ForPatients
by Roche

Alzheimer's Disease (AD)

A Study of Gantenerumab in Participants With Prodromal Alzheimer's Disease

Trial Status	Trial Runs In	Trial Identifier
Completed	24 Countries	NCT01224106 2010-019895-66 WN25203

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:

Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Two Year Study to Evaluate the Effect of Subcutaneous RO4909832 on Cognition and Function in Prodromal Alzheimer's Disease With Option for up to an Additional Two Years of Treatment and an Open-Label Extension With Active Study Treatment

Trial Summary:

This multi-center, randomized, double-blind, placebo-controlled parallel-group study will evaluate the effect of gantenerumab (RO4909832) on cognition and functioning and the safety and pharmacokinetics in participants with prodromal Alzheimer's Disease. Participants will be randomized to receive subcutaneous (SC) injections of either gantenerumab or placebo. Participants who consent to be part of the sub study will undergo positron emission tomography (PET) scanning to assess brain amyloid. The anticipated time on study treatment is 104 weeks in Part 1, with an option for an additional up to 2 years of treatment in Part 2, followed by an open-label extension (Part 3) until July 2020. The dosing for Parts 1 and 2 was stopped after a planned futility interim analysis showed a low probability of meeting the primary outcome measure with the doses studied. The study has converted to open-label to investigate higher gantenerumab doses.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT01224106 2010-019895-66 WN25203
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#50 Years & # 85 Years	No

Inclusion Criteria:

- Adult participants, 50-85 years of age
- Participants with prodromal Alzheimer's disease who are not receiving memantine or cholinesterase inhibitors
- Has a study partner who in the investigator's judgement has frequent and sufficient contact with the participant as to be able to provide accurate information as to the participant's cognitive and functional abilities, who agrees to provide information at clinic visits which require partner input for scale completion
- Has had sufficient education or work experience to exclude mental retardation
- Study partner has noticed a recent gradual decrease in participant's memory (over the last 12 months), which the participant may or may not be aware of
- Screening Mini Mental State Exam (MMSE) score of 24 or above

Additional inclusion criteria for sub study:

- Able and willing to travel to PET imaging center and complete the planned scanning sessions
- Past and planned exposure to ionizing radiation not exceeding safe and permissible levels

Exclusion Criteria:

- Other prior or current neurologic or medical disorder which may currently or during the course of the study impair cognition or psychiatric functioning
- A history of stroke
- A documented history of transient ischemic attack within the last 12 months
- History of schizophrenia, schizoaffective or bipolar disorder
- Currently meets criteria for major depression
- Within the last 2 years, unstable or clinical significant cardiovascular disease (myocardial infarction, angina pectoris)

Additional exclusion criteria for sub study:

- Inclusion in a research and/or medical protocol involving PET ligands or other radioactive agents within 12 months
- Present or planned participation in a research and/or medical protocol involving PET ligands or radioactive agents other than study WN25203
- Have planned or are planning to have exposure to ionizing radiation that in combination with the planned administration with study amyloid PET ligand would result in a cumulative exposure that exceeds local recommended exposure limits