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Eisai Co., Ltd.

## **EISAI TO PRESENT LATEST DATA ON LEMBOREXANT AT WORLD SLEEP CONGRESS**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") today announced that latest data on lemborexant, an investigational sleep-wake regulation agent being studied for the treatment of sleep-wake disorders, including insomnia and Irregular Sleep-Wake Rhythm Disorder (ISWRD) associated with Alzheimer's disease/dementia will be presented at World Sleep Congress (World Sleep 2019), from September 20 to 25 in Vancouver, Canada.

At this congress, oral presentations will be given including the first congress presentation about the analysis of results at the end of 12 months from phase III clinical study (SUNRISE-2) evaluating long-term effectiveness and safety of lemborexant in patients with insomnia and the effect on sleep architecture in older adults with insomnia from phase III clinical study (SUNRISE-1) evaluating the efficacy and safety of lemborexant. Furthermore, one more oral presentation for nonclinical research about efficacy of lemborexant with ISWRD model mouse will be held. In addition, six poster presentations, including on the effect of lemborexant on fatigue by patient-reported outcomes from the 6-month placebo-controlled treatment period of SUNRISE-2 as a subgroup analysis will be given.

Lemborexant acts on the orexin neurotransmitter system and is believed to facilitate sleep onset, sleep maintenance, and wake by regulating sleep-wake rhythm.

Lemborexant is being developed for the treatment of sleep-wake disorders including insomnia disorder, and Eisai has submitted new drug applications seeking approval of lemborexant for use in the treatment of insomnia disorder in the United States (December 2018), Japan (March 2019), and Canada (August 2019), respectively. Additionally, a Phase II clinical study of lemborexant in patients with ISWRD associated with mild to moderate Alzheimer's dementia is underway. For the ongoing clinical studies, please visit [clinicaltrials.gov](http://clinicaltrials.gov).

Through the development of lemborexant, Eisai aims for contribution for rework/recovery by bringing an active daytime life by fast sleep onset and good quality sleep to patients suffering from sleep-wake disorders including insomnia, and is striving to further contribute to satisfying unmet medical needs and improve the benefits to patients and their families.

■ Oral presentations:

Session / Scheduled presentation date (local time)	Presentation Title
O01: Insomnia treatment and mechanisms <i>Monday, September 23th</i> 9:45-10:00	Long-term Effectiveness and Safety of Lemborexant in Adults with Insomnia Disorder: 12-month Results from SUNRISE-2
O01: Insomnia treatment and mechanisms <i>Monday, September 23th</i> 10:15-10:30	Effect of Lemborexant Compared With Placebo and Zolpidem Extended Release on Sleep Architecture in Older Adults With Insomnia Disorder
O30: Pharmacological interventions <i>Wednesday, September 25th</i> 16:30-16:45	Senescence-Accelerated Mouse Prone-8 SAMP8 Mice as a Preclinical Model for Irregular Sleep Wake Rhythm Disorder and Efficacy of the Dual Orexin (Hypocretin) Receptor Antagonist Lemborexant

■ Poster presentations:

Session / Poster No. Scheduled presentation date (local time)	Presentation Title
Poster session 1 / #118 <i>Sunday, September 22th</i> 16:30-18:00	Impact of Lemborexant Treatment on the Patient Global Impression – Insomnia Scale
Poster session 1 / #131 <i>Sunday, September 22th</i> 16:30-18:00	The Impact of Lemborexant Treatment on Insomnia Disease Severity: Results From a Pooled Analysis of Two Phase 3 Studies
Poster session 3 / #127 <i>Tuesday, September 24th</i> 17:30-19:00	Do Insomnia Patients in Insomnia Clinical Trials Endorse Daytime Sleepiness?
Poster session 3 / #139 <i>Tuesday, September 24th</i> 17:30-19:00	Insomnia Impacts the Patient and the Household: Perceptions of the Burden of Insomnia on Next-Day Functioning
Poster session 3 / #153 <i>Tuesday, September 24th</i> 17:30-19:00	Long-Term Effect of Lemborexant on Fatigue in Subjects with Insomnia Disorder: Patient-Reported Outcome from the 6-Month Placebo-Controlled Treatment Period of the Phase 3 Study SUNRISE-2
Poster session 3 / #160 <i>Tuesday, September 24th</i> 17:30-19:00	Patient-reported Sleep Onset and Sleep Maintenance: Pooled Responder Analyses of Lemborexant Phase 3 Studies

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**[Notes to editors]**

**1. About Lemborexant**

Lemborexant, a dual orexin receptor antagonist, is Eisai's in-house discovered and developed small molecule that inhibits orexin neurotransmission by binding competitively to the two subtypes of orexin receptors (orexin receptor 1 and 2). Faster on/off receptor kinetics of lemborexant to orexin receptor 2, which also suppresses non-REM sleep, indicate its potential to be facilitate the onset and maintenance of sleep. As a result of clinical studies, the effect of lemborexant are suggested not only for primary insomnia but also for insomnia which the diseases, such as depression, associated with (SUNRISE-1 and SUNRISE-2). In addition, the result of clinical study on lemborexant demonstrated no significant differences in next-morning driving performance of healthy adults and healthy elderly participants versus placebo (Study 106). Eisai has submitted new drug applications seeking approval of lemborexant for use in the treatment of insomnia disorder in the United States (December 2018), Japan (March 2019), and Canada (August 2019), respectively. Additionally, a Phase II clinical study of lemborexant in patients with ISWRD associated with mild to moderate Alzheimer's dementia is underway.

**2. About Sleep-Wake Disorders and Insomnia**

Sleep-wake disorders consist of disease categories such as insomnia, ISWRD, hypersomnia and breathing-related sleep disorders. Among the sleep-wake disorders, insomnia is the most common with persistent insomnia symptoms experienced by approximately 30 percent of the adult population worldwide.<sup>1,2</sup> 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.<sup>3,4</sup>

Good quality sleep is essential for good health, including brain health, and studies suggest an optimal sleep duration between seven and eight hours.<sup>5</sup> 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.<sup>3,6</sup>

Women are 1.4 times more likely than men to suffer from insomnia.<sup>7</sup> Older adults also have higher prevalence of insomnia; aging is often accompanied by changes in sleep patterns, including disrupted sleep, frequent waking, and early waking, that can lead to less sleep time.<sup>8</sup>

**References**

1. Ferrie JE, et al. Sleep epidemiology – a rapidly growing field. *Int J Epidemiol.* 2011;40(6):1431–1437.
2. Roth T. Insomnia: definition, prevalence, etiology and consequences. *J Clin Sleep Med.* 2007;3(5 Suppl):S7–S10.
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8. Crowley, K. Sleep and sleep disorders in older adults. *Neuropsychol Rev*. 2011;21(1):41-53.