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Eisai Co., Ltd.

EISAI TO PRESENT LATEST DATA ON LEMBOREXANT INCLUDING INTEGRATED ANALYSIS OF PHASE III CLINICAL STUDIES AT 33RD ANNUAL SLEEP MEETING

Eisai Co.,Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") today announced that latest information on lemborexant, an investigational sleep-wake regulation agent being studied for the treatment of multiple sleep-wake disorders, including insomnia and Irregular Sleep-Wake Rhythm Disorder (ISWRD) will be presented at the 33rd Annual Meeting of the Associated Professional Sleep Societies (SLEEP 2019), from June 8 to 12 in San Antonio, Texas, the United States.

Eight posters including the integrated analysis of lemborexant's effects on daily function and disease severity as well as sleep onset and sleep maintenance for the combined 1,955 patient population of two pivotal clinical Phase III studies, SUNRISE 1 (Study 304) and SUNRISE 2 (Study 303) in insomnia disorders, and an evaluation of results on respiratory function after administration of lemborexant in elderly and mild obstructive sleep apnea, and the latest pre-clinical data on ISWRD will be presented.

Lemborexant acts on the orexin neurotransmitter system and is believed to regulate sleep and wake by controlling arousal without affecting awakening by external stimuli, and is being developed for the treatment of multiple sleep-wake disorders including insomnia disorder. In December 2018 and March 2019, new drug applications seeking approval of lemborexant for use in the treatment of insomnia disorder were submitted in the United States and Japan, respectively. For the ongoing clinical studies, please visit clinicaltrials.gov.

Through the development of lemborexant, Eisai is aiming to bring to patients suffering from sleep-wake disorders a new treatment option to improve their ability to fall and stay asleep and wake without impairing the next morning, and is striving to further contribute to satisfying unmet medical needs and improve the benefits to patients and their families.

■Presentations for Lemborexant:

Poster session: P18, Presentation date: Monday June 10, 5:15pm - 7:15pm (local time)

	Presentation Title
Poster Number: 102 Abstract: 0367	Lemborexant Treatment for Insomnia: Six-month Safety
Poster Number: 105 Abstract: 0368	Efficacy and Tolerability of Lemborexant in Female and Male Subjects With Insomnia
Poster Number: 106 Abstract: 0369	Effect of Lemborexant on Sleep Architecture in Older Adults With Insomnia Disorder
Poster Number: 107 Abstract: 0370	Patient-Reported Sleep Onset and Sleep Maintenance: Pooled Analyses of Lemborexant Phase 3 Studies
Poster Number: 108 Abstract: 0371	Lemborexant Treatment for Insomnia in Phase 3: Impact on Disease Severity
Poster Number: 103 Abstract: 0429	Respiratory Safety of Lemborexant in Adult and Elderly Subjects With Mild Obstructive Sleep Apnea
Poster Number: 104 Abstract: 0430	Respiratory Safety of Lemborexant in Healthy Adult and Elderly Subjects
Poster Number: 022 Abstract: 0056	SAMP8 Mice as a Preclinical Model for Irregular Sleep-Wake Rhythm Disorder and Efficacy of the Dual Orexin (Hypocretin) Receptor Antagonist Lemborexant

Separate from the poster presentations, Eisai will host a symposium, an interactive dialogue on insomnia diagnostic and therapeutic decision making, which will be held on Sunday, June 9, from 6:15pm – 8:30pm (local time).

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[Notes to editors]

1. About Lemborexant

Lemborexant is a novel investigational small molecule compound, discovered and developed by Eisai, that inhibits orexin signaling by binding competitively to both orexin receptor subtypes (orexin receptors 1 and 2). In individuals with normal daily sleep-wake rhythms, orexin signaling is believed to promote periods of wakefulness. In individuals with sleep-wake disorders, it is possible that orexin signaling that regulates wakefulness is not functioning normally, suggesting that inhibiting inappropriate orexin signaling may enable initiation and maintenance of sleep. Eisai is investigating lemborexant as a potential treatment option for multiple sleep-wake disorders, such as insomnia.

Additionally, a Phase 2 clinical study of lemborexant in patients with irregular sleep-wake rhythm disorder (ISWRD) and mild to moderate Alzheimer's dementia is underway.

2. About Sleep Disorders

Several population studies show that sleep disorders affect many more people worldwide than previously thought.[1] Insomnia disorder is the most common sleep disorder, with persistent insomnia symptoms experienced by approximately 30 percent of the adult population.[1,2] Insomnia disorder is characterized by difficulty falling asleep, staying asleep, or both, despite an adequate opportunity to sleep, that can lead to daytime consequences such as fatigue, difficulty concentrating and irritability.[3,4]

Sleeping well is essential for good health, including brain health. Poor sleep is associated with a wide range of health consequences, including an increased risk of hypertension, accidental injury, diabetes, obesity, depression, heart attack, stroke, dementia, as well as adverse effects on mood and behavior.[3,5]

Experimental studies in animals and humans provide evidence of associations between sleep and disease risk factors, diseases, and mortality.[6] Studies suggest an optimal sleep duration between seven and eight hours.[7]

Women are 1.4 times more likely than men to suffer from insomnia.[8] Older adults also have higher prevalence of insomnia; aging is often accompanied by changes in sleep patterns, including disrupted sleep, frequent walking, and early waking, that can lead to less sleep time.[9]

References

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9. Crowley, K. Sleep and sleep disorders in older adults. *Neuropsychol Rev*. 2011;21(1):41-53.