ForPatients
by Roche

Alzheimer's Disease (AD)

A Study to Evaluate the Efficacy and Safety of RO7105705 in Patients With Prodromal to Mild Alzheimer's Disease

Trial Status	Trial Runs In	Trial Identifier
Terminated	13 Countries	NCT03289143 2017-001800-31 GN39763

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 Prodromal to Mild Alzheimer's Disease

Trial Summary:

This was a phase II, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of Semorinemab in participants with prodromal to mild Alzheimer's disease. An optional 96-week open-label extension period was available to participants who completed the double-blind treatment period and who, in the judgment of the investigator, would potentially benefit from open-label Semorinemab treatment.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT03289143 2017-001800-31 GN39763
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 50 Years & # 80 Years	No

Inclusion Criteria:

- Age between 50 and 80 years
- National Institute on Aging/Alzheimer's Association core clinical criteria for probable Alzheimer's disease (AD) dementia or mild cognitive impairment (prodromal AD)

- Evidence of the AD pathological process, by a positive amyloid assessment either on cerebrospinal fluid A#1-42 OR amyloid positron emission tomography (PET) scan. Historical amyloid PET scans may be accepted in some cases
- Mild AD symptomatology, as defined by a screening Mini-Mental State Examination score of >= 20 points and Clinical Dementia Rating (CDR) -Global Score of 0.5 or 1
- Abnormal memory function at screening
- Availability of a person with sufficient contact with the participant to be able to provide accurate information on the participant's cognitive and functional ability

Exclusion Criteria:

- Pregnant or breastfeeding
- Inability to tolerate magnetic resonance imaging (MRI) procedures or contraindication to MRI
- Contraindications to both PET imaging and lumbar dural puncture (must be able to undergo at least one of these procedures to be eligible)
- Residence in a skilled nursing facility
- Any serious medical condition or abnormality in clinical laboratory tests that remains abnormal on retest and, 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
- Alcohol or 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 and any passive immunotherapy (immunoglobulin) against tau, except use of RO7105705 in Genentech Study GN39058, as long as the last dose was at least 90 days prior to screening
- Use of any passive immunotherapy (immunoglobulin) against A#, unless the last dose was at least 1 year prior to screening and any active immunotherapy (vaccine) that is under evaluation to prevent or postpone cognitive decline
- Any previous treatment with medications specifically intended to treat Parkinsonian symptoms or any other 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, which is permitted except within 2 days or 5 half-lives (whichever is longer) prior to any COA: atypical antipsychotics, 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