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Eisai Co., Ltd.

Anti-MTBR (microtubule binding region) Tau Antibody Etalanetug Granted FDA Fast Track Designation

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that etalanetug (development code: E2814), an investigational anti-MTBR (microtubule binding region) tau antibody, was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). Fast Track designation is an FDA program that is intended to facilitate and expedite development of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition, such as Alzheimer's disease (AD), and provide opportunities for frequent interactions with the FDA.

AD is a chronic, progressive, neurodegenerative disease characterized by formation of protein deposits known as plaques made of amyloid-beta aggregates and neurofibrillary tangles made of tau protein in the brains of people living with AD. The data show that amyloid-beta protofibrils and tau tangles play roles in the neurodegeneration process.[1,2,3]

Etalanetug is an anti-tau antibody that targets specific tau species containing MTBR, tau seeds that spread tau pathology to different brain regions. Etalanetug was discovered as part of the research collaboration between Eisai and University College London.

In the Phase I/II clinical trial (Study 103, NCT04971733) targeting patients with Dominantly Inherited Alzheimer's Disease (DIAD), target engagement with MTBR-tau species in cerebrospinal fluid (CSF) with etalanetug was confirmed. Additionally, there was a reduction in CSF MTBR-tau243, a biomarker reflecting brain tau pathophysiology, as well as a trend towards suppression or decrease in tau PET signal. These results suggest that etalanetug inhibited tau propagation and suppressed the accumulation of tau aggregates in brains of people living with DIAD.

Currently, etalanetug is being evaluated with a standard of care treatment, an anti-amyloid β protofibril antibody, lecanemab in two clinical trials: the Tau NexGen Phase II/III clinical trial (NCT05269394) for DIAD, led by the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) at Washington University School of Medicine in St. Louis, and a Phase II clinical trial (Study 202, NCT06602258) targeting sporadic early AD.

Following the development of treatments targeting amyloid beta, if treatments targeting tau become available, it is expected that this will be a further major breakthrough in the treatment of AD.

Eisai positions neurology as one of its key therapeutic areas, and it will continue to create innovation in the development of novel medicines based on cutting-edge neurology research as it seeks to contribute further to improving the benefits of affected individuals and their families in diseases with high unmet needs, such as dementia including AD.

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[Notes to editors]

1. About the U.S. Food and Drug Administration's Fast Track Designation

Fast Track is a special measure provided by the U.S. Food and Drug Administration (FDA) to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The Fast Track designation is available not only when treatments do not exist, but also for drugs that demonstrate a potential advantage over existing treatments. Once a drug has granted Fast Track designation, the FDA will increase the frequency of meetings to discuss development, and if supported by clinical data at the time of New Drug Application submission, the drug may also be eligible for Priority Review and Accelerated Approval.

2. Biomarkers related to AD tau pathology

As fluid biomarkers related to AD tau pathology, tau containing the residue 243 (MTBR-tau243) and tau phosphorylated at the residue 217 (p-tau217) in CSF have been reported.[4] In addition, positron emission tomography (tau PET), which specifically detects tau aggregates, is used as an imaging biomarker. These biomarkers are included in the Revised criteria for diagnosis and staging of AD published by the National Institute on Aging and the Alzheimer's Association (NIA-AA) in June 2024.[5]

References

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