Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

MINDSET 1 STUDY

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MINDSET 1 study

1. Study Information	
Name of the study	A study to evaluate the efficacy and safety of KarXT + KarX-EC for cognitive impairment in Alzheimer's disease
Study sponsor	Bristol-Myers Squibb
Disease	Mild to moderate Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drugs	KarXT + KarX-EC KarXT is the main investigational medicine that combines two agents: xanomeline (a drug that stimulates certain brain receptors important for cognition and behaviour) and trospium (a compound that helps reduce side effects outside the brain). KarX-EC is an enteric-coated formulation of xanomeline, meaning the xanomeline is coated to be released in the intestine rather than the stomach, which can improve tolerability and the delivery profile.
Administration	Oral administration (capsules)
Is the drug already on the market for another medical condition?	KarXT is approved in the US, Israel and China for the treatment of schizophrenia in adults.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral administration of KarXT + KarX-EC • An oral administration 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 see if people with mild to moderate Alzheimer's disease taking KarXT+KarX-EC will help their thinking skills and daily functioning.
How long will the treatment last?	• 24 weeks for treatment
What your involvement will entail?	• During the study, participants and their caregivers will be asked to complete assessments that will assess the patient's memory, behaviour and activities of daily living (ADAS-Cog, ADCS-ADL, MMSE, NPI, CIBIC+) • Undergo brain scan (MRI) • Complete some laboratory tests and physical/neurological examination to evaluate the emergent adverse events (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 60 and 85 years old • Have a confirmed diagnosis of mild or moderate Alzheimer's disease, as defined by the National Institute on Aging and Alzheimer's Association (NIA-AA) criteria • Have a score between 12 and 22 in the MMSE test (a test about your thinking skills) • 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.

	• 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 12 weeks prior to the first study visit and not expected to change during study participation.
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., hepatic impairment, urinary retention, active biliary disease, moderate-severe renal impairment and unstable hypertension or tachycardia) • Severe psychiatric symptoms or psychiatric diagnoses such as major depression, schizoaffective disorder, or bipolar disorder • History of schizophrenia or other chronic psychosis • Patients who have been on an anti-amyloid therapy in the last 6 months. 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	• Croatia • Czechia • Germany • Greece • Italy • Poland • Romania • Spain

Estimated start date of recruitment	November 2025

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06976216	**EU CT Number**	2025-520746-30
Study contact information	Clinical.Trials@bms.com		
Link to full text	https://clinicaltrials.gov/study/NCT06976216 https://euclinicaltrials.eu/ctis-public/view/2025-520746-30-00		
Study's website	https://www.bmsclinicaltrials.com/us/en/clinical-trials/NCT06976216?id=NCT06976216		

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

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

- ✓ The pharmaceutical company running this trial has reviewed this document.