

VISION AD-JP: A Prospective Multicenter Real-World Study of Japanese Patients With Early Alzheimer's Disease Treated With Lecanemab

Koji Tsuboi¹, Mariko Matsumoto¹, Hironori Sakai¹, Yosuke Nakamura¹, Tomoo Ogawa¹, Atsushi Iwata²

1. Eisai Co., Ltd., Tokyo, Japan; 2. Tokyo Metropolitan Institute for Geriatrics and Gerontology, Tokyo, Japan

PROTOCOL POSTER

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Phase 4

Prospective Real-World Study of Lecanemab

Observational framework



~30 sites

Japanese routine care

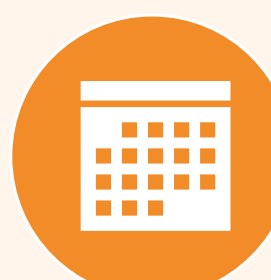
Multicenter network



~750 patients

Early Alzheimer's disease (AD)

MCI due to AD or mild AD



Up to 5 years

Longitudinal follow-up

Every 6 months

Introduction and rationale



Why a prospective real-world study?

- Real-world management of Alzheimer's disease (AD) requires evidence meaningful to patients, study partners/caregivers, and physicians.
 - Lecanemab was approved in Japan in December 2023; treatment in this study follows the Japanese prescribing information and Optimal Use Guidance (OUG).
- A subcutaneous formulation of lecanemab is under regulatory review in Japan.
- Prospective real-world studies that systematically assess long-term clinical progression with biomarkers, digital measures, and patient-centered outcomes remain limited.
- VISION AD-JP is designed to complement pivotal trials and Japanese real-world case studies with a prospective 5-year framework.

Objectives

Primary objective

Evaluate the association between long-term lecanemab treatment and clinical progression to the next stage of AD using global Clinical Dementia Rating (CDR).

Secondary objectives

Characterize longitudinal clinical, biomarker, digital, treatment-pattern, focused safety, and patient-centered outcomes.

Exploratory objectives

Explore relationships among CDR, clinical outcomes, biomarkers, and factors associated with treatment discontinuation.

Population and treatment framework

Early AD

Japanese patients with mild cognitive impairment (MCI) due to AD or mild AD.

Treatment setting

Lecanemab treatment decisions are made before enrollment and use follows the approved Japanese label/OUG.

5-year study journey

Pretreatment phase

up to 6 months

V1

V2

6

12

18

24

30

36

42

48

54

60

Months

Treatment / observation phase

Up to 60 months after the first dose of lecanemab



Baseline assessments

Eligibility, amyloid PET/CSF, APOE4 status, clinical outcomes, biomarkers, and optional wearable/app data.



Real-world lecanemab use

Treatment is prescribed by the physician according to the approved label/OUG; no protocol-driven treatment assignment.



Continuation principle

Scheduled assessments continue even after lecanemab discontinuation unless consent is withdrawn.

Primary endpoint and analysis

1. First lecanemab dose

2. Global CDR + ≥ 0.5

3. Confirmed at two consecutive visits

4. Progression event

5. Kaplan-Meier summary

- Primary endpoint:** Time from the first dose of lecanemab to progression in global CDR score, confirmed at two consecutive visits.
- Full Analysis Set:** ≥ 1 lecanemab dose, baseline assessment, and ≥ 1 postdose global CDR assessment.
- If no event occurs, time to progression is censored at the last global CDR assessment.
- Analyses:** **Interim:** 18 months after LPI; **Final:** 60 months after LPI.

Assessment schedule overview

Assessment / domain	BL V1/ V2	6	12	18	24	30	36	42	48	54	60	Disc
CDR / CDR-SB	●	●	●	●	●	●	●	●	●	●	●	●
MMSE / QDRS	●	●	●	●	●		●		●		●	●
Care level	●	●	●	●	●	●	●	●	●	●	●	●
ADCS-MCI-ADL	●		●		●		●		●		●	●
EQ-5D-5L / ZBI / WPAI / care-related questionnaires	●	●	●	●	●		●		●		●	●
AD blood biomarkers (incl. plasma p-tau217)	●	●	●	●	●		●		●		●	●
Wearable / ePSOM / app data*	○	○	○	○	○	○	○	○	○	○	○	○
Brain MRI ARIA / ICH >1 cm	●	†	†	†	†	†	†	†	†	†	†	†

BL = baseline; Disc. = final/discontinuation visit; ● = scheduled assessment; ○ = optional/consenting participants. After Month 24, some clinical and blood biomarker assessments are collected annually per protocol. † ARIA/ICH >1 cm is collected during lecanemab treatment; MRI for eligibility and ARIA monitoring follows the Japanese label/OUG and physician judgment. Visit windows: Visits 3–6 ± 2 weeks; Visit 7 onward ± 4 weeks; other-study assessments within windows may be used where applicable.

Data ecosystem



Clinical progression

Global CDR, CDR-SB, MMSE, QDRS



Function / daily life

ADCS-MCI-ADL, Care-needs level



Patient & caregiver

EQ-5D-5L, WPAI, ZBI, care-related questionnaires



Biomarkers

Plasma p-tau217, baseline amyloid PET/CSF, APOE4 status



Digital biomarkers

Wearable-derived activity/sleep



Patient-centered apps

electronic Person-Specific Outcome Measure (ePSOM), Sasaeru



Lecanemab-treated early AD patient + study partner

Integrated longitudinal data capture

Designed to link clinical progression with biomarker, digital, treatment-pattern, and patient-centered outcomes.

Focused safety and treatment-pattern data



Safety capture during lecanemab treatment

- Amyloid-related imaging abnormalities (ARIA) and intracerebral hemorrhage (ICH) >1 cm, including magnetic resonance imaging (MRI) findings and symptomatic status as applicable.
- Treatment duration, treatment compliance, and discontinuation rate will be characterized.
- Safety Analysis Set includes participants receiving ≥ 1 lecanemab dose.

Conclusions

- VISION AD-JP is designed to generate clinically relevant real-world evidence on long-term monitoring and management of lecanemab-treated early AD in Japan.
- The integrated study design enables comprehensive assessment of clinical progression, treatment patterns, selected safety outcomes, blood-based biomarkers, digital biomarkers, and patient-centered outcomes. As this is an observational study without a control group, causal inferences should be interpreted with caution.
- This protocol poster presents study rationale, design, assessment framework, planned endpoints, and analysis approach.

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Disclosures

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For questions on this poster, contact Eisai Medical Information at ESI_Medinfo@eisai.com or 888-274-2378

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Abbreviations: AD (Alzheimer's disease); ADCS-MCI-ADL (Alzheimer's Disease Cooperative Study—Activities of Daily Living Scale for Mild Cognitive Impairment); APOE4 (apolipoprotein E4); ARIA (amyloid-related imaging abnormalities); CDR (Clinical Dementia Rating); CDR-SB (CDR—Sum of Boxes); CSF (cerebrospinal fluid); ePSOM (electronic Person-Specific Outcome Measure); EQ-5D-5L (EuroQol 5 Dimensions 5 Level); ICH (intracerebral hemorrhage); LPI (Last Patient In); MCI (mild cognitive impairment); MMSE (Mini-Mental State Examination); MRI (magnetic resonance imaging); OUG (optimal-use guidance); PET (positron emission tomography); p-tau217 (tau phosphorylated at threonine 217); QDRS (Quick Dementia Rating System); WPAI (Work Productivity and Activity Impairment); ZBI (Zarit Burden Interview).