An Extension Study of ABBV-8E12 in Early Alzheimer's Disease

Published: 12-05-2020
Last updated: 08-04-2024

1. To assess the long-term safety and tolerability of ABBV-8E12 in subjects with early Alzheimer's disease (AD).2. To assess the pharmacokinetics (PK) of ABBV-8E12 in subjects with early AD.The exploratory objectives of this study are:• To...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49765

Source
ToetsingOnline

Brief title
M15-570

Condition

- Other condition

Synonym
Alzheimer's, Alzheimer's disease

Health condition

neurologisch

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie Deutschland GmbH & Co. KG
Source(s) of monetary or material Support: AbbVie B.V.

Intervention

Keyword: Early Alzheimer's Disease, Extension study, Intraveneous (IV), Long-term safety and tolerability, Monoclonal antibody ABBV-8E12, Tauprotein

Outcome measures

Primary outcome

Adverse events, vital signs, physical examination, neurologic examination,

electrocardiogram (ECG), laboratory tests, Columbian Suicide Severity Rating

Scale (C-SSRS), MRI, and immunogenicity assessments.

Timepoint of evaluation: Week 280

Secondary outcome

Pharmacokinetics (Clearance and Volume of Distribution)

Timepoint of evaluation: Week 280

Study description

Background summary

Alzheimer's disease (AD) is the most prevalent neurodegenerative disease among the elderly population and the most common cause of dementia. At present, approved pharmacological therapy for AD consists of symptomatic treatment. Thus, there is a medical need for treatment modifying the course of the disease on a biological level.
ABBV-8E12 is a humanized antibody being studied to target the tau protein, which is thought to stabilize intracellular structures required for maintenance and transport in neurons. Abnormal accumulation of altered tau protein is a hallmark in a variety of neurodegenerative conditions, where the development of tau pathology strongly correlates with clinical disease progression.

Study objective

1. To assess the long-term safety and tolerability of ABBV-8E12 in subjects with early Alzheimer's disease (AD).

2. To assess the pharmacokinetics (PK) of ABBV-8E12 in subjects with early AD.
The exploratory objectives of this study are:
• To assess the long-term efficacy of ABBV-8E12 in slowing disease progression in subjects with early AD. • To assess the long-term effect of ABBV-8E12 on a range of disease-related and drug-related biomarkers in subjects with early AD.

Study design

A Phase 2 extension of Study M15-566 evaluating the long-term safety and tolerability of ABBV-8E12 in subjects with early Alzheimer's disease.
The study will consist of a 5-year treatment period and a follow-up period of approximately 20 weeks following the last study drug administration.

Intervention

Eligible subjects will receive ABBV-8E12 via intravenous (IV) infusion on Day 1 of Study M15-570 as follows:
• Subjects who received placebo in Study M15-566 will receive 2000 mg ABBV-8E12 in Study M15-570;
• Subjects who received 300 mg ABBV-8E12 in Study M15-566 will receive 1000 mg ABBV-8E12 in Study M15-570; and
• Subjects who received 1000 mg or 2000 mg ABBV-8E12 in Study M15-566 will continue on the same dose in Study M15-570.
Note: if any changes are made to alter Study M15-566 with regards to the treatment arms due to safety, efficacy, or other reasons, a corresponding change will be implemented in Study M15-570. This change may include, but is not limited to, adding or dropping treatment arm(s).

Study burden and risks

Subjects participating in this trial will experience a higher burden compared to standard of care. The subject will visit the hospital more frequent and spend more time during visits. Subject will receive IV infusion of ABBV-8E12 and undergo various procedures; these include blood sampling and questionnaires. So far, no notable safety findings were discovered. The benefit risk profile will be further defined in this trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Subject has voluntarily provided written informed consent
- Subject completed the 96-week treatment period of Study M15-566.
- Subject has an identified, reliable study partner who has frequent contact with the subject and who will provide information as to the subject's cognitive and functional abilities.
- The study partner has provided written informed consent.
- If female, subject must be postmenopausal or permanently surgically sterile (bilateral oophorectomy, bilateral salpingectomy or hysterectomy).
- If the male subject is sexually active with female partner(s) of childbearing potential, he must agree, from Study Day 1 through 20 weeks after the last dose of study drug to practice the protocol specified contraception and must refrain from sperm donation.

Exclusion criteria

- Subject has any significant change in his/her medical condition since

participation in Study M15-566 that could interfere with the subject's participation in Study M15-570, could place the subject at increased risk,or could confound interpretation of study results. This would include any clinically significant neurological, hematological, autoimmune, endocrine, cardiovascular, neoplastic, renal, hepatic, metabolic, psychiatric, pulmonary, gastrointestinal, or other major disorder or contraindication to or inability to tolerate brain MRI or PET scans.
- More than 8 weeks have elapsed since the subject received his/her last dose of study drug in Study M15-566.
- Subject is concurrently enrolled in another interventional clinical study (with the exception of Study M15-566) involving a therapeutic agent.
- Subject is considered by the investigator to be an unsuitable candidate to receive ABBV-8E12 or the subject is considered by the investigator to be unable or unlikely to comply with the dosing schedule or study evaluations.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	7
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	ABBV-8E12
Generic name:	Tilavonemab

Ethics review

Approved WMO Date:	12-05-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-07-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2018-000268-26-NL
ClinicalTrials.gov	NCT03712787
CCMO	NL70032.028.20