Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

T-817MA STUDY

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T-817MA study

1. Study Information	
Name of the study	Efficacy and Safety of T-817MA in patients with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease
Study sponsor	FUJIFILM Toyama Chemical Co., Ltd.
Disease	Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	T-817MA (also named Edonerpic)
Administration	Tablet
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 oral tablet of T-817MA (224mg) once daily for first 4 weeks and then two oral tablets of T-817MA (448mg) for the following weeks • An oral tablet of placebo (inactive substance identical in appearance to the drug being tested). 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 T-817MA in people with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease.
How long will the treatment last?	• Around 1.5 year (5 visits)
What your involvement will entail?	• During the study, participants will have to undergo brain scan (MRI) and CSF examination (spinal tap) to see if they have amyloid pathology in their brain

	• Complete a memory test (MMSE) to assess cognitive function • Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR) • Perform an electroencephalogram (this is a test or record of brain electrical activity using electrodes placed along the scalp) • Complete some laboratory tests 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 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 50 to 80 years old • Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have evidence of abnormal accumulation of amyloid and p-tau181 in their brain (as per results of CSF examination (spinal tap)) • Have a score between 24 and 30 points in the MMSE test (a test about your memory). This would suggest that the person has an impairment in their memory that is at a very mild stage • Be post-menopausal or permanently sterilized for female participants

	• Be required to use highly effective methods of contraception during the study and until 104 days after the last dose for male participants • If the person is taking acetylcholinesterase inhibitors as an approved anti-dementia medication (i.e. donepezil, rivastigmine, galantamine) the dosing regimen must have been stable for at least 3 months 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.
Who cannot participate in the study?	Exclusion criteria include: • Contraindication to PET imaging, MRI procedures and lumbar puncture • Any results within the previous two years that showed a pathology inconsistent with a diagnosis of Alzheimer's disease • A current treatment of memantine. 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	• Czech Republic • Germany • Hungary • Netherlands • Spain • UK
Estimated start date of recruitment	December 2019

6. Information for your doctor			
EudraCT Number:	2018-003567-66	**Clinicaltrials.gov identifier**	NCT04191486
Study contact information	Larah de Groot +31 30 656 9186 larah.degroot@juliusclinical.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04191486		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on May 2020.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.