Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

SHINE STUDY

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SHINE study

1. Study Information	
Name of the study	A study to evaluate the safety and efficacy of CT1812 in subjects with mild to moderate Alzheimer's disease
Study sponsor	Cognition Therapeutics
Disease	Mild to moderate Alzheimer's disease
Phase	II

2. Information about the drug that will be tested in the study	
Name of drug	CT1812
Administration	Oral capsules 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: • 2 oral capsules of CT-812 (100 mg) • 2 oral capsules of CT-812 (300 mg) • 2 oral capsules 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 evaluate the safety and efficacy of CT-812 in people with mild to moderate Alzheimer's disease.
How long will the treatment last?	• Participants will take the investigational drug or the placebo during approximately 6 months • The total duration of participation in the study is approximately 8 months.
What your involvement will entail?	• During the study, participants will be asked to complete some laboratory and biological tests (i.e. blood test, urine test, electrocardiogram) to evaluate the emergent adverse effects

	(unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • To complete mental health questionnaires and physical examinations • Participants will have to undergo brain scan (MRI, PET) and lumbar punctures (CSF) to see if they have amyloid pathology in their brain. 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 50 and 85 years old • Have a diagnosis of mild to moderate Alzheimer's disease according to the 2011 NIA-AA criteria • Have a score between 18-26 points in the MMSE test (a test about a range of everyday mental skills). This would suggest that the person has an impairment that is still at a mild to moderate stage • Have evidence of abnormal accumulation of amyloid in their brain (as per results of PET brain scan or CSF) • 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: • Male/women of childbearing potential • Participants living in a continuous care nursing facility

	• A disease or condition that may interfere with the safety, tolerability and/or study assessments (e.g., major depression, schizophrenia, bipolar disorder, chronic liver disease, respiratory insufficiency, heart disease) • Diagnosis or history of other neurodegenerative diseases such as Parkinson's disease, Huntington disease, Lewy Bodies Dementia, Frontotemporal dementia, seizure disorder) • History of cancer within the last 3 years • Positive HIV test or history of hepatitis B and/or C. • Any alcohol or drug abuse. 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	• Czech Republic • Netherlands • Spain
Estimated start date of recruitment	January 2023

6. Information for your doctor			
EudraCT Number	2022-002326-27	**Clinicaltrials.gov identifier**	NCT03507790
Study contact information	awarsi@cogrx.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03507790		

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on August 2023.

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