Alzheimer Europe

Making dementia a priority:
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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADEPT-3 STUDY

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ADEPT-3 study

1. Study Information	
Name of the study	Open-label extension study to assess the long-term safety and tolerability of KarXT in subjects with psychosis associated with Alzheimer's disease
Study sponsor	Bristol Myers Squibb
Disease	Psychosis associated with Alzheimer's disease
Phase	Phase III – Open Label Extension study

2. Information about the drug that will be tested in the study	
Name of drug	KarXT (combines xanomeline with trospium chloride)
Administration	Oral administration (capsules)
Is the drug already on the market for another medical condition?	KarXT is approved in the US and China for the treatment of schizophrenia in adults.
Will all participants receive the same drug?	All participants will receive capsules of KarXT (different doses)

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the long-term safety and tolerability of KarXT in people with psychosis associated with Alzheimer's disease.
How long will the treatment last?	• Up to 54 weeks.
What your involvement will entail?	• During the study, participants will be asked to complete laboratory and 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) 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 completed previous studies investigating KarXT (studies CN012-0026, CN012-0027 or CN012-0056) • If the participant needs to relocate to a nursing home facility, the medical team must approve his/her participation in the study • 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.
Who cannot participate in the study?	Exclusion criteria include: • A disease or a condition that may interfere with the safety or study assessments (e.g., pulmonary, hepatic, renal, hematologic, gastrointestinal, endocrine, immunologic, dermatologic, neurologic, cardiovascular, or oncologic disease • Participation in another clinical study or planning on participating in another clinical study during this study. 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)	• Belgium • Bulgaria • Croatia • Czechia • Italy • France • Poland • Romania

	• Serbia • Slovakia • Spain
European countries that will be involved in the trial (planned)	• Germany • Greece • Hungary • Israel • Portugal • Turkey
Estimated start date of recruitment	May 2024

6. Information for your doctor

Clinicaltrials.gov identifier	NCT05980949	**EUCT Number**	2023-504151-27-00
Study contact information	Clinical.Trials@bms.com		
Link to full text	https://clinicaltrials.gov/study/NCT05980949 https://euclinicaltrials.eu/ctis-public/view/2023-504151-27-00		
Study's website	https://www.bmsclinicaltrials.com/content/studyconnect/us/en/clinical-trials/NCT05980949.html		

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) in April 2026.

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

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