Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

ADVANCE STUDY

Alzheimer Europe • R.C.S. LUXEMBOURG F2773 • 5 Heienhaff, L-1736 Senningerberg
Tel. +352 29 79 70 • Fax +352 29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

ADVANCE study

1. Study Information	
Name of the study	A Phase 2b, multicenter, randomised, placebo-controlled, double-blind study to assess the safety and efficacy of AD04 in patients with early Alzheimer's disease - ADVANCE
Study sponsor	ADvantage Therapeutics GmbH
Disease	Early Alzheimer's disease
Phase	Phase IIb

2. Information about the drug that will be tested in the study	
Name of drug	AD04
Administration	The drug will be administered via a subcutaneous injection (an injection under the skin).
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: • A subcutaneous injection of AD04 • A subcutaneous injection 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 efficacy and safety of AD04 in slowing progression of early Alzheimer's disease.
How long will the treatment last?	1 year
What your involvement will entail?	During the study, participants will be asked:

	• To complete some laboratory and biological tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • To do some blood and cerebrospinal fluid (CSF) tests to evaluate the effect of AV04 on analysis of biomarkers of Alzheimer's disease • To complete several tests that will assess memory, cognition, daily function and quality of life (i.e. tests like ADAS-Cog, ADCS-ADL, GST, CGIC, CDR-SB, QOL-AD) • To undergo brain scan (MRI). 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 probable Alzheimer's disease according to the National Institute of Neurological and Communicative Disorders and Stroke - Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria, integrating both clinical and neuropathological criteria • Have a score between 22-30 points in the MMSE test (a test about a range of everyday mental skills) • Have brain scan (MRI) results showing medial temporal lobe atrophy

	• Have results of a physical examination, including visual and auditory acuity within the acceptable range for the age group to allow neuropsychological testing • Provide written informed consent of study-related procedures and of genetic investigations • 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: • Known or suspected allergy, or history of anaphylaxis, to vaccines or their excipients • Any other cause of dementia or type of neurological disease that might cause the participant's cognitive impairment • A disease or condition that may interfere with the safety, tolerability and/or study assessments (e.g., autoimmune disease, autoinflammatory syndrome, immunological deficiency syndrome, HIV, cardiovascular disease, hepatic disease, malignant disease, kidney failure) • Any alcohol or drug abuse • Hemochromatosis • If the person is taking approved symptomatic medication for dementia (i.e. donepezil, galantamine) or anticholinergics, the dosing regimen must have been stable for at least three months prior to the screening visit

	• Current or anticipated use of immunosuppressive drugs (e.g. azathioprine, cyclosporine) or allergy immunotherapies • Have received or plan to receive any aluminium-adjuvanted vaccines within 14 days prior to any dose of study drug • A pregnancy or breast-feeding for female participants • Contraindication for MRI imaging and CSF collection • Have received any vaccine targeting Aβ or tau for the treatment of Alzheimer's disease. For all other experimental Alzheimer's disease drugs, participation in the active treatment phase within the past three months • Have participated in a clinical study within the last month. 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 (active)	• Austria
European countries that will be involved in the trial (planned)	• Bulgaria • France • Germany • Poland • Slovakia • UK
Estimated start date of recruitment	December 2023

6. Information for your doctor	
EudraCT Number	2022-003532-73
Study contact information	office@advantagetherapeutics.com
Link to full text	https://www.clinicaltrialsregister.eu/ctr-search/trial/2022-003532-73/BG

- ✓ The information contained in this document is based on information available on public registries (e.g. clinical trials register website) on February 2024.