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Eisai Co., Ltd.

DELIBERATIONS AT THE CHMP REGARDING THE MARKETING AUTHORIZATION APPLICATION IN THE EU FOR LECANEMAB HAVE BEEN RESCHEDULED DUE TO PROCEDURAL REASONS AT THE EUROPEAN MEDICINES AGENCY

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the Oral Explanation scheduled for March 19 at the Committee for Medicinal Products for Human Use (CHMP) for lecanemab, which is currently under review by the European Medicines Agency (EMA), did not take place due to procedural reasons at the EMA.

On March 14, 2024, the Court of Justice of the European Union ruled on the organisation of EMA's Scientific Advisory Groups (SAGs) attendance. The judgment has implications on EMA's policy on the handling of competing interests of experts, in relation to SAG members. For this reason, the EMA has decided to annul the advice obtained at the SAG-N (Scientific Advisory Group on Neurology) meeting for lecanemab held on March 11, 2024. The EMA will reconvene another SAG-N meeting for lecanemab. The timing for the new meeting has not been determined yet.

This decision is entirely related to procedural reasons at the EMA and is not related to the marketing authorization application (MAA) for lecanemab itself. Eisai will continue to collaborate with the EMA towards the deliberations of lecanemab.

Eisai serves as the lead of lecanemab development and regulatory submissions globally with both Eisai and Biogen co-commercializing and co-promoting the product and Eisai having final decision-making authority.

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[Notes to editors]

1. About Lecanemab (generic name, brand name: LEQEMBI®),

Lecanemab is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). In the U.S., LEQEMBI was granted traditional approval by the U.S. Food and Drug Administration (FDA) on July 6, 2023. LEQEMBI is an amyloid beta-directed antibody indicated as a disease-modifying treatment for Alzheimer's disease (AD) in the U.S. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. In Japan, Eisai received approval from the Ministry of Health, Labour and Welfare (MHLW) on September 25, 2023, to manufacture and market LEQEMBI as a treatment for slowing progression of MCI and mild dementia due to AD. Furthermore, in China, LEQEMBI was approved by the National Medical Products Administration (NMPA) as a treatment of mild cognitive impairment (MCI) due to AD and mild AD dementia on January 5, 2024.

Please see full U.S. Prescribing Information for LEQEMBI, including Boxed WARNING.

Eisai has also submitted applications for approval of lecanemab in Canada, Great Britain, Australia, Switzerland, South Korea, Israel and other countries in addition to EU. In Israel the application has been designated for priority review, and in Great Britain lecanemab has been designated for the Innovative Licensing and Access Pathway (ILAP), which aims to reduce the time to market for innovative medicines.

Eisai has completed a lecanemab subcutaneous bioavailability study, and subcutaneous dosing is still being evaluated in the Clarity AD (Study 301) open-label extension (OLE). A maintenance dosing regimen has been evaluated as part of Study 201.

Since 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, is ongoing. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium that provides the infrastructure for academic clinical trials in AD and related dementias in the U.S, funded by the National Institute on Aging, part of the National Institutes of Health, Eisai and Biogen.

Since January 2022, the Tau NexGen clinical study for Dominantly Inherited AD (DIAD), that is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis, is ongoing and includes lecanemab as the backbone anti-amyloid therapy.

2. About the Collaboration between Eisai and Biogen for AD

Eisai and Biogen have been collaborating on the joint development and commercialization of AD treatments since 2014. Eisai serves as the lead of LEQEMBI development and regulatory submissions globally with both companies co-commercializing and co-promoting the product and Eisai having final decision-making authority.

3. About the Collaboration between Eisai and BioArctic for AD

Since 2005, Eisai and BioArctic have had a long-term collaboration regarding the development and commercialization of AD treatments. Eisai obtained the global rights to study, develop, manufacture and market LEQEMBI for the treatment of AD pursuant to an agreement with BioArctic in December 2007. The development and commercialization agreement on the antibody LEQEMBI back-up was signed in May 2015.