Alzheimer Europe

Making dementia a priority:
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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADEPT-1 STUDY

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ADEPT-1 study

1. Study Information	
Name of the study	A study to assess efficacy and safety of KarXT for the treatment of psychosis associated with Alzheimer's disease dementia
Study sponsor	Karuna Therapeutics
Disease	Psychosis associated with Alzheimer's Disease dementia
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	KarXT (combines xanomeline with trospium)
Administration	Oral capsules
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 capsule of KarXT. KarXT is flexible, starting with 20mg xanomeline/2mg trospium and increasing to a maximum of 66.7mg xanomeline/6,67mg trospium • An oral capsule 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 and efficacy of KarXT for the treatment of psychosis associated with Alzheimer's disease dementia.
How long will the treatment last?	• 38 weeks
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their illness, memory, psychosis (i.e. tests like CGI-S, 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 55 to 90 years old • Have a diagnosis of possible or probable Alzheimer's disease • Have results of brain scans (MRI, CT) consistent with the clinical diagnosis of Alzheimer's disease • Live at the same home or residential assisted-living facility for a minimum of six weeks before screening • Have a study partner who has a sufficient contact with the participant (10 hours/week), is willing to participate in study procedures throughout the study duration • History of psychotic symptoms (according to the International Psychogeriatric Association [IPA] criteria) during the past two months • Have a score of 4 or above in the Clinical Global Impressions-Severity (CGI-S) scale. This brief test provides to the clinician the patient's global functioning prior to and after initiating a study medication • Have moderate to severe delusions and hallucinations • Have a score between 8 and 22 in the MMSE test questionnaire test (a test about memory) • 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 6 months prior to screening and be maintained to a stable dose for the duration of the study • Have a body mass index between 18 to 40 kg/m^2 • Use highly effective contraception • Women of non-childbearing potential (surgically sterilized or post-menopausal).
Who cannot participate in the study?	Exclusion criteria include: • Psychotic symptoms that are primarily attributable to a condition other than Alzheimer's disease causing dementia (e.g., schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features) • History of major depressive episode with psychotic features during the last 12 months • A disease that may interfere with the safety or study assessments (e.g., pulmonary, hepatic, renal, hematologic, gastrointestinal, endocrine, immunologic, dermatologic, neurologic, or oncologic disease) • History of ischemic stroke within the last 12 or any evidence of hemorrhagic stroke • History of cerebral amyloid angiopathy, epilepsy, central nervous system neoplasm, unstable thyroid function, or unexplained syncope • HIV infection, cirrhosis, biliary duct abnormalities, hepatobiliary carcinoma, and/or active hepatic viral infections • Prior exposure to KarXT

	• Participation in another clinical study in which the participant received an experimental or investigational drug within the past 3 months or has participated in more than two clinical studies in the past year. 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	• Bulgaria • Croatia • Czech Republic • France • Germany • Italy • Serbia • Slovakia • Spain
Estimated start date of recruitment	March 2023

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT05511363	**EUCT Number**	2024-511740-11-00
Study contact information	medinfo@karunatx.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05511363 https://euclinicaltrials.eu/ctis-public/view/2024-511740-11-00		

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

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