Alzheimer Europe

Making dementia a priority:
changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Green Memory STUDY

Alzheimer Europe A.S.B.L. • R.C.S. Luxembourg F2773 • 14, rue Dicks • L-1417 Luxembourg
Tel.: +352-29 79 70 • Fax: +352-29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

Green Memory study

1. Study Information	
Name of the study	A study of Sodium Oligomannate (GV-971) in participants with mild to moderate Alzheimer's disease
Study sponsor	Green Valley (Shanghai) Pharmaceuticals Co., Ltd.
Disease	Mild to moderate Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	GV-971
Administration	The drug will be administered orally once daily.
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral dose of GV-971 • An oral dose 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 safety, tolerability and efficacy of GV-971 in mild to moderate Alzheimer's disease.
How long will the treatment last?	• Around 1.5 year (12 visits to the study center and up to 6 telephone calls with the study team)
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their cognition, functioning and (i.e. tests like ADCS-CGIC, ADAS-Cog)

	• During the study, participants will have to complete some laboratory/biological tests (i.e., blood samples, ECG, heart rate) • Participants will also need to complete some other questionnaires to evaluate their cognition, behaviour and function (e.g. NPI, MMSE) • Participants will be asked to undertake brain scans (MRI) to see changes in biomarkers in the brain. Further information on the 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 50 to 85 years old • Have a diagnosis of mild to moderate Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a history of cognitive and functional decline over at least 1 year • Have a score between11 and 24 in the MMSE test (a test about your memory. This would suggest that the person has an impairment in their memory that is at a mild to moderate stage • Have evidence of abnormal accumulation of amyloid in their brain (brain MRI scan) • Have a study partner who has a sufficient contact with the participant is willing to participate in study procedures throughout the study duration.

Who cannot participate in the study?	Exclusion criteria include: • Participant who have a diagnosis of a dementia-related central nervous system disease other than Alzheimer's disease • Brain scans showing significant abnormality • Major medical illness or unstable medical condition within the past six months • Use of approved symptomatic medication for dementia (i.e. donepezil, rivastigmine, galantamine or memantine) within the past 30 days. 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 • France • Netherlands • Poland
Estimated start date of recruitment	December 2021

6. Information for your doctor			
EudraCT Number:	2020-001755-41	**Clinicaltrials.gov identifier**	NCT04520412
Study contact information	greenmemory@shgvp.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04520412		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on January 2022.
- ✓ This document has not been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.