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April 8, 2022
Eisai Co., Ltd.

EISAI STATEMENT ON THE CENTERS FOR MEDICARE AND MEDICAID SERVICES' NATIONAL COVERAGE DETERMINATION WITH COVERAGE WITH EVIDENCE DEVELOPMENT FOR MONOCLONAL ANTIBODIES DIRECTED AGAINST AMYLOID FOR THE TREATMENT OF ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") stands with people living with Alzheimer's disease (AD) and their families, health care professionals and other members of our AD community. We respect that the Centers for Medicare and Medicaid Services (CMS) has committed to quickly reconsider the National Coverage Determination (NCD) once an anti-amyloid drug for the treatment of AD has met the Coverage with Evidence Development (CED) requirements with quality evidence.

Eisai anticipates completing our anti-amyloid-beta (A β) protofibril antibody lecanemab's rolling submission of a Biologics License Application to the FDA under the accelerated approval pathway in the first quarter of our fiscal year 2022, which began April 1, 2022. Additionally, the readout of the Phase 3 confirmatory Clarity AD clinical trial will occur in the Fall of 2022. Eisai believes Clarity AD has a robust design, which could meet the "high level of evidence" criteria set forth by CMS in the NCD decision memo if the result is positive; therefore, creating the potential for CMS to reconsider full coverage of lecanemab should it be approved by the FDA. We look forward to engaging constructively with CMS to ensure appropriate Medicare beneficiaries have access to this potential new therapy.

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.

The impact of the NCD on access to aducanumab is currently under review. If Eisai determines that revisions of the forecast for the fiscal year ending March 31, 2022 are necessary, Eisai will make an announcement as soon as possible.

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120