Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ALZ-801 STUDY

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ALZ-801 study

1. Study Information	
Name of the study	Biomarker Eêffects of ALZ-801 in APOE4 Carriers with early Alzheimer's disease
Study sponsor	Alzheon Inc.
Disease	Early Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	ALZ-801
Administration	A tablet taken orally once a day for two weeks and twice daily thereafter.
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Yes, all the participants will receive the same drug: a tablet of ALZ-801 (265mg)

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, safety and tolerability of ALZ-801 in people with early Alzheimer's disease who have the genotype most at risk for Alzheimer's disease (APOE4/4 or APOE3/4 genotype).
How long will the treatment last?	• About 2 years.
What your involvement will entail?	• During the study, participants will have to complete a PET brain scan or CSF examination (lumbar puncture) to see if they have amyloid pathology in their brain • Complete some laboratory tests (i.e. blood pressure, heart rate) to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study)

	• Complete a test that will assess memory, orientation, judgment and problem solving and personal care (this is a test called CDR) • Participants will also need to complete some other tests to evaluate their thinking skills, behaviour, function and quality of life (e.g. RAVLT, DSST, A-IADL, MMSE). Further information on the number of 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 50 to 80 years old • Have a diagnosis of probable Alzheimer's disease dementia or mild cognitive impairment due to Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a genotype at risk for Alzheimer's disease (who carry the ε4 Variant of the Apolipoprotein E Gene (APOE4/4 or APOE3/4)) • Have a score of 0.5 to 1 in the Clinical Dementia Rating-Global Score (CDR) and a score of 22 or above in the MMSE test (a test about your memory). This would suggest that the person has an impairment in their memory that is at a very mild stage • Have evidence of abnormal accumulation of amyloid in their brain (PET scan or CSF) • If the person is taking approved symptomatic medication for dementia (i.e. donepezil, rivastigmine or galantamine) the dosing regimen must have been stable.

Who cannot participate in the study?	Exclusion criteria include: • Brain scans showing significant abnormality • Any other type of neurological disease that is not Alzheimer's disease (e.g. epilepsy) • A current diagnosis of major depressive disorder • A current treatment of memantine. 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	• Czechia • Netherlands
Estimated start date of recruitment	September 2020

6. Information for your doctor			
EudraCT Number:	2020-000986-17	**Clinicaltrials.gov identifier**	NCT04693520
Study contact information	clinicaltrialsinfo@alzheon.com		
Link to full text	www.clinicaltrials.gov/ct2/show/NCT04693520		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on February 2021.
- ✓ This document has not 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.