Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADEPT-2 STUDY

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ADEPT-2 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
Study sponsor	Karuna Therapeutics
Disease	Psychosis associated with Alzheimer's disease
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: • Capsules of KarXT. KarXT is flexible, starting with 20mg xanomeline/2mg trospium and increasing to a maximum of 66.7mg xanomeline/6,67mg trospium • Capsules 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 in people who have mild to severe Alzheimer's disease with moderate to severe psychosis related to Alzheimer's disease.

How long will the treatment last?	• 14 weeks
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their memory, hallucination, delusion, agitation and psychosis (MMSE, NPI-C, CGI-S, CMAI). 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 90 years old • Have a diagnosis of possible or probable 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 or hallucinations

	• Have a score between 8 and 22 in the MMSE test questionnaire test (a test about memory).
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 • History of bipolar disorder, schizophrenia or schizoaffective disorder • A disease that may interfere with the safety or study assessments (e.g., pulmonary, hepatic, renal, hematologic, gastrointestinal, endocrine, immunologic, dermatologic, neurologic, cardiovascular, or oncologic disease) • 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 (active)	• Greece • Poland • Turkey

European countries that will be involved in the trial (planned)	• Belgium • Hungary • UK
Estimated start date of recruitment	April 2024

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT06126224
Study contact information	medinfo@karunatx.com
Link to full text	https://www.clinicaltrials.gov/study/NCT06126224

- ✓ 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 a member of the European Dementia Carers Working Group.