ForPatients
by Roche

Alzheimer's Disease (AD)

CREAD Study: A Study of Crenezumab Versus Placebo to Evaluate the Efficacy and Safety in Participants With Prodromal to Mild Alzheimer's Disease (AD)

Trial Status	Trial Runs In	Trial Identifier
Terminated	30 Countries	NCT02670083 BN29552

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 Crenezumab in Patients With Prodromal to Mild Alzheimer's Disease.

Trial Summary:

This randomized, double-blind, placebo-controlled, parallel group study will evaluate the efficacy and safety of crenezumab versus placebo in participants with prodromal to mild AD. Participants will be randomized 1:1 to receive either intravenous (IV) infusion of crenezumab or placebo every 4 weeks (Q4W) for 100 weeks. The final efficacy and safety assessment will be performed 52 weeks after the last crenezumab dose. Participants will then have the option to enter the Open Label Extension (OLE) study if eligible. Participants who do not enter the OLE study will have additional follow-up visits at 16 and 52 weeks after the last dose, primarily for safety and also for limited efficacy assessments.

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

NCT02670083 BN29552
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Weight between 40 and 120 kilograms (Kg) inclusive
- Availability of a person (referred to as the "caregiver") who in the investigator's judgment:
- Has frequent and sufficient contact with the participant to be able to provide accurate information regarding the participant's cognitive and functional abilities, agrees to provide information at clinic visits (which require partner input for scale completion), signs the necessary consent form, and has sufficient cognitive capacity to accurately report upon the participant's behavior and cognitive and functional abilities
- Fluency in the language of the tests used at the study site
- Adequate visual and auditory acuity, in the investigator's judgment, sufficient to perform the neuropsychological testing (eye glasses and hearing aids are permitted)
- Evidence of the AD pathological process, by a positive amyloid assessment either on cerebrospinal fluid (CSF) amyloid beta 1-42 levels as measured on the Elecsys beta-amyloid(1-42) test system or amyloid PET scan by qualitative read by the core/central PET laboratory
- Demonstrated abnormal memory function at screening (up to 4 weeks before screening begins) or screening (FCSRT cueing index =<0.67 AND free recall =<27)
- Screening mini mental state examination (MMSE) score of greater than or equal to (>=) 22 points and Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1.0
- 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 (MCI)
- If receiving symptomatic AD medications, the dosing regimen must have been stable for 3 months prior to screening
- Participant must have completed at least 6 years of formal education after the age of 5 years

Exclusion Criteria:

- Any evidence of a condition other than AD that may affect cognition such as other dementias, stroke, brain damage, autoimmune disorders (e.g. multiple sclerosis) or infections with neurological sequelae.
- History of major psychiatric illness such as schizophrenia or major depression (if not considered in remission)
- At risk of suicide in the opinion of the investigator
- Any abnormal MRI findings, such as presence of cerebral vascular pathology, cortical stroke, etc or inability to tolerate MRI procedures or contraindication to MRI
- Unstable or clinically significant cardiovascular (e.g., myocardial infarction), kidney or liver disease
- Uncontrolled hypertension
- Screening hemoglobin A1c (HbA1C) >8%
- Poor peripheral venous access
- History of cancer except:

If considered to be cured or If not being actively treated with anti-cancer therapy or radiotherapy

- Known history of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric, human, or humanized antibodies or fusion proteins