Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Clarity AD STUDY

Alzheimer Europe A.S.B.L. • R.C.S. Luxembourg F2773 • 14, rue Dicks • L-1417 Luxembourg
Tel.: +352-29 79 70 • Fax: +352-29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

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Clarity AD study

1. Study Information	
Name of the study	A study to confirm safety and efficacy of BAN2401 in participants with early Alzheimer's disease
Study sponsor	Eisai
Disease	Early Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	BAN2401
Administration	The drug will be administered via an intravenous infusion (an injection into the vein) every two weeks.
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants will be selected at random to either receive one of the following options: • An intravenous infusion of BAN2401 • An intravenous infusion of placebo (a substance which looks like the trial drug but has no study drug in it). Neither the participant, nor their study doctor will know if the person is receiving the investigational drug or the placebo.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the efficacy and safety of BAN2401 in people with early Alzheimer's disease.
How long will the treatment last?	• 18 months
What your involvement will entail?	• Participants will have to complete a PET brain scan or CSF examination (lumbar puncture) to see if they have amyloid pathology in their brain • Participants will be asked to complete a test that will assess their memory, orientation, judgment and problem solving,

	personal care and community affairs (this is a test called the Clinical Dementia Rating scale (CDR)). The study partner will also be asked to answer these questions. This will be performed at the beginning of the study and at several times during the 18-month study period • Participants and their partners will also need to complete some other tests to evaluate their thinking skills, behaviour, function and quality of life (e.g. ADAS-Cog, MMSE) • Participants will be evaluated for adverse effects (which refers to unfavourable signs, symptoms or diseases experienced during the study. These events may or may not be associated with the use of the drug tested in the study) • During the study participants will be asked to undertake regular brain scans (MRI scans) to ensure safety Further information on the procedures, tests and visits can be obtained from the study team.

4. Who can participate in this study?	
Who can participate in the study?	To take part in the study, participants must: • Be between 50 and 90 years old • Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or a diagnosis of mild Alzheimer's disease dementia according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a score of 0.5 to 1 in the Clinical Dementia Rating-Global Score (CDR) and CDR Memory Box score of 0.5 or greater at the beginning of the study • Have a score between 22 and 30 points in the MMSE test (a test about your general thinking skills) at the beginning of the study

	• Have evidence of a problem with memory as measured using the Wechsler Memory Scale IV Logical Memory test • Have evidence of abnormal accumulation of amyloid in the brain (determined either through CSF examination (lumbar puncture) or with the use of an amyloid PET scan) • Have a body mass index between 17 and 35 • If the person is taking approved symptomatic medication for dementia (i.e. donepezil, rivastigmine, galantamine or memantine) the dosing regimen must have been stable for at least 12 weeks prior to the baseline visit • If the person is taking other medications not related to their Alzheimer's disease, the dosing regimen must have been stable for at least 4 weeks prior to the baseline visit • Have someone available who can act as a study partner. This person should spend at least 8 hours per week with the study participant and be willing to support the participant for the duration of the study.
Who cannot participate in the study?	Exclusion criteria include: • Any neurological condition that may contribute to cognitive impairment above and beyond that caused by the participant's Alzheimer's disease • History of a stroke, transient ischemic attack or seizures within the past year • Any psychiatric diagnosis or symptoms (for example, hallucinations, major depression or delusion) that could interfere with study procedures • A score >=8 in the Geriatric Depression Scale (GDS) score (a test used to identify depression in the elderly)

	• Any contraindication to MRI scans (for instance due to having a cardiac pacemaker) • Evidence of clinically significant lesions on brain MRI that could indicate a dementia diagnosis other than Alzheimer's disease, or other significant pathological findings on brain MRI at screening • A medical condition that is unstable or not adequately controlled and could affect the participant's safety and/or could interfere with study assessments (e.g. cardiac, respiratory, gastrointestinal, renal or immunological disease, or bleeding disorder) • Participation in a clinical study with exposure to BAN2401 • Participation in other clinical studies involving anti-amyloid therapies, unless it can be confirmed that the participant only received placebo • Participation in other clinical studies involving new medications for Alzheimer's disease (other than anti-amyloid therapies) within 6 months prior to Screening, unless it can be confirmed that the participant only received placebo. The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.

5. Where and when will the study be conducted?	
European countries involved in the trial	• France • Germany • Italy • Spain

	• UK • Sweden
Estimated start date of recruitment	August 2019

6. Information for your doctor			
EudraCT Number:	2018-004739-58	**Clinicaltrials.gov identifier**	NCT03887455
Study contact information	esi_medinfo@eisai.com		
Link to full text	https://clinicaltrials.gov/ct2/show/study/NCT03887455		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on May 2020.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.