

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADAGIO 3 STUDY

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 | <p>KarXT + KarX-EC</p> <p>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).</p> <p>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.</p> |
| 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? | <ul style="list-style-type: none">• 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? | <ul style="list-style-type: none">• 26 weeks |
| What your involvement will entail? | <ul style="list-style-type: none">• During the study, participants will be asked to complete tests that will assess their memory, activities of daily living, agitation |

| | |
|--|--|
| | <p>and aggression</p> <ul style="list-style-type: none"> • 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. <p>Further information on the procedures, tests and number of visits can be obtained from the study team.</p> |
|--|--|

| | |
|---|--|
| <p>4. Who can participate in this study?</p> | |
| <p>Who can participate in the study?</p> | <p>To take part in the study, participants must:</p> <ul style="list-style-type: none"> • 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. |
| <p>Who cannot participate in the study?</p> | <p>Exclusion criteria include:</p> <ul style="list-style-type: none"> • 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) | <ul style="list-style-type: none"> • UK |
| European countries that will be involved in the trial (planned) | <ul style="list-style-type: none"> • Bulgaria • Croatia • Czechia • France • Germany • Greece • Hungary • Israel • Italy • Poland • Portugal • Romania • Spain • Ukraine |
| 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 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.