2401

BAN2401 is a humanized monoclonal antibody for Alzheimer's disease that is the result of a strategic research alliance between Eisai and BioArctic. BAN2401 selectively binds to neutralize and eliminate soluble, toxic A β aggregates (protofibril) that are thought to contribute to the neurodegenerative process in Alzheimer's disease. As such, BAN2401 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 BAN2401 for the treatment of Alzheimer's disease 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 BAN2401 and the parties amended that agreement in October 2017.

2. About Study 201

Study 201 is a placebo-controlled, double-blind, parallel-group, randomized Phase II clinical study in 856 patients with mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's dementia (collectively known as early Alzheimer's disease) with confirmed amyloid pathology in the brain. This study used Bayesian Adaptive Randomization Design to automatically allocate newly enrolled patients into the study to treatment arms showing higher probability of efficacy based on the results of interim analyses. The study design included five dose regimens and placebo, and considered the efficacy of BAN2401 as well as dose responsiveness through 16 interim analyses that assessed potential for early success, an analysis based on ADCOMS at 12 months, and a comprehensive final analysis at 18 months (secondary endpoints). Patients who received treatment with BAN2401 were randomized to five dose regimens, 2.5 mg/kg biweekly (52 patients), 5 mg/kg monthly (51 patients), 5 mg/kg biweekly (92 patients), 10 mg/kg monthly (253 patients), or 10 mg/kg biweekly (161 patients). Biomarker endpoints included changes in A β accumulated in the brain as measured by amyloid PET (positron emission tomography) as well as in cerebrospinal fluid (CSF), while ADCOMS (Alzheimer's Disease Composite Score), Clinical Dementia Rating Sum of Boxes (CDR-SB) and Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-Cog) were measured as efficacy endpoints (clinical).

Detailed results of Study 201 were presented at Alzheimer's Association International Conference 2018 and Clinical Trials on Alzheimer's Disease 2018 in July 2018 and October 2018, respectively.

Currently, an open-label extension phase of Study 201 is ongoing. Eligible patients are those enrolled in Study 201, and receive the highest dose of BAN2401 (10 mg/kg biweekly).

3. About BioArctic AB

BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease modifying treatments and reliable biomarkers and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. The company also develops a potential treatment for Complete Spinal Cord Injury. BioArctic focuses on innovative treatments in areas with high unmet medical needs. The company was founded in 2003 based on innovative research from Uppsala University, Sweden. Collaborations with universities are of great importance to the company together with our strategically important global partners in the Alzheimer (Eisai) and Parkinson (AbbVie) projects. The project portfolio is a combination of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market- and out-licensing potential. BioArctic's B-share is listed on Nasdaq Stockholm Mid Cap (STO:BIOA B). www.bioarctic.com.