Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

TargetTau-1 STUDY

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TargetTau-1 study

1. Study Information	
Name of the study	Study to evaluate the efficacy, safety, and tolerability of an anti-MTBR Tau monoclonal antibody (BMS-986446) in participants with early Alzheimer's disease
Study sponsor	Bristol-Myers Squibb
Disease	Early Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	BMS-986446
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: • BMS-986446 (Dose A) • BMS-986446 (Dose B) • 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 assess the effectiveness, safety, and tolerability of BMS-986446 in people with early Alzheimer's disease.
How long will the treatment last?	• Around 1.5 years

What your involvement will entail?	• During the study, participants will be asked to complete some tests that will assess their cognition, function, memory and daily living activities (i.e. CDR-SB, ADAS-Cog14, ADCS-iADL, iADRS, MMSE) • To undergo 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 80 years old • Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease dementia according to the National Institute on Aging and the Alzheimer's Association (NIA-AA) core clinical criteria • Have evidence of Alzheimer's disease pathology • Have objective impairment in episodic memory (indicated by a low score on a standard memory test scale named the Wechsler Memory Scale IV-Logical Memory Subtest II (WMS-IV LM II)) • Have a score between 22-30 points on the recognised memory test MMSE.
Who cannot participate in the study?	Exclusion criteria include: • Any evidence of a condition that may affect cognition other than Alzheimer's disease • Contraindications to brain imaging (PET, MRI) such as having a pacemaker, artificial heart valves, or other metal foreign body; claustrophobia that cannot be medically

	managed • Any serious disease or condition that could, in the opinion of the investigator, interfere with the safety, tolerability and/or study assessments (e.g., major depression, schizophrenia, vascular disease, stroke, trauma) • Mild or severe depression (a score greater than or equal to 8 in the Geriatric Depression Scale (GDS)). 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 that are involved in the trial (active)	• Belgium • Spain • Sweden • UK
European countries that will be involved in the trial (planned)	• France • Netherlands
Estimated start date of recruitment	October 2024

6. Information for your doctor

Clinicaltrials.gov identifier	NCT06268886	**EU CT Number**	2023-504840-32-00
Study contact information	Clinical.Trials@bms.com		
Link to full text	https://clinicaltrials.gov/study/NCT06268886 https://euclinicaltrials.eu/ctis-public/view/2023-504840-32-00		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) in May 2025.

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

- ✓ The pharmaceutical company running this trial has reviewed this document.