Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

E2814-G000-103 STUDY

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E2814-G000-103 study

1. Study Information	
Name of the study	A study to assess safety and target engagement of E2814 in participants with mild to moderate cognitive impairment due to dominantly inherited Alzheimer's disease
Study sponsor	Eisai
Disease	Mild to moderate cognitive impairment due to dominantly inherited Alzheimer's disease (DIAD). This is form of dementia caused by rare, inherited gene mutations.
Phase	Phase I/II

2. Information about the drug that will be tested in the study	
Name of drug	E2814
Administration	The drug will be administered via an intravenous infusion (an injection into the vein).
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 intravenous infusion of E2814, at set intervals over 12 weeks in Phase Ib • An intravenous infusion of E2814, at set intervals over 96 weeks in Phase II.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to assess the safety and target engagement of E2814 in people with mild to moderate cognitive impairment due to dominantly inherited Alzheimer's disease (DIAD).
How long will the treatment last?	• Around 2.5 years

What your involvement will entail?	• During the study, participants will be asked to complete some laboratory/biological tests (i.e., blood, heart rate – ECG) to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR-SB) • Participants will be asked to undertake brain scans (MRI, PET) or lumbar punctures (CSF) 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 18 to 80 years old • Have a mutation positive associated with dominantly inherited Alzheimer's disease (i.e. presenilin 1 (PSEN1), amyloid precursor protein (APP), or presenilin 2 (PSEN2) gene) • Have a score between 5 and 12 in the Clinical Dementia Rating-Global Score (CDR). 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 (PET scan)

	• Able to undergo brain scans, lumbar puncture and complete all study-related testing and evaluations • 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: • A pregnancy or lactation for female participants • A disease or conditions that may interfere with the safety, tolerability and/or study assessments, or put the participant at special risk (e.g. psychiatric symptoms, auto-immune disease, inflammatory neurological disorders) • History of a stroke, transient ischemic attack or seizures within the past 12 months • Contraindication to PET brain scans • History of HIV or hepatitis B/C infection • Drug or alcohol abuse or dependence • Participation in other clinical studies involving any anti-amyloid therapies within the past six months • Current participation in a clinical study involving any anti-tau therapies. 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 country involved in the trial	• UK
Estimated start date of recruitment	June 2021

6. Information for your doctor			
EudraCT Number:	2020-005728-12	**Clinicaltrials.gov identifier**	NCT04971733
Study contact information	esi_medinfo@eisai.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04971733		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on March 2022.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.