Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADAGIO 3 STUDY

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ADAGIO 3 study

1. Study Information	
Name of the study	A study to evaluate the long-term efficacy and safety of KarXT + KarX-EC for agitation associated with Alzheimer's disease
Study sponsor	Bristol-Myers Squibb
Disease	Agitation 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 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 and China for the treatment of schizophrenia in adults.
Will all participants receive the same drug?	All participants will receive one an oral administration of KarXT + KarX-EC.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of this study is to evaluate the long-term efficacy and safety of KarXT + KarX-EC in people with agitation related to Alzheimer's disease, who completed the ADAGIO-1 or ADAGIO-2 study.
How long will the treatment last?	• 26 weeks
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their memory, activities of daily living, agitation

	and aggression • Complete some laboratory tests to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Do physical examination and an electrocardiogram (ECG), which is a test that records the electrical activity of the heart. 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: • Have completed the ADAGIO-1 or ADAGIO-2 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 medical condition that may interfere with the safety and/or efficacy of the study (e.g. •untreated or unstable hypertension, clinically significant tachycardia, pulmonary, renal, hematologic, GI e.g. obstructive disorders, endocrine, immunologic, dermatologic, neurologic, or oncologic disease) • All grades of hepatic impairment • Risk of suicidal behaviour.

	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)	• Italy • Israel • Spain • Ukraine • UK
European countries that will be involved in the trial (planned)	• Bulgaria • Croatia • Czechia • France • Germany • Greece • Hungary • Poland • Portugal • Romania
Estimated start date of recruitment	April 2026

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06937229	**EU CT Number**	2024-519994-20-00
Study contact information	Clinical.Trials@bms.com		
Link to full text	https://clinicaltrials.gov/study/NCT06937229 https://euclinicaltrials.eu/ctis-public/view/2024-519994-20-00		
Study's website	https://www.bmsclinicaltrials.com/us/en/clinical-trials/NCT06937229?		

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