ForPatients
by Roche

Alzheimer's Disease (AD)

A Clinical Trial of Trontinemab in Participants With Early Symptomatic Alzheimer's Disease

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07170150 WN45447

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 Trontinemab in Participants With Early Symptomatic Alzheimer's Disease (MCI to Mild Dementia Due to AD)

Trial Summary:

The purpose of this study is to assess the efficacy and safety of trontinemab in participants with early symptomatic Alzheimer's disease (AD) (mild cognitive impairment [MCI] to mild dementia due to AD).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT07170150 WN45447
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Willingness and ability to complete all aspects of the study (including MRI, clinical genotyping, and PET imaging or CSF as applicable) for the duration of the study. The participant should be capable of completing assessments either alone or with the help of the study partner
- Adequate visual and auditory acuity, in the investigator's judgment, sufficient to perform the neuropsychological testing (eyewear and hearing aids are permitted)

- Evidence of AD pathological process, as confirmed on amyloid PET scan. A CSF tau181/A#42 ratio may be used as an alternative option if amyloid PET is not available
- Probable AD dementia or MCI due to AD, also known as an Alzheimer's clinical syndrome clinical Stage 3 or Stage 4
- Screening MMSE score # 22 and CDR-GS of 0.5 or 1.0
- Participant- and/or Informant-reported history of cognitive decline with gradual onset and progression over the last 1 year before screening
- A Repeatable Battery for the Assessment of Neuropsychological Status Delayed Memory Index (RBANS DMI) score of 85 or order
- Availability of a "study partner" as defined by the protocol

Exclusion Criteria:

- Any evidence of a condition other than AD that may affect cognition
- History or presence of clinically significant cerebrovascular disease
- History of severe, clinically significant (persistent neurologic deficit or structural brain damage) central nervous system (CNS) trauma
- History or presence of clinically significant intracranial mass
- MRI evidence of significant cerebral abnormalities or inability to tolerate MRI procedures or contraindication to MRI
- Any other medical conditions (e.g., cardiovascular, hepatic, renal disease) which are not stable and adequately controlled or which in the opinion of the investigator could affect the participant's safety in the study or interfere with the study assessments
- History of malignancy with the following exceptions: if considered to be cured; malignancies with a negligible risk of metastasis or death