Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

GV1001 STUDY

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GV1001 study

1. Study Information	
Name of the study	GV1001 subcutaneous for the treatment of mild to moderate Alzheimer's disease
Study sponsor	GemVax & Kael
Disease	Mild to moderate Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	GV1001
Administration	The drug will be administered via a subcutaneous injection (an injection under the skin) every week for 4 weeks followed by every second week through week 50.
Is the drug already on the market for another medical condition?	Yes – approved in Korea for pancreatic cancer
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • A subcutaneous injection of GV1001 (0.56 mg) • A subcutaneous injection of GV1001 (1.12 mg) • 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 safety and efficacy of GV1001 administered subcutaneously for the treatment of mild to moderate Alzheimer's disease.
How long will the treatment last?	• 52 weeks

	• The study will consist of a screening visit (up to 60 days prior to first dose), a 52-week double-blind treatment period, and an end-of-study visit 2 weeks after the last dose of study drug.
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) • Participants will be asked to do some blood and cerebrospinal fluid (CSF) tests to evaluate the effect of GV1001 on analysis of biomarkers of Alzheimer's disease • To complete several tests that will assess memory, cognition, activities of daily living, suicidal ideation and behaviour (i.e. tests or scales like MMSE, ADAS-Cog. CDR-SB, NPI, C-SSRS) • To undergo brain scan (PET) to see if they have amyloid pathology in their brain if no amyloid PET scan or CSF examination results are available). 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 55 and 85 years old • Have a diagnosis of probable Alzheimer's disease according to the NINCDS-ADRDA criteria • Have a score between 13-24 points in the MMSE test (a test about a range of everyday mental skills). This would suggest that the person has an impairment that is at mild to moderate stage

	• Have evidence of abnormal accumulation of amyloid in their brain (as per results of PET brain scan) • If the person is taking an approved anti-dementia medication (i.e. donepezil, rivastigmine, galantamine or memantine) the dosing regimen must have been stable for at least 12 weeks prior to the screening visit • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Be willing to use effective contraception for the duration of the trial and for a least 3 months after the last dose of study treatment • Female participant is eligible to participate if she is not pregnant and not breastfeeding.
Who cannot participate in the study?	Exclusion criteria include: • Any other cause of dementia or type of neurological disease (e.g. vascular dementia, cerebrovascular dementia, Parkinsonism, Huntington's disease, subdural hematoma, normal pressure hydrocephalus, brain tumor, Creutzfeldt-Jakob disease) • A disease or condition that may interfere with the safety, tolerability and/or study assessments (e.g., psychiatric symptoms, schizophrenia, renal impairment, severe liver dysfunction, cardiovascular disease, uncontrolled hypertension, uncontrolled diabetes, head trauma) • Abnormal laboratory results (e.g. Vitamin B12, folic acid, thyroid stimulating hormone (TSH)) that are thought to contribute to the severity of dementia or cause dementia

	• Any alcohol or drug abuse • A pregnancy or breast-feeding for female participants • Have participated in a recent clinical study within the last month • Have participated in a clinical study with aducanumab or are treated with aducanumab • Body weight ≤35 kg • Resides in a moderate to high dependency continuous care facility. 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)	• Spain
European countries that will be involved in the trial (planned)	• Finland • France • Italy • Netherlands • Poland • Portugal
Estimated start date of recruitment	March 2023

6. Information for your doctor			
EudraCT Number	2021-004809-40	**Clinicaltrials.gov identifier**	NCT05189210
Study contact information	clinical@gemvax.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05189210		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on April 2023.

- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.