ForPatients
by Roche

Alzheimer's Disease (AD)

A study of a new medicine (semorinemab) in patients with moderate Alzheimer's disease

A Study of Semorinemab in Patients With Moderate Alzheimer's Disease

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT03828747 GN40040

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 II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy, and Safety Study of MTAU9937A in Patients With Moderate Alzheimer's Disease

Trial Summary:

This Phase II, multicenter, randomized, double-blind, placebo-controlled, parallel-group study will evaluate the clinical efficacy, safety, pharmacokinetics, and pharmacodynamics of semorinemab in patients with moderate AD. The study consists of a screening period, a double-blind treatment period, an optional open-label extension (OLE) period, and a safety follow-up period. There may be up to two study cohorts.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT03828747 GN40040
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years & # 85 Years	No

Inclusion Criteria:

- National Institute on Aging/Alzheimer's Association core clinical criteria for probable AD dementia
- Evidence of the AD pathological process, by a positive amyloid assessment either on CSF A#1-42 as measured on Elecsys #-Amyloid(1-42) Test System OR amyloid PET scan

- AD dementia of moderate severity, as defined by a screening MMSE score of 16-21 points, inclusive, and a CDR-GS of 1 or 2
- Availability of a person with sufficient contact with the participant to be able to provide accurate information on the participant's cognitive, behavioral and functional ability

Exclusion Criteria:

- Pregnant or breastfeeding
- Inability to tolerate MRI procedures or contraindication to MRI
- Contraindication to PET imaging
- Residence in a skilled nursing facility
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study, or bias the assessment of the clinical or mental status of the participant to a significant degree
- Any evidence of a condition other than AD that may affect cognition
- Substance abuse within the past 2 years
- Use of any experimental therapy within 90 days or 5 half-lives prior to screening, whichever is greater, or any passive immunotherapy against tau
- Use of any passive immunotherapy (immunoglobulin) against A#, unless the last dose was at least 1 year prior to screening or any active immunotherapy (vaccine) that is under evaluation to prevent or postpone cognitive decline
- Any other biologic therapy or previous treatment with medications specifically intended to treat Parkinsonian symptoms or any other non-AD neurodegenerative disorder within 1 year of screening
- Systemic immunosuppressive therapy within 12 months of screening through the entire study period
- Typical antipsychotic or neuroleptic medication within 6 months of screening
- Daily treatment with any of the following classes of medication (except for intermittent short-term use): opiates or opioids, benzodiazepines, barbiturates, hypnotics, or any medication with clinically significant centrally-acting antihistamine or anticholinergic activity
- Stimulant medications, unless the dose has been stable within the 6 months prior to screening and is expected to be stable throughout the study