Alzheimer Europe

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CLINICAL TRIALS WATCH

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CELIA STUDY

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CELIA study

1. Study Information	
Name of the study	A randomised, double-blind, placebo-controlled, parallel-group study to assess the efficacy, safety, and tolerability of BIIB080 in subjects with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease dementia
Study sponsor	Biogen
Disease	Mild cognitive impairment or mild dementia due to Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	BIIB080
Administration	Cerebrospinal fluid injection. Cerebrospinal fluid is the fluid around the spinal cord.
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: • A low dose of BIIB080 • A high dose of BIIB080 • 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 main question researchers are trying to answer is if BIIB080 can slow the worsening of Alzheimer's disease more than placebo. It will focus on what dose of BIIB080 slows worsening of Alzheimer's disease the most. To help answer this question,

	researchers will use the Clinical Dementia Rating-Sum of Boxes, also known as the CDR-SB • Clinicians use the CDR-SB to measure several categories of dementia symptoms • The results for each category are added together for a total score. Lower scores are better • Researchers will also learn about the safety of BIIB080.
How long will the treatment last?	• The study will be split into two parts. The 1st part is the Placebo-Controlled Period. The 2nd part is the Long-Term Extension Period • After screening, participants will first receive either BIIB080 (low or high dose) or a placebo once every 12 weeks or 24 weeks • After 76 weeks of treatment in the Placebo-Controlled Period, eligible participants will move onto the Extension Treatment period, which will last 96 weeks • In the extension period, participants who received placebo will be switched to high dose BIIB080 every 12 or 24 weeks • Participants may be in the study for up to 201 weeks, or about 4 years. This includes the screening and follow-up periods. • After the screening period, most participants will visit the clinic every 6 weeks.
What your involvement will entail?	• During the study, participants will be asked to complete tests that will assess their cognition, memory and orientation (i.e. CDR, RBANS, MMSE) • Participants will also undergo lumbar puncture (CSF) or 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 Placebo-Controlled Period, key inclusion criteria for participants are:
	
	• Be between 50 and 80 years old
	• Have a diagnosis for mild cognitive impairment due to Alzheimer's disease (stage 3) or mild Alzheimer's disease dementia (stage 4) according to the National Institute on Aging at National Institutes of Health and the Alzheimer's Association (NIA-AA) and must have the following at screening visit 1:
	
	  ○ Have a Delayed Memory Index score of ≤85 in the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), indicative of objective evidence of memory impairment
	  ○ Have a score of 0.5 for Mild Cognitive Impairment due to Alzheimer's disease or 1 for mild Alzheimer's disease dementia in the Clinical Dementia Rating-Global Score (CDR)
	  ○ Have a score of 21-30 (inclusive) points in the MMSE test (a test about a range of everyday mental skills)
	  ○ Have a score of ≥0.5 in the CDR Memory Box
	• Have evidence of amyloid pathology as measured by positive emission tomography (PET) or cerebrospinal fluid (CSF) sampling
	• Have a study partner who has frequent and sufficient contact with the participant (at least 10 hours/week) to be able to provide accurate information about the participant's cognitive and functional abilities.
	
	To take part in the Long-Term Extension Period, key inclusion criteria for participants are:
	
	• Have completed the placebo-controlled period of the study, including the Week 76 visit
	• Have taken at least 5 doses of BIIB080 or placebo during the placebo-controlled period

	• Have a MMSE score >10 at the Week 76 visit • Have a study partner who has frequent and sufficient contact with the participant (at least 10 hours/week) to be able to provide accurate information about the participant's cognitive and functional abilities.
Who cannot participate in the study?	Exclusion criteria for the Placebo-controlled period include: • Known allergy to BIIB080 or a history of hypersensitivity to any of the inactive ingredients in the drug product • Previous participation in previous studies with BIIB080 • Use of symptomatic medication for dementia (i.e. donepezil, rivastigmine, galantamine, tacrine or memantine) at doses that have not been stable for at least 8 weeks prior to screening visit 1 and during the screening period up to Day 1 • Prior participation in any active or passive immunotherapy study targeting Aβ or tau, unless documentation of receipt of placebo is available • Contraindications to having a MRI brain scan (e.g., pacemaker, MRI-incompatible aneurysm clips, artificial heart valves, or other metal foreign body, claustrophobia that cannot be medically managed) • Any vaccination given within 10 days prior to Day 1 (COVID-19 vaccinations are allowed during the study, as well as other types of immunisation/vaccination/booster, except during the 10 days before and after clinic visits) • Current enrolment or a plan to enrol in any interventional clinical study in which an investigational treatment or approved therapy for investigational use is administered within 52 weeks prior to the Baseline Visit. Key exclusion criteria for Long-Term Extension Period includes: • Any medical or psychiatric contraindication or clinically significant abnormality that, in the opinion of the Investigator, will substantially increase the risk associated

	with the participant's enrolment in and completion of the study. 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	• Belgium • Czechia • Denmark • Finland • France • Germany • Italy • Netherlands • Poland • Spain • Sweden • Switzerland • UK
Estimated start date of recruitment	August 2022

6. Information for your doctor			
EudraCT Number	2022-501644-15	**Clinicaltrials.gov identifier**	NCT05399888
Study contact information	clinicaltrials@biogen.com		
Link to full text	https://clinicaltrials.gov/study/NCT05399888		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on April 2024.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.