Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ACP-204-006 STUDY

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ACP-204-006 study

1. Study Information	
Name of the study	ACP-204 in adults with Alzheimer's disease psychosis
Study sponsor	ACADIA Pharmaceuticals
Disease	Alzheimer's disease with psychotic symptoms (hallucinations and delusions)
Phase	Phase II/III

2. Information about the drug that will be tested in the study	
Name of drug	ACP-204
Administration	The drug will be administered orally once daily at approximately the same time of day, with or without food.
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: • ACP-204 (30 mg) • ACP-204 (60 mg) • Placebo (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 efficacy and dose response of ACP-204 compared to placebo in adults with Alzheimer's disease with psychotic symptoms (hallucinations and delusions).
How long will the treatment last?	• 6 weeks • The study consists of a screening period (up to 42 days) following by the treatment period (6 weeks). Participants who

	complete the treatment period will then enter a safety follow-up period (30 days) or will have the option of participating in the long-term extension study.
What your involvement will entail?	• During the study, participants will be asked to complete some tests that will assess their cognition and psychotic symptoms including hallucinations and delusions • To undergo brain scans (CT, 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 must: • Be between 55 and 84 years old • Have a diagnosis of a possible or probable Alzheimer's disease according to the National Institute on Aging-Alzheimer's Association (NIA-AA) criteria • Have a diagnosis of psychosis in major or mild neurocognitive disorder according to the International Psychogeriatrics Association (IPA) • Have a score between 6 and 24 in the MMSE score. This would suggest that the person has an impairment in their memory that is at a mild to moderate stage • Have psychotic symptoms for at least 2 months • Live in a stable place of residence and there are no plans to change living arrangements • Have a study partner who has a sufficient contact with the participant, willing to participate in study procedures

	throughout the study duration • If the person is taking approved symptomatic medication for dementia (i.e. cholinesterase inhibitors), the dosing regimen must be on a stable dose.
Who cannot participate in the study?	Exclusion criteria include: • Living in hospice or requiring skilled nursing care • Have psychotic symptoms that are primarily attributable to delirium, substance abuse, or a medical or psychiatric condition other than dementia • A disease or medical condition that may interfere with the study assessments (i.e. cerebral amyloid angiopathy, epilepsy, central nervous system neoplasm, unexplained syncope, hypotension) • Heart condition that causes an irregular and often rapid heart rhythm (atrial fibrillation). 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 (active)	• Bulgaria • Czechia • France • Italy • Serbia • Spain
Estimated start date of recruitment	July 2024

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06159673	**EU CT Number**	2023-507325-42-00
Study contact information	Christine Murphy cmurphy@acadia-pharm.com		
Link to full text	https://clinicaltrials.gov/study/NCT06159673		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on November 2024.

- ✓ This document has been reviewed by the pharmaceutical company running this trial.

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