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Eisai Co., Ltd.  
Biogen Japan Ltd.

## **EISAI SIGNS RESEARCH COLLABORATION AGREEMENT WITH THE NATIONAL CENTER OF NEUROLOGY AND PSYCHIATRY TO INITIATE APOLIPOPROTEIN E GENETIC TESTING IN THE “AD-DMT REGISTRY” IN JAPAN**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and Biogen Japan Ltd. (Headquarters: Tokyo, President and Representative Director: Takatsugu Den, “Biogen Japan”) announced today that Eisai has entered into a research collaboration agreement with the National Center of Neurology and Psychiatry (Location: Tokyo, “NCNP”) to conduct apolipoprotein E (APOE) genetic testing in the dementia research and development program, “Development and Analysis of a National Clinical Registry of Disease-Modifying Therapies for Alzheimer’s Disease” (“AD-DMT Registry”). The research will be implemented by the Japan Agency for Medical Research and Development (AMED), with NCNP as the lead research institution.

The APOE gene is known to be a risk factor for the onset of Alzheimer’s disease and is also associated with the frequency of amyloid-related imaging abnormalities (ARIA) in anti-amyloid  $\beta$  antibody treatments such as lecanemab (LEQEMBI®).<sup>1</sup>

In Japan, at present, APOE genetic testing is not available for routine clinical practice under National Health Insurance. For this reason, by using APOE genetic information collected in the AD-DMT Registry, Eisai and NCNP can further study the relationship between the APOE genotype and the safety and efficacy of treatment with lecanemab.

Based on this research collaboration agreement with NCNP, Eisai will cover the cost of the APOE genetic testing conducted in the AD-DMT Registry. The findings, along with data collected from the lecanemab-specific post-marketing surveillance (all-case surveillance), will be part of the reexamination of lecanemab’s application by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to ensure the label reflects the latest scientific understanding with the goal of improving patient outcomes.

Eisai and Biogen Japan will continue to contribute to the advancement of Alzheimer’s disease treatment through ongoing collaboration with academia.

Eisai serves as the lead of lecanemab development and regulatory submissions globally with both Eisai and Biogen Inc. (U.S.) co-commercializing and co-promoting the product and Eisai having final decision-making authority. In Japan, Eisai and Biogen Japan will co-promote lecanemab, with Eisai distributing the product as the Marketing Authorization Holder.

<sup>1</sup>. Foley KE and Wilcock DM (2024). Three major effects of APOE $\epsilon$ 4 on A $\beta$  immunotherapy induced ARIA. *Front. Aging Neurosci.* 16:1412006. doi: 10.3389/fnagi.2024.1412006

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### [Notes to Editors]

#### 1. About the “Development and Analysis of a National Clinical Registry of Disease-Modifying Therapies for Alzheimer’s Disease”

The National Center of Neurology and Psychiatry (NCNP) is the lead research institution for the dementia research and development program “Development and Analysis of a National Clinical Registry of Disease-Modifying Therapies for Alzheimer’s Disease” under the Japan Agency for Medical Research and Development (AMED). The research is being conducted with the aim of collecting clinical information and test data obtained from routine medical care using treatments including anti-amyloid  $\beta$  antibody drugs such as lecanemab, evaluate the efficacy and safety of these drugs, and perform blood sampling for APOE genotyping and measurement of other biomarkers in patients receiving the drugs. Some of these results will be reported to the participating patients,

and the safety and efficacy of the drugs will be examined based on APOE genotype and other factors. Eisai plans to conduct large-scale and efficient research by sharing data of patients who have given their consent from the specific post-marketing surveillance.

For more details on AMED’s dementia research and development program, please visit the [AMED website](#).

#### 2. About Eisai

Eisai’s Corporate Concept is “to give first thought to patients and people in the daily living domain, and to increase the benefits that health care provides.” Under this Concept (also known as *human health care (hhc)* Concept), we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology, Oncology and Global Health.

Theoria technologies Co., Ltd., a member of the Eisai Group, operates the dementia portal site “Theotol” (<https://theotol.soudan-e65.com/>), which provides easy-to-understand contents and services for the general public about MCI and various types of dementia, their causes, treatments, as well as caregiving methods and personal experiences. (Japanese only)

#### 3. About Biogen Japan

Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients’ lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

We routinely post information on Biogen Japan that may be important to investors on our website at <https://www.biogen.com/> and social media [Facebook](#), [Twitter](#), [Instagram](#), [YouTube](#), [LinkedIn](#), [LINE](#).