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Eisai Co., Ltd.

Update Regarding the Regulatory Status of LEQEMBI® Subcutaneous Formulation

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") reconfirmed today that the regulatory status for anti-amyloid beta (Aβ) protofibril antibody LEQEMBI® (generic name: lecanemab) subcutaneous (SC) autoinjector, explained at the Financial Disclosure Meeting on August 2, 2024, is as follows.

The SC formulation (including initiation and maintenance dosing) received Fast Track designation from the U.S. Food and Drug Administration (FDA). In agreement with the FDA, Eisai initiated a rolling submission and review for SC maintenance dosing in May 2024. In parallel, discussions are ongoing with the FDA regarding optimal dosage and the fastest regulatory pathway for the SC initiation dosing. There are no changes to the previously announced timeline for the SC application at this time. We expect to complete the rolling application for SC maintenance dosing in the third quarter of fiscal year 2024 ending March 2025, with a review period of six months if designated for priority review or ten months under standard review. For SC initiation dosing, we aim to obtain a regulatory approval by the end of fiscal year 2025 ending March 2026.

A supplemental Biologics License Application (sBLA) for intravenous (IV) maintenance dosing was submitted to the FDA in March 2024 and accepted in June of the same year. The PDUFA (Prescription Drugs User Fee Act) action date is set for January 25, 2025.

Eisai is committed to making the IV maintenance dosing and SC formulation available as new treatment options to people with early AD as soon as possible.

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

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