Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

SERENADA STUDY

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SERENADA study

1. Study Information	
Name of the study	Safety and efficacy of EXV-802 and EXV-801 in the treatment of agitation in Alzheimer's disease dementia
Study sponsor	Exciva GmbH
Disease	Agitation in Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drugs	EXV-802 (also called deraphan) + EXV-801 (also called deramciclane) EXV-802 is a fixed-dose combination of the approved drug dextromethorphan and the experimental drug EXV-801.
Administration	Oral administration (capsules twice a day)
Is the drugs already on the market for another medical condition?	No, however dextromethorphan, one of the components of EXV-802, is a cough suppressant used in many cough and cold medicines. Additionally, the combination medicine dextromethorphan and bupropion is approved to treat agitation linked to Alzheimer's disease dementia in US.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral administration of EXV-802 • An oral administration of EXV-801 • 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 this study is to evaluate the efficacy and safety of EXV-802 and EXV-801 in treatment of agitation in people with Alzheimer's disease dementia.

How long will the treatment last?	• 6 weeks
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their agitation and aggression (e.g., CMAI, CGI-S, NPI-C). 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 confirmed diagnosis of Alzheimer's disease dementia • Have a clinically significant, moderate/severe agitation • Have a diagnosis of agitation, according to the International Psychogeriatric Association (IPA) provisional definition of agitation • Have a study partner who has a sufficient contact with the participant (at least on four individual days for at least two hours per day), is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • Confirmed primary diagnosis of another form of dementia other than Alzheimer's disease dementia • Agitation symptoms that are primarily attributable to a condition other than Alzheimer's disease dementia • History of uncontrolled seizures or a history of epilepsy

	• Major medical illness or unstable medical condition. 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	• Czechia • Germany • Italy • Poland • Slovakia • Spain • UK
Estimated start date of recruitment	April 2026

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT07284472	**EU CT Number**	2024-517388-22-00
Study contact information	studies@exciva.com		
Link to full text	https://clinicaltrials.gov/study/NCT07284472 https://euclinicaltrials.eu/ctis-public/view/2024-517388-22-00		

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