ForPatients
by Roche

Alzheimer's Disease (AD)

A Study of Gantenerumab in Participants With Mild Alzheimer Disease

Trial Status	Trial Runs In	Trial Identifier
Completed	22 Countries	NCT02051608 2013-003390-95 WN28745

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Efficacy and Safety Study of Gantenerumab in Patients With Mild Alzheimer's Disease; Part II: Open-Label Extension For Participating Patients

Trial Summary:

Part 1 is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study will evaluate the efficacy and safety of gantenerumab in participants with mild Alzheimer disease. Participants will be randomized to receive either gantenerumab subcutaneously every 4 weeks or placebo subcutaneously every 4 weeks. Approved Alzheimer medication is allowed if on stable dose for 3 months prior to screening. Part 2 is an open-label extension (OLE). A positron emission tomography (PET) imaging substudy will be conducted within the main study. Eligible participants who provide separate informed consent will undergo PET imaging scans using the radioligand florbetapir as a pharmacodynamic measure of changes in brain amyloid load over time.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years & # 90 Years	No

Inclusion Criteria:

- Clinical diagnosis of probable mild Alzheimer disease (AD) based on National Institute of Neurological and Communicative Disorders and Stroke/Alzheimer's Disease and Related Disorders Association (NINCDS/ADRDA) criteria or major NCD based whether or not receiving AD approved medication
- Cerebral spinal fluid (CSF) result consistent with the presence of amyloid pathology
- Availability of a person ('caregiver') who in the investigator's judgment has frequent and sufficient contact with the participant, and is able to provide accurate information regarding the participant's cognitive and functional abilities
- Fluency in the language of the tests used at the study site
- Willingness and ability to complete all aspects of the study
- Adequate visual and auditory acuity, in the investigator's judgment, sufficient to perform the neuropsychological testing (eye glasses and hearing aids are permitted)
- If currently receiving approved medications for AD, the dosing regimen must have been stable for 3 months prior to screening
- Agreement not to participate in other research studies for the duration of this trial and its associated substudies

PART 2 - All participants who have been randomized and are actively participating in the study are eligible for Part 2

Exclusion Criteria:

- Dementia or neurocognitive disorder (NCD) due to a condition other than AD, including, but not limited to, frontotemporal dementia, Parkinson disease, dementia with Lewy bodies, Huntington disease, or vascular dementia
- History or presence of clinically evident vascular disease potentially affecting the brain that in the opinion of the investigator has the potential to affect cognitive function
- History or presence of stroke within the past 2 years or documented history of transient ischemic attack within the last 12 months
- History or presence of systemic autoimmune disorders potentially causing progressive neurologic disease with associated cognitive deficits
- History of schizophrenia, schizoaffective disorder, or bipolar disorder
- Alcohol and/or substance use disorder (according to the DSM-5) within the past 2 years (nicotine use is allowed)
- History or presence of atrial fibrillation
- Within the last 2 years, unstable or clinically significant cardiovascular disease (e.g., myocardial infarction, angina pectoris, cardiac failure New York Heart Association Class II or higher)
- Uncontrolled hypertension
- Chronic kidney disease
- Impaired hepatic function

PET imaging substudy, in addition to above:

- Prior participation in other research study or clinical care within the last year such that the total radiation exposure would exceed the local or national annual limits

Part 2 Participants who have been discontinued from the study