Alzheimer Europe

Making dementia a priority:
changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

GRADUATION STUDY

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GRADUATION study

1. Study Information	
Name of the study	A study to evaluate the pharmacodynamic effects of once weekly administration of Gantenerumab in participants with early Alzheimer's disease
Study sponsor	Hoffmann-La Roche
Disease	Early Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	Gantenerumab
Administration	The drug will be administered via a subcutaneous injection (an injection under the skin).
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	All Participants will receive a subcutaneous injection of Gantenerumab at a dose of: • 120 mg every 4 weeks for 12 weeks, followed by • 255 mg every 4 weeks for 12 weeks, and • 255 mg every 2 weeks for another 12 weeks, followed by the target dose • 255 mg once weekly for up to Week 103.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the effects of once weekly administration of Gantenerumab in participants with early (prodromal to mild) Alzheimer's disease.
How long will the treatment last?	• Around 2 years.
What your involvement will entail?	• During the study, participants will have to undergo brain scan (PET, MRI) to see if they have amyloid pathology in their brain

	• Complete a test to evaluate suicide risk (this test is called the Columbia-Suicide Severity Rating Scale) • Participants will be asked to complete some laboratory tests to evaluate the side effects (it refers to 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 90 years old • Have results of brain scans consistent with the clinical diagnosis of Alzheimer's disease • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Agree to undergo brain scans (MRI, PET) • Have a score of 22 or above in the MMSE test (a test about a range of everyday mental skills), between 0.5 and 1 in the Clinical Dementia Rating-Global Score (CDR-GS) and >/=0.5 on the Clinical Dementia Rating global score (CDR-GS). This would suggest that the person has an impairment that is at prodromal or mild stage • If the person is taking treatment for Alzheimer's disease, the dosing regimen must have been stable within the past 3 months • Agree not to participate in other research studies for the duration of this trial

	• Females must be surgically sterile (e.g. have undergone surgical operation, be post-menopausal, or use adequate contraception).
Who cannot participate in the study?	Exclusion criteria include: • Ongoing neurological disorders, major psychiatric disorder, systematic vascular disease, intracranial mass or medical condition that may interfere with the safety or study assessments or could be the cause of the cognitive impairment • History of schizophrenia (mental disorder which affects how a person thinks, feels and acts) or other depressive disorder • History or presence of any stroke with clinical symptoms within the past 12 months • Suicidal behaviour in the opinion of the investigator • Alcohol or drug abuse or dependence in the past two years. 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 (active)	• Belgium • Germany • Poland • UK
European countries that will be involved in the trial (planned)	• France • Italy • Spain
Estimated start date of recruitment	End 2020

6. Information for your doctor			
EudraCT Number:	2020-001384-87	**Clinicaltrials.gov identifier**	NCT04592341
Study contact information	global-roche-genentech-trials@gene.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04592341		

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