ForPatients
by Roche

Alzheimer's Disease (AD)

A Study of Crenezumab in Participants With Mild to Moderate Alzheimer Disease

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02353598 GN29632

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 Ib, Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel-Arm, Multiple-Dose Study to Assess The Safety, Tolerability, And Pharmacokinetics of Intravenous Crenezumab Administered in Patients With Mild to Moderate Alzheimer's Disease

Trial Summary:

This randomized, placebo-controlled, double-blind, parallel-arm study will evaluate the safety and tolerability of at least two dose levels of intravenous (IV) crenezumab in 24-72 participants with mild to moderate Alzheimer disease (AD) (mini-mental state examination [MMSE] 18 to 28 points, inclusive). An optional open-label extension (OLE) will be offered after the completion of initial double-blind stage.

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT02353598 GN29632
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Body weight greater than or equal (>/=) 45 kilograms (kg) and less than or equal (</=) 120 kg
- Ages 50-90 years, inclusive
- Availability of a person ("caregiver") who, in the investigator's judgment, has frequent and sufficient contact with the participant and is 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, and signs the necessary consent form
- Willingness and ability to complete all aspects of the study; the participant should be capable of completing assessments either alone or with the help of the caregiver
- Adequate visual and auditory acuity, in the investigator's judgment, sufficient to perform the neuropsychological testing
- Clinical diagnosis of probable mild to moderate AD based on the national institute on neurological and communication disease and stroke/Alzheimer's disease and related disorders association (NINCDS/ADRDA) criteria or probable major neurocognitive disorder due to AD of mild to moderate severity based on diagnostic and statistical manual of mental disorders, version 5 (DSM-5) criteria
- Screening MMSE score of 18-28 points, inclusive
- Screening clinical dementia rating global score (CDR-GS) of 0.5 or 1.0
- Screening geriatric depression (GDS)-15 score less than (<) 6
- Positive florbetapir amyloid positron emission tomography (PET) scan by qualitative read conducted by the core/central PET laboratory
- Women must be postmenopausal or surgically sterile
- Men with female partners of childbearing potential agree to remain abstinent or use adequate methods of contraception as defined by protocol during the treatment period and for at least 8 weeks after the last dose of study drug and agreement to refrain from donating sperm during this same period

Exclusion Criteria:

- History or presence of clinically evident vascular disease potentially affecting the brain that, in the opinion of the investigator, has the potential to affect cognitive function
- History or presence of stroke within the previous 2 years or documented history of transient ischemic attack within the previous 12 months
- History of severe, clinically significant central nervous system trauma
- History or presence of intracranial tumor that is clinically relevant in the opinion of the investigator
- Presence of infections that affect brain function or history of infections that resulted in neurologic sequelae
- History or presence of systemic autoimmune disorders potentially causing progressive neurologic disease with associated cognitive deficits
- History or presence of a neurologic disease other than AD that may affect cognition
- Presence of superficial siderosis, more than four cerebral microhemorrhages, or evidence of a prior cerebral macrohemorrhage
- Inability to tolerate magnetic resonance imaging (MRI) procedures or contraindication to MRI
- History or presence of atrial fibrillation except if only one episode that resolved more than 1 year ago and for which treatment is no longer indicated or that in the investigator's judgment poses no risk for future stroke
- Within the previous 2 years, unstable or clinically significant cardiovascular disease
- Uncontrolled hypertension
- Chronic kidney disease of Stage >/= 4, according to the national kidney foundation kidney disease outcomes quality initiative (NKF KDOQI) guidelines for chronic kidney disease
- Impaired hepatic function
- Clinically significantly abnormal screening blood or urine that remain abnormal on retest
- History of malignancies within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, or Stage I uterine cancer; cancer that is considered likely to be cured, is not being actively treated with anti-cancer therapy or radiotherapy and not likely to require treatment in the ensuing 5 years as well as cancers that are considered to have low probability of recurrence are allowed
- Known history of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric, human, or humanized antibodies or fusion proteins

- Severe or unstable medical condition that, in the opinion of the investigator or sponsor, could be expected to progress, recur, or change to such an extent that it could put the patient at special risk, bias the assessment of the clinical or mental status of the patient to a significant degree, interfere with the patient's ability to complete the study assessments, or would require the equivalent of institutional or hospital care
- Any previous treatment with medications used to treat Parkinsonian symptoms or any other neurodegenerative disorder within 1 year before screening even if the patient is taking the medicine for a non-neurodegenerative disorder such as restless leg disorder
- Typical anti-psychotic or neuroleptic medication within 6 months before screening except as brief treatment for a non-psychiatric indication
- Antihemostasis medication within 2 weeks before screening
- Sedative, hypnotic, or benzodiazepine medication within 3 months before screening except intermittent use of the following for sleep or anxiety: alprazolam, lorazepam, oxazepam, temazepam, diazepam, or a short-acting benzodiazepine-like medication