Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ANAVEX®2-73-AD-004 STUDY

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ANAVEX®2-73-AD-004 study

1. Study Information	
Name of the study	ANAVEX2-73 for treatment of early Alzheimer's disease
Study sponsor	Anavex Life Sciences Corp.
Disease	Alzheimer's disease
Phase	Phase II/III

2. Information about the drug that will be tested in the study	
Name of drug	ANAVEX2-73 (also named blarcamesine)
Administration	Capsules
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 capsule of ANAVEX2-73 (high dose) once daily • An oral capsule of ANAVEX2-73 (mid dose) once daily • An oral capsule of placebo (inactive substance identical in appearance to the drug being tested) once daily. 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 ANAVEX2-73 on cognition and function for the treatment of early Alzheimer's disease.
How long will the treatment last?	• 48 weeks
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their functioning, behaviour and quality of life (i.e. tests like ADAS-Cog and ADCS-ADL)

	• Complete some laboratory tests 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) • Complete a questionnaire that assess reported sleep continuity (this is a test called RSCAQ) • During the study, participants will have to undergo brain scan (MRI) and CSF examination (spinal tap) to see if they have amyloid pathology in their 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 60 to 85 years old • Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or early stage mild dementia due to Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a diagnosis of Alzheimer's disease pathology by an appropriately qualified medical specialist (as per results of CSF examination (spinal tap) or amyloid PET scan) • Have a score between 20 and 28 points 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 stage

	• Have a study partner who has a sufficient contact with the participant (at least 10 hours per week) is willing to participate in study procedures throughout the study duration • Have no history of suicides in the past two years.
Who cannot participate in the study?	Exclusion criteria include: • Participant who have a progressive medical or neurological condition that in the opinion of the investigator would interfere with the conduct of the study • History of clinical hepatic dysfunction or indication of liver disease • History of cancer within the last 3 years • Contraindication to PET imaging, MRI procedures and lumbar puncture • Any results within the previous two years that showed a pathology inconsistent with a diagnosis of Alzheimer's disease • Have any contraindication to brain MRI scans (due to having prostheses, implants, a pacemaker or claustrophobia) • Alcohol or drug abuse • Any prior exposure to ANAVEX2-73. 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	• Germany • Netherlands • UK
Estimated start date of recruitment	June 2020

6. Information for your doctor			
EudraCT Number:	2019-003302-27	**Clinicaltrials.gov identifier**	NCT03790709
Study contact information	alz@anavex.com Moyra Coull +441908251492 mcoull@orphan-reach.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03790709		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on February 2021.
- ✓ This document has 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.