Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

RoAD STUDY

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RoAD study

1. Study Information	
Name of the study	A Phase 2, randomised, prospective double-blind, single-center, placebo-controlled study to evaluate safety, tolerability, target engagement, and efficacy of PrimeC in patients with mild to moderate Alzheimer's disease
Study sponsor	NeuroSense Therapeutics Ltd
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	PrimeC
Administration	Two tablets twice daily (4 tablets a day)
Is the drug already on the market for another medical condition?	PrimeC is not on the market. PrimeC is a combination of Ciprofloxacin and Celecoxib administered in a unique novel extended-release formulation with unique doses of both compounds.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • Tablets of PrimeC • Tablets 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 PrimeC in people with mild to moderate Alzheimer's disease.
How long will the treatment last?	Around 1 year

What your involvement will entail?	During the study, participants will be asked: • To complete some laboratory, biological and physical tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study). Tests include blood tests and electrocardiogram (ECG), which is a test that records the electrical activity of the heart • To undergo lumbar puncture (CSF) • To complete several tests that will assess memory, cognition, daily function, quality of life and suicide rate (i.e. tests like ADAS-Cog, ADCS-ADL, CDR-SB, MMSE). 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 • Be evaluated by independent neurologist to be able to provide written informed consent form • Have a diagnosis of probable Alzheimer's disease according to the National Institute on Aging and Alzheimer's Association • Have a score between 18-24 points in the MMSE test (a test about a range of everyday mental skills) • If the person is treating with rivastigmine, donepezil, galantamine, memantine or donezepil, the dosing regimen must have been stable for a least 30 days before the enrolment

	• If the person is treating with aducanumab or lecanemab, the dosing regimen must have been stable for a least 3 months before the enrolment • Have a Body Mass Index (BMI) between 18 and 30 • Have a study partner who has a sufficient contact with the participant (at least 10 hours per week), is willing to participate in all study procedures throughout the study duration • Have brain scan results (CT or MRI) within 12 months before the enrolment to the study, which could explain the cognitive impairment, except for brain atrophy or white matter hyperintensities which can be observed in people with Alzheimer's disease • To be tested with CT or MRI within 3 months before the lumbar puncture • To be found with the presence of pTau 181 in CSF at screening • Not be at childbearing potential for female (at least 1 year postmenopausal or surgical contraception).
Who cannot participate in the study?	Exclusion criteria include: • Any significant neurologic or medical disorders other than Alzheimer's disease, which might be the cause of the existing cognitive deficit (e.g. other neurodegenerative disease, seizures, Huntington's disease, Amyotrophic lateral sclerosis, multiple sclerosis, HIV) • A disease or condition that may interfere with the safety, tolerability and/or study assessments (e.g., cardiac, pulmonary, musculoskeletal, psychiatric illness, chronic

	asthma, uncontrolled diabetes mellitus) • Stroke or Transient Ischemic Attack (TIA) within 6 months of screening visit • Major depressive disorder requiring hospitalization within the previous 90 days before screening • Any contraindication to conduct lumber puncture • History of severe head trauma, clinical significant peripheral neuropathy, myasthenia gravis or myasthenic syndrome, psychiatric disorders, significant impairment of renal function, myocardial infarction • Suicidal ideation and behaviour • Serum B12 clinically significantly below the lower limit of normal at screening • Aortic aneurysms, heart valve regurgitation/incompetence, epilepsy, impaired hepatic function • Known predisposition to tendinitis • Participants who take tizanidine • If the participant is taking antipsychotic, antidepressant, antianxiety or any other psychotropic before enrolment to the study there was no dose change 30 days before enrolment • Any contraindication for ciprofloxacin and celecoxib.

	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	• Israel
Estimated start date of recruitment	January 2024

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT06185543
Study contact information	Ferenc Tracik +49 1577 7721200 Ferenc@neurosense-tx.com
Link to full text	https://clinicaltrials.gov/study/NCT06185543

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

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