ForPatients
*by Roche*

Alzheimer's Disease (AD)

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

A Study of MTAU9937A 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 clinical trial tested a drug called semorinemab that may be useful for treating moderate Alzheimer's disease. The goal was to see if the drug was effective and look at safety. This was a phase II trial where some people got a placebo to compare against people who got semorinemab. It was a double-blind study, so doctors and patients did not know who was getting semorinemab and who was getting the placebo. The study took place at 49 centers in 4 countries: the United States (31 centers), Spain (6 centers), Poland (7 centers), and France (5 centers).

| **Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)** | **Phase 2** |
|---|---|
| Sponsor | 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