August 17, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Donanemab (genetical recombination), lecanemab (genetical recombination)

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	a. Donanemab (genetical recombination) b. Lecanemab (genetical recombination)	a. Kisunla Intravenous Infusion 350 mg (Eli Lilly Japan K.K.) b. Leqembi for Intravenous Infusion 200 mg, 500 mg (Eisai Co., Ltd.)
Japanese market launch	a. November 2024, b. December 2023	
Indications	Slowing the progression of mild cognitive impairment and mild dementia due to Alzheimer's disease	
Summary of revisions	a., b. 1. A statement to the effect that apolipoprotein E (APOE) genetic testing should be considered before starting treatment with this drug should be added to the precautions concerning amyloid-related imaging abnormalities (ARIA) in the 1. WARNINGS section. 2. A cautionary statement regarding the implementation of APOE genetic testing should be added to the 8. IMPORTANT PRECAUTIONS section.	
Investigation results and background of the revision	Materials including post-marketing surveillance, adverse reaction reports in Japan, clinical studies submitted for the approval, overseas product labeling, and guidelines, etc., were reviewed. As a result of consultation with expert advisors, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary for the following reasons: A trend toward a higher incidence of ARIA in APOEε4 homozygote carriers has been identified; and APOE genetic testing became covered by health insurance in July 2026.	
Reference: Number of cases*[1,2] involving ARIA reported in Japan	a. A total of 95 cases have been reported to date. No deaths have been reported to date. b. A total of 87 cases have been reported to date. A total of 1 death have been reported to date.	

*1: Cases collected in PMDA's safety database for drugs.
*2: Cases corresponding to any of MedDRA PTs "Amyloid related imaging abnormalities," "Amyloid related imaging abnormality-oedema/effusion," "Brain oedema," "Vasogenic cerebral oedema," "Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits," "Cerebellar microhaemorrhage," "Cerebral haemorrhage," "Haemorrhage intracranial," "Thalamus haemorrhage," "Superficial siderosis of central nervous system," "Cerebral microhaemorrhage," and "Brain stem haemorrhage." The causality assessment of the cases has not been implemented.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).