Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

PROGRESS-AD STUDY

Alzheimer Europe A.S.B.L. • R.C.S. Luxembourg F2773 • 14, rue Dicks • L-1417 Luxembourg
Tel.: +352-29 79 70 • Fax: +352-29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

PROGRESS-AD study

1. Study Information	
Name of the study	Efficacy and safety of GSK4527226 in participants with early Alzheimer's disease
Study sponsor	GlaxoSmithKline
Disease	Early Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	GSK4527226 (also called AL101)
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 GSK4527226 (dose 1) • An intravenous infusion of GSK4527226 (dose 2) • An intravenous infusion 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 GSK4527226 in people with early Alzheimer's disease (including mild cognitive impairment and mild dementia due to Alzheimer's disease) of 2 dose levels of GSK4527226 compared to placebo.

How long will the treatment last?	• Around 1.5 years
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their cognition, function, memory and activities of daily living (i.e. CDR-SB, iADRS, ADAS-Cog14, ADCS-iADL, ADCOMS) • Participants will also undergo lumbar puncture (CSF) or brain scans (PET). 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 early Alzheimer's disease according to the 2018 National Institute on Aging and Alzheimer's Association (NIAAA) Research Framework • Have evidence of abnormal accumulation of amyloid in the brain (determined either through CSF examination (lumbar puncture) or with the use of an amyloid PET scan) • Have a score between 21 and 29 points in the MMSE test (a test about your general thinking skills) • Have a score of 0.5 to 1 in the Clinical Dementia Rating Global Score (CDR) and CDR Memory Box score of 0.5 or greater • If the person is taking approved symptomatic medication for dementia (i.e. donepezil, rivastigmine, galantamine or memantine), the dosing regimen must have been stable for at least 4 weeks prior to the baseline visit and not expected to change during study participation • Have a body weight between 45 and 120kg with a body mass index between 17 and 34.9 kg/m^2 • Use contraception

	• Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration and report on cognitive and functional abilities.
Who cannot participate in the study?	Exclusion criteria include: • A disease or condition that may interfere with the safety, tolerability and/or study assessments (e.g., major depression, schizophrenia, vascular disease, stroke, trauma) • High risk of suicide • Any alcohol or drug abuse within the past two years • Chronic active immune disorder requiring systemic immunosuppressive therapy within six months prior to baseline visit • History of cancer • Planned surgery during the study which requires general, spinal, or epidural anesthesia that would take place during the study • Pregnancy or breastfeeding for female participants 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	• Finland • France • Germany • Italy • Netherlands • Norway • Spain • Sweden

	• Turkey • UK
Estimated start date of recruitment	February 2024

6. Information for your doctor			
EudraCT Number	2023-505083-11-00	**Clinicaltrials.gov identifier**	NCT06079190
Study contact information	GSKClinicalSupportHD@gsk.com		
Link to full text	https://clinicaltrials.gov/study/NCT06079190		

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