Alzheimer Europe

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CLINICAL TRIALS WATCH

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EMBARK STUDY

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EMBARK study

1. Study Information	
Name of the study	A study to evaluate safety and tolerability of aducanumab in participants with Alzheimer's disease who had previously participated in the aducanumab studies 221AD103, 221AD301, 221AD302 and 221AD205
Study sponsor	Biogen
Disease	Alzheimer's disease
Phase	Phase III – Extension study (enrolling by invitation)

2. Information about the drug that will be tested in the study	
Name of drug	Aducanumab (BIIB037)
Administration	The drug will be administered via an intravenous infusion (an injection into the vein) every four weeks.
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Yes, all the participants will be administered 10mg/kg of aducanumab by intravenous (IV) infusions every four weeks for a total duration of 100 weeks.

3. Information about participating in the trial	
What are the researchers trying to find out?	The purpose of the study is to evaluate the long-term safety and tolerability of aducanumab in participants who had previously participated in aducanumab studies and received aducanumab or placebo (a substance identical in appearance to the drug being tested with no active therapeutic effect).
How long will the treatment last?	Each participant will receive aducanumab for 100 weeks.
What your involvement will entail?	• Participants will be also requested to complete some tests to evaluate the potential side effects (it refers to unfavourable

	signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • During the study participants will be asked to undertake brain scans (i.e. MRI scans) • Participants will be also requested to provide blood samples for laboratory tests. Further information on the procedures, tests and visits can be obtained from the sponsor.

4. Who can participate in this study?	
Who can participate in the study?	To take part in the study, participants must: • Have participated in a previous aducanumab clinical study at the time of the announcement of early termination including - PRIME study (221AD103) - ENGAGE study (221AD301) - EMERGE study (221AD302) - EVOLVE study (221AD205) • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration and report on cognitive and functional abilities.
Who cannot participate in the study?	Exclusion criteria include: • Any medical or neurological condition (other than Alzheimer's Disease) that might be a contributing cause of the subject's cognitive impairment. • Stroke or any unexplained loss of consciousness within 1 year prior to screening.

	• Clinically significant unstable psychiatric illness in past 6 months. • History of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within 1 year prior to screening. • A seizure event that occurred after stopping the feeder study and before Screening for this study. • Evidence of impaired liver function as shown by an abnormal liver function profile at screening. • History of or known seropositivity for HIV (having a positive result of a blood test for antibodies to HIV) • Clinically significant systemic illness or serious infection within 30 days prior to or during screening. • Contraindications (a condition which makes a particular treatment or procedure potentially risky to the person) to having a brain magnetic resonance imaging (MRI). 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	• Austria • Belgium • Denmark • Finland • France • Germany • Italy • Netherlands

	• Poland • Portugal • Spain • Sweden • Switzerland • UK
Estimated start date of recruitment	June 2020

6. Information for your doctor			
EudraCT Number:	2019-004368-22	**Clinicaltrials.gov identifier**	NCT04241068
Study contact information	clinicaltrials@biogen.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04241068		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on June 2021.
- ✓ 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.