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Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA AT 10TH CLINICAL TRIALS ON ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the latest data on its oral dual orexin receptor antagonist lemborexant and its oral beta secretase cleaving enzyme (BACE) inhibitor elenbecestat* will be presented at the 10th Clinical Trials on Alzheimer's Disease (CTAD), taking place in Boston, the United States, from November 1 to 4.

At the CTAD meeting, there will be a poster presentation on the characteristics of sleep and wakefulness measured by actigraphy** in patients with Irregular Sleep-Wake Rhythm Disorder (ISWRD) and Alzheimer's disease (AD) dementia. This is the first clinical study of lemborexant to assess the circadian rhythm of sleep-wake patterns in this patient population. ISWRD is a type of circadian rhythm sleep disorder where the pattern of sleep and wakefulness that repeats itself over a 24-hour period in healthy individuals is broken down, and sleeping and waking occur instead at various times during the day and night. It is a common comorbid condition in AD, appears early in the course of disease, and is associated with many of the behavioral disturbances in AD patients such as agitation, restlessness and wandering.
For elenbecestat, there are two poster presentations scheduled, including a presentation on the use of the International Shopping List Test as the objective assessment of cognitive impairment to identify subjects with early Alzheimer's disease in the phase 3 clinical trials.

Lemborexant, a dual orexin receptor antagonist, is an in-house discovered novel small molecule which inhibits orexin by binding competitively to two subtypes of orexin receptors (orexin receptor 1 and 2). Lemborexant is being jointly developed by Eisai and Purdue Pharma L.P. (Headquarters: Connecticut, United States, President and CEO: Craig Landau).
Elenbecestat, its in-house discovered BACE inhibitor, is being jointly developed by Eisai and Biogen Inc. (Headquarters: Massachusetts, United States, CEO: Michel Vounatsos, "Biogen"). Two global Phase 3 clinical studies (known as MISSIONAD1 and MISSIONAD2) are ongoing in patients with early AD. In addition, the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of elenbecestat, a process allowing priority reviews by the FDA for drugs deemed as having potential to treat serious conditions and tackle key unmet medical needs.

Furthermore, there will be several oral presentations for anti-Aβ antibody aducanumab. Eisai has exercised its option to jointly develop and commercialize aducanumab with Biogen.

Eisai considers dementia a therapeutic area of focus and is committed to new drug development in this field. Eisai strives to bring promising therapies to patients worldwide as early as possible.

* The generic name is not yet fixed at this time.
** Actigraphy is a non-invasive method for measuring and assessing the circadian rhythm of sleep-wake patterns continuously over several weeks through a device worn on the wrist.

Major poster presentations at the CTAD meeting include:

Product, Poster No.	Poster title and scheduled presentation date
Lemborexant Poster No: LBP20	Characteristics of Sleep and Wakefulness Measured with Actigraphy in Patients with Irregular Sleep-Wake Rhythm Disorder and Alzheimer's Disease Dementia Wednesday November 1 and Thursday November 2
Elenbecestat Poster No: LBP54	Use of the International Shopping List Test as the objective assessment of cognitive impairment to identify subjects with early Alzheimer's disease in the Eisai elenbecestat MissionAD phase 3 clinical trials Friday November 3 and Saturday November 4
Elenbecestat Poster No: LBP58	Utility of the International Shopping List Test for detection of memory impairment associated with prodromal and early Alzheimer's disease in clinical trials Friday November 3 and Saturday November 4

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