Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

IL-2-AD STUDY

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IL-2-AD study

1. Study Information	
Name of the study	Therapeutic evaluation of low-dose IL-2-based immunomodulatory approach in patients with early Alzheimer's disease
Study sponsor	Centre Hospitalier St Anne
Disease	Early Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	IL-2 (PROLEUKIN ®)
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?	Yes - indicated for the treatment of adults with metastatic renal cell carcinoma and metastatic melanoma.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • A subcutaneous injection of IL-2 • 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 low-dose IL-2 in people with early Alzheimer's disease.
How long will the treatment last?	• The treatment consists of 21 cures of subcutaneous injections of either placebo or IL-2 • Participants will receive 5 consecutive injections during the induction phase which will be followed by a week break. During

	the maintenance phase a total of 16 injections will be administered weekly • The total duration of treatment for each participant is anticipated to be 18 weeks. Participants will be followed-up for 18 months after the first injection.
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their memory, functioning and cognition (i.e. tests like MMSE, CDR-SB, ADAS-Cog) • Participants will be asked to undertake brain scans (PET, MRI) • To complete some laboratory/biological tests (i.e. blood tests, blood pressure, weight, temperature, ECG) to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study). 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 with must: • Have >18 years old • Have an age of disease onset < 70 years • Have a diagnosis of Alzheimer's disease • Have evidence of abnormal accumulation of amyloid in their brain (MRI) • Have a score of 0.5 or 1 in the Clinical Dementia Rating-Global Score (CDR). This would suggest that the person has

	an impairment in its memory that is at a mild stage • If the person is taking antidepressant or approved symptomatic medication for dementia (i.e. donepezil, rivastigmine, galantamine or memantine) the dosing regimen must have been stable for at least 3 months prior to the baseline visit • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Have adequate vision and hearing for neuropsychological testing in the opinion of the investigator • Have a French social security number and be fluent in French.
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., psychiatric symptoms, epilepsy, renal dysfunction, Chronic hepatic diseases, clinically significant abnormalities of thyroid function) • Any alcohol or drug abuse • Women of childbearing potential • Diagnosis or history of other neurodegenerative diseases such as Parkinson's disease, Huntington disease, Lewy Bodies Dementia, Frontotemporal dementia) • Positive HIV test or Active hepatitis B and/or C.

	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	• France
Estimated start date of recruitment	October 2022

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT05468073
Study contact information	Khaoussou SYLLA +33 1 45 65 76 78 k.sylla@ghu-paris.fr Viviane AWASSI +33 1 45 65 84 86 v.awassi@ghu-paris.fr Simge OKSUM simge.oksum@ghu-paris.fr
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05468073

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on October 2022.

- ✓ This document has been reviewed by the pharmaceutical company running this trial.