Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

TOGETHER STUDY

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TOGETHER study

1. Study Information	
Name of the study	A study to test the efficacy, safety, and tolerability of bepranemab in patients with mild cognitive impairment or mild Alzheimer's disease
Study sponsor	UCB Biopharma SRL
Disease	Mild cognitive impairment or mild Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	Bepranemab (also called UCB0107)
Administration	The drug will be administered via an intravenous infusion (an injection into the vein) every four weeks
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 intravenous infusion of Bepranemab (Dose 1 or 2) • An intravenous infusion 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 Bepranemab in people with prodromal to mild Alzheimer's disease.
How long will the treatment last?	• 80 weeks (around 1.5 years)

	• After the 80-week period, study participants will be eligible to enter a 48-week open-label extension period with planned treatments of Bepranemab.
What your involvement will entail?	• During the study, participants will be asked to complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR) • To complete other tests that will assess their memory, suicidal behaviour, functioning, cognition improvement and activities of daily living (i.e. tests like ADAS-Cog, MMSE, C-SSRS) • To complete some laboratory/biological tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Participants will be asked to undertake brain scans (PET) to see changes in biomarkers in the brain. 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 prodromal/mild cognitive impairment due to Alzheimer's disease or a diagnosis of mild Alzheimer's disease 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 a score of above 20 in the MMSE test questionnaire test (a test about your memory). This

	would suggest that the person has an impairment in their memory that is at a mild stage • 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 study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration (at least 5 hours a week).
Who cannot participate in the study?	Exclusion criteria include: • Any evidence of a condition that may affect cognition other than Alzheimer's disease • Contraindication to PET imaging and MRI procedures • A disease or conditions that may interfere with the safety, tolerability and/or study assessments, or put the participant at special risk (e.g. psychiatric symptoms, auto-immune disease, inflammatory neurological disorders) • Any alcohol or drug abuse within the past two years • Participation in another clinical study within the past six months • Previous treatment with medication intended to treat a neurodegenerative disorder (other than Alzheimer's disease) within the past year • Treatment with atypical antipsychotics, opiates or opioids, benzodiazepines, barbiturates or hypnotics. 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	• Belgium • France • Germany • Italy • Netherlands • Poland • Spain • UK
Estimated start date of recruitment	June 2021

6. Information for your doctor			
EudraCT Number:	2020-005829-88	**Clinicaltrials.gov identifier**	NCT04867616
Study contact information	UCBCares@ucb.com		
Link to full text	https://clinicaltrials.gov/ct2/show/study/NCT04867616		

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

- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.