Alzheimer Europe

Making dementia a priority:
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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Polaris-AD STUDY

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Polaris-AD study

1. Study Information	
Name of the study	Phase 3, double-blind, randomised, placebo-controlled trial to evaluate the efficacy and safety of AR1001 in participants with early Alzheimer's disease
Study sponsor	AriBio Co
Disease	Early Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	AR1001
Administration	Oral tablet
Is the drug already on the market for another medical condition?	Yes. AR1001 is approved for erectile dysfunction, only in South Korea.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral tablet of AR1001 (30 mg) daily • An oral tablet of placebo daily (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 efficacy and safety of AR1001 for the treatment of participants with early Alzheimer's disease.
How long will the treatment last?	• 52 weeks • After the initial 52-week treatment phase, all participants can then enter an extension phase of 52 weeks and receive AR1001 (30 mg) daily.

What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their cognition, memory, and behaviour (i.e. tests like CDR-SB, MMSE) • To complete other tests that will assess their cognition, daily living activities and depression (i.e. ADAS-Cog, A-IADL-Q-SV, GDS) • During the study, participants will have to undergo brain scan or lumbar puncture (CSF). 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 55 to 90 years old • Have a clinical diagnosis of mild cognitive impairment or mild dementia consistent with Alzheimer's disease defined by stages 3/4 according to the National Institute on Aging and Alzheimer's Association (NIA-AA) • Have a score of 0.5 to 1 on the Clinical Dementia Rating Scale – Sum of Boxes (CDR-SB) and a score of 20 or above on the MMSE (a test about your memory). This would suggest that the person has an impairment in their memory that is at a mild stage • Have evidence of abnormal accumulation of amyloid in their brain (cerebrospinal fluid CSF or PET brain scan) • Have a study partner who has a sufficient contact with the participant and is willing to participate in study procedures throughout the study duration.

Who cannot participate in the study?	Exclusion criteria include: • A pregnancy or not practicing effective contraception for female participants • Any diagnosis of dementia or cognitive decline other than that related to Alzheimer's disease such as history of head trauma, frontotemporal dementia, Huntington Disease, Parkinson's disease, Dementia with Lewy Bodies • A disease or medical condition that may interfere with the study assessments and will make the participant unsuitable for participation in or completion of the trial procedures (i.e. delirium, psychosis, psychiatric disorder) • History of myocardial infarction, unstable angina, coronary artery disease, cancer or malignant tumor within 5 years, untreated thyroid disorder • Uncontrolled hypertension or hypotension • Participation in other clinical studies within the previous 30 days • Use of symptomatic treatments of Alzheimer’s disease (e.g. acetylcholinesterase inhibitors including donepezil, galantamine, rivastigmine) if not on stable dose for at least 3 months before screening • Treatment with memantine, anti-amyloid, anti-tau, or other investigational therapies for Alzheimer’s disease. 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 • Denmark • France • Germany • Italy • Netherlands • Poland • Spain • UK
Estimated start date of recruitment	June 2024

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT05531526	**EUCT Number**	2023-508306-15-00
Study contact information	Polaris-ad@aribiousa.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05531526 https://euclinicaltrials.eu/ctis-public/view/2023-508306-15-00		

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) in November 2024.

✓ 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.