Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

APOLLOE4 STUDY

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APOLLOE4 study

1. Study Information	
Name of the study	A Phase 3, multicenter, randomised, double-blind, placebo-controlled study of the efficacy, safety and biomarker effects of ALZ-801 in subjects with early Alzheimer's disease and APOE4/4 genotype
Study sponsor	Alzheon Inc.
Disease	Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	ALZ-801
Administration	Oral tablet in the morning and one tablet in the evening
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral tablet of ALZ-801 (265mg) twice daily • An oral capsule of placebo (inactive substance identical in appearance to the drug being tested) twice daily. Neither the participant nor their 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 safety and efficacy of ALZ-801 in people with early Alzheimer's disease with the APOE4/4 genotype
How long will the treatment last?	• 78 weeks (one year and a half)
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their functioning, behaviour and quality of life (i.e. tests like ADAS-Cog)

	• Complete some laboratory tests to evaluate the emergent adverse effects (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, personal care and community affairs (this is a test called CDR) • During the study, participants will have to undergo brain scan (MRI) and CSF examination (spinal tap). 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 mild cognitive impairment or mild dementia due to Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Carry on two copies of the ε4 allele of the apolipoprotein E gene (APOE4/4 homozygotes) • Have a score between 22 and 30 points in the MMSE test (a test about your memory) and a score of 0.5 to 1 in the Clinical Dementia Rating-Global Score (CDR). This would suggest that the person has an impairment in their memory that is at a mild stage • Have evidence of progressive memory loss over the last 12 months per investigator assessment.

Who cannot participate in the study?	Exclusion criteria include: • Participant who have a neurological condition other than Alzheimer's disease that in the opinion of the investigator would interfere with the conduct of the study • Currently taking memantine • History of suicidal behavior within one year prior to screening • History of seizures • History of cerebral infarct or transient ischemic attack within one year prior to screening. 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 • Spain • UK
Estimated start date of recruitment	June 2021

6. Information for your doctor			
EudraCT Number:	2020-005755-20	**Clinicaltrials.gov identifier**	NCT04770220
Study contact information	clinicaltrialsinfo@alzheon.com		
Link to full text	https://www.clinicaltrials.gov/ct2/show/NCT04770220		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on January 2022.
- ✓ 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.