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Eisai Co., Ltd.

EISAI PRESENTS DATA SHOWING QUANTIFICATION OF TAU MICROTUBULE BINDING REGION IN CEREBROSPINAL FLUID AND THE IDENTIFICATION OF A TARGET ENGAGEMENT BIOMARKER FOR THE NEW ANTI-TAU ANTIBODY E2814 AT ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE (AAIC)2019

Eisai Co.,Ltd.(Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced that data relating to a new anti-tau antibody E2814*1 was presented at the Alzheimer's Association International Conference (AAIC) held in Los Angeles, California, United States, from July 14 to 18, 2019 (Poster Presentation No.: P4-696).

Neurofibrillary tangles composed of aggregated tau protein is one of the pathological features of Alzheimer's disease (AD). During the course of the disease, tau is believed to spread throughout the brain via synaptically-connected pathways. The propagation of this pathology is thought to be mediated by tau species ("seeds") containing the microtubule binding region of tau (MTBR). E2814 is designed to target MTBR containing tau species, preventing build-up and spreading of tau seeds, and thus may slow the course of the disease.
The data presented describes a method for quantification of MTBR-containing tau fragments MTBR in cerebrospinal fluid (CSF) from patients with AD. In addition, an E2814 target engagement biomarker assay is binding to fragments including MTBR of E2814 target with this assay in the clinical study.

The results confirmed that MTBR-containing tau species can be quantified in human CSF and there was a significant increase in MTBR in CSF of patients with AD (Caucasian aged between 64 and 84, MMSE: 13-26) in comparison with healthy adults (Caucasian aged between 46 and 75) ($p<0.0001$). Furthermore, MTBR-containing tau species in the CSF of AD patients was well correlated with phosphorylated tau (R^2 = 0.8849) rather than total tau (R^2 = 0.7811), maybe indicating the pathological species for tau propagation.
In vitro experiments using CSF from patients with AD spiked with E2814, showed that E2814 was able to bind the majority of MTBR-containing tau in the samples. Additionally, in vivo experiments in non-human primates demonstrated dose-dependent binding of E2814 to MTBR-containing tau fragments in CSF samples and a concomitant reduction in free MTBR-containing tau species.

Eisai aims to realize the prevention and cure of dementia through a multi-dimensional and holistic approach with a foundation of over 35 years of experience of drug discovery activities in the area of Alzheimer's disease and dementia. Eisai strives to create innovative medicines as soon as possible to further contribute to addressing the unmet medical needs of, as well as increasing the benefits provided to, patients and their families.

*1 E2814 is the first clinical candidate discovered as part of a research collaboration with University College London in UK.

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[Notes to editors]

1. **About E2814**

An investigational anti-tau monoclonal antibody. E2814 is being developed as a disease modifying agent for Alzheimer's disease and other tauopathies, Phase I clinical studies are under preparation. The clinical candidate was discovered as part of the research collaboration between Eisai and University College London. E2814 is designed to prevent the spreading of tau seeds within the brains of affected individuals.