ForPatients
by Roche

Alzheimer's Disease (AD)Neurodegenerative Disorder

Efficacy and Safety Study of Gantenerumab in Participants With Early Alzheimer's Disease (AD)

Trial Status	Trial Runs In	Trial Identifier
Terminated	15 Countries	NCT03444870 2017-001364-38 WN29922

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, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy, and Safety Study of Gantenerumab in Patients With Early (Prodromal to Mild) Alzheimer's Disease

Trial Summary:

This randomized, double-blind, placebo-controlled, parallel-group study will evaluate the efficacy and safety of gantenerumab versus placebo in participants with early (prodromal to mild) AD. All participants must show evidence of beta-amyloid pathology. Eligible participants will be randomized 1:1 to receive either subcutaneous (SC) injection of gantenerumab or placebo. The primary efficacy assessment will be performed at the end of the double blind period at week 116. Participants will then be offered to enter into an open-label extension (OLE). Participants not willing to go to the OLE will participate in a long term follow-up period for up to 50 weeks after the last gantenerumab dose.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03444870 2017-001364-38 WN29922
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Meets National Institute on Aging/Alzheimer's Association (NIAAA) core clinical criteria for probable AD dementia or prodromal AD (consistent with the NIAAA diagnostic criteria and guidelines for mild cognitive impairment)
- Evidence of the AD pathological process, as confirmed by CSF tau/A-beta42or amyloid PET scan
- Demonstrated abnormal memory function
- MMSE score greater than or equal to 22 (# 22)
- Clinical dementia rating-global score (CDR-GS) of 0.5 or 1.0
- Availability of a reliable study partner who accepts to participate in study procedures throughout the 2 years duration of study
- If receiving symptomatic AD medications, the dosing regimen must have been stable for 3 months prior to screening and until randomization
- For enrollment in the China extension, patients must have residence in mainland China, Hong Kong, or Taiwan and be of Chinese ancestry
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods

Exclusion Criteria:

- Any evidence of a condition other than AD that may affect cognition
- History of schizophrenia, schizoaffective disorder, major depression, or bipolar disorder
- History or presence of clinically evident systemic vascular disease that in the opinion of the investigator has the potential to affect cognitive function
- History or presence of clinically evident cerebrovascular disease
- History or presence of posterior reversible encephalopathy syndrome
- History or presence of any stroke with clinical symptoms within the past 12 months, or documented history within the last 6 months of an acute event that is consistent with a transient ischemic attack
- History of severe, clinically significant CNS trauma
- History or presence of intracranial mass (e.g., glioma, meningioma) that could potentially impair cognition
- Presence of infections that affect brain function or history of infections that resulted in neurologic sequelae
- History or presence of systemic autoimmune disorders that potentially cause progressive neurologic disease with associated cognitive deficits
- At risk for suicide in the opinion of the investigator
- Alcohol and/or substance abuse or dependants in past 2 years
- Relevant brain hemorrhage, bleeding disorder and cerebrovascular abnormalities
- Any contraindications to brain MRI
- Unstable or clinically significant cardiovascular, kidney or liver disease
- Uncontrolled hypertension
- Unstable or clinically significant cardiovascular disease
- Abnormal thyroid function
- Patients with evidence of folic acid deficiency

Exclusion for Open-Label Extension (OLE):

- Discontinued from study treatment during the double-blind treatment period
- Received any other investigational medication during the double-blind treatment period or after the end of double-blind treatment
- Participation in the OLE deemed inappropriate by the investigator
- Presence of ARIA-E findings at the Week 116 MRI scan