Alzheimer Europe

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CLINICAL TRIALS WATCH

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ABATE STUDY

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ABATE study

1. Study Information	
Name of the study	A study to assess the effects of ACI-24.060 in Alzheimer's disease and in down syndrome
Study sponsor	AC Immune SA
Disease	Prodromal Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	ACI-24.060
Administration	The vaccine will be administered via a subcutaneous injection (an injection under the skin).
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants with prodromal Alzheimer's disease will be selected by chance to receive one of the following options: • A subcutaneous injection of ACI-24.060 • A subcutaneous injection of placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect). 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, tolerability and efficacy of ACI-24.060 in people with prodromal Alzheimer's disease and in people with down syndrome.
How long will the treatment last?	• 48 weeks for people with prodromal Alzheimer's disease
What your involvement will entail?	• During the study, participants will be asked to complete a test that will assess their suicidal ideation behaviour (this is a test called C-SSRS)

	• To complete some laboratory/biological tests (i.e. blood tests) to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • To complete other tests that will assess their cognition and memory (i.e. tests like CDR, RBANS, ADAS-Cog, mCRT, CANTAB-PAL) • Participants will be asked to undertake brain scans (PET, MRI) Further information on the procedures, tests and 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 with prodromal Alzheimer's disease must: • Be 50 to 75 years old • Have evidence of abnormal accumulation of amyloid in their brain (PET scan) • Have a score of 0.5 in the Clinical Dementia Rating-Global Score (CDR). This would suggest that the person has an impairment in its memory that is at a mild stage • 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 2 months prior to the baseline visit.
Who cannot participate in the study?	Exclusion criteria include: • A disease or condition that may interfere with the safety, tolerability and/or study assessments (e.g. moderate and/or

	severe untreated obstructive sleep apnea, clinically significant reduction in serum B12 or folate levels, clinically significant abnormalities of thyroid function, stroke, or other cerebrovascular conditions • Any alcohol or drug abuse • Concomitant or past history psychiatric or neurologic disorder other than those considered to be related to Alzheimer's disease (e.g. head injury with loss of consciousness, symptomatic stroke, Parkinson's disease, severe carotid occlusive disease, transient ischemic attacks hemorrhagic and/or non-hemorrhagic stroke) • Significant risk of suicide • Positive HIV test or Active hepatitis B and/or C • Ongoing participation in other clinical studies with any approved anti-amyloid passive immunotherapy for Alzheimer's disease • Previous treatment with ACI-24 or any immunotherapy against Alzheimer's disease • Use of symptomatic treatments of Alzheimer's disease (e.g. acetylcholinesterase inhibitors and memantine) if not on stable dose for at least 2 months before 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 country involved in the trial	• UK
Estimated start date of recruitment	June 2022

6. Information for your doctor			
EudraCT Number	2021-006195-17	**Clinicaltrials.gov identifier**	NCT05462106
Study contact information	clinicaltrials@acimmune.com +41 21 345 9121		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05462106		

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