Table 1. Inclusion/exclusion criteria in Clarity AD, and recommendations for lecanemab use in Singapore.

	Clarity study inclusion criteria[3]	**Recommendations for Singapore: Initiation of lecanemab treatment**
Diagnosis	• Diagnosis of MCI due to AD (global CDR 0.5) and mild AD dementia • CDR memory score 0.5−1.0 • Wechsler memory scale-IV logical memory test showing objective memory impairment below one standard deviation vs age-adjusted mean • MMSE ≥22 and ≤30 at screening and baseline	• Clinical diagnosis of MCI due to AD and mild AD dementia, based on clinicians' judgement + Singapore-validated cognitive tests, e.g. MMSE, MoCA, QDRS, CDR, others ○ MMSE score alone should not be used for identifying Singaporean patients with early dementia • Care should be taken in the evaluation of patients with lower literacy/education levels
Amyloid pathology	• Positive amyloid PET or CSF test	• Positive amyloid PET or CSF test
Age	• 50–90 years	• Based on the physician's judgement, if outside 50–90 years
BMI	• >17 and <35 kg/m^2 at screening	• Physician judgement if outside >17 and <35 kg/m^2 at screening
Concomitant medications	• If receiving an acetylcholinesterase inhibitor (donepezil, rivastigmine, galantamine) or memantine, or both, participants must be on a stable dose for at least 12 weeks prior to baseline • Unless otherwise stated, participants must have been on stable doses of all other (that is, non-AD-related) permitted concomitant medications for at least 4 weeks prior to baseline	• Other AD treatments approved for use in Singapore may be used concomitantly
Patient support	• Have an identified study partner	• Ensure the patient has a carer or family member to provide support during treatment • Ensure the patients and carer/family members understand the risks and benefits of treatment
	Exclusion criteria in Clarity AD	**Recommendations for Singapore: Considerations for exclusion or additional caution**
Additional causes of cognitive impairment	• Any neurological condition that may be contributing to cognitive impairment beyond that caused by the participant's AD	• Any medical, neurological, or mental health condition that may be a primary cause of cognitive impairment or non-AD MCI or dementia
MRI contra-indications	• Patients with contraindications to MRI scan were excluded from the study	• Patients with contraindications to MRI scan or unable to tolerate repeated MRI (e.g. claustrophobia)
Brain MRI findings	• >4 microhaemorrhages (≤10 mm at the greatest diameter) • A single macrohaemorrhage (>10 mm at greatest diameter) • An area of superficial siderosis • Evidence of vasogenic oedema • Multiple lacunar infarcts or stroke involving a major vascular territory • Severe small vessel disease, or other major intracranial pathology • Other clinically significant lesions on brain MRI indicative of a dementia diagnosis other than AD	• >4 microhaemorrhages (≤10 mm at the greatest diameter) • A single macrohaemorrhage (>10 mm at greatest diameter) • An area of superficial siderosis; evidence of vasogenic oedema • >2 lacunar infarcts or stroke involving a major vascular territory. Severe small vessel disease consistent with a Fazekas score of 3, or other major intracranial pathology • Brain MRI evidence of ABRA or CAA-ri • Other major intracranial pathology that may cause cognitive impairment, including contusions or gliosis due to past traumatic injuries, aneurysms, vascular malformations, infective lesions or brain tumours • Severe enlarged perivascular spaces in the centrum semiovale are not an absolute exclusion criterion but may be a pointer to underlying cerebral a myloid angiopathy and require heightened clinical vigilance

Table 1. Inclusion/exclusion criteria in Clarity AD, and recommendations for lecanemab use in Singapore. (Cont'd)

	Clarity study inclusion criteria[3]	Recommendations for Singapore: Initiation of lecanemab treatment
CV history	• History of TIA, stroke, seizures within 12 months of screening	• History of TIA, stroke, or seizures within 12 months of treatment initiation
Other psychiatric diagnoses	• Any psychiatric diagnosis or symptoms (e.g. hallucinations, major depression, or delusions) that could interfere with study procedures in the participant • Geriatric Depression Scale-15 score ≥8 at screening	• Any mental illness that interferes with comprehension of the requirements, potential benefits, and potential harms of treatment, and is considered by the physician to render the patient unable to comply with management requirements • Major depression that will interfere with comprehension of the requirements, potential benefit, and potential harms of treatment; patients for whom disclosure of a positive biomarker may trigger suicidal ideation. • Patients with less severe depression or whose depression resolves may be treatment candidates
Immunological diseases	• Any immunological disease that is not adequately controlled, or that requires treatment with immunoglobulins, systemic monoclonal antibodies (or derivatives of monoclonal antibodies), systemic immunosuppressants, or plasmapheresis during the study	• Any immunological disease that is not adequately controlled • Patients treated with other monoclonal antibodies can be considered for lecanemab treatment, based on the treating clinician's individualised risk assessment • For patients treated with other monoclonal antibodies, consultation with the treating physician is required
Bleeding disorders	• Participants with a bleeding disorder that is not under adequate control (including a platelet count <50,000 or INR >1.5 for participants who are not on anticoagulant treatment, for example, warfarin)	• Untreated bleeding disorder, platelet count <50,000 x 10^9/L, or INR >1.5 but not on anticoagulant
Anticoagulants	• Participants on anticoagulants should have their anticoagulant status optimised and have a stable dose for 4 weeks before screening	• Patients taking anticoagulants must be evaluated with additional caution • Consider consultation with neurologists/stroke specialists/cardiologists/ anticoagulant prescribing physicians to discuss suitability and risks of lecanemab treatment
Other medical conditions	• Any other medical conditions (e.g. cardiac, respiratory, gastrointestinal, renal disease) that are not stably and adequately controlled, or which could affect the participant's safety or interfere with the study assessments	• Any other medical condition with the potential to affect lecanemab treatment

ABRA: amyloid beta-related angiitis; AD: Alzheimer's disease; BMI: body mass index; CAA-ri: cerebral amyloid angiopathy-related inflammation; CDR: Clinical Dementia Rating; CSF: cerebrospinal fluid; CV: cardiovascular; INR: international normalised ratio; MCI: mild cognitive impairment; MMSE: Mini Mental State Examination; MoCA: Montreal Cognitive Assessment; MRI: magnetic resonance imaging; PET: positron emission tomography; QDRS: Quick Dementia Rating System; TIA: transient ischaemic attack; vs: versus

Adapted from van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in Early Alzheimer's Disease. N Engl J Med 2023;388:9-21.[3] Changes were made: inclusion and exclusion criteria were reorganised into a single table, and a column of recommendations for Singapore was added.

Superscript number: refer to REFERENCES