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Eisai submits marketing authorization application for Insomnia drug

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Eisai Co., Ltd. has announced that a marketing authorization application has been submitted in Japan for lemborexant, an investigational agent for sleep-wake regulation, seeking approval for use in the treatment of insomnia disorder.

This application was based on the results of two pivotal Phase III clinical studies in patients with insomnia, SUNRISE 1 (Study 304) and SUNRISE 2 (Study 303), enrolling approximately 2,000 patients combined, as well as important safety studies, including assessment of postural stability after middle-of-the-night awakening, and a next-morning driving study (Study 106, Study 108).

SUNRISE 1 was a placebo-controlled 1-month Phase III clinical study evaluating the efficacy and safety of lemborexant versus zolpidem tartrate extended release (zolpidem ER) in 1,006 male or female adult patients 55 years and older (45% of patients were 65 years and older) with insomnia disorder, which was characterized by difficulty staying asleep.

SUNRISE 2 was a placebo-controlled 12-month Phase III clinical study conducted globally including in Japan to evaluate the long-term efficacy and safety of lemborexant in 949 male or female adult participants 18 to 88 years of age with insomnia disorder, which was characterized by difficulty falling asleep and/or staying asleep. During the first six months, patients were administered either lemborexant (5 mg, 10 mg) or placebo.

Lemborexant acts on the orexin neurotransmitter system and is believed to regulate sleep and wake by dampening wakefulness without impeding the ability to awaken to external stimuli. Lemborexant is being developed for the treatment of multiple sleep-wake disorders, including insomnia disorder. In addition to this marketing authorization application submitted in Japan, a New Drug Application was submitted in the United States to the Food and Drug Administration on December 27, 2018.

Furthermore, a Phase II clinical study of lemborexant in patients with irregular sleep-wake rhythm disorder and mild to moderate Alzheimer's dementia is ongoing.

It is estimated that approximately 1 in every 5 people (over 20 million people) in Japan suffers from a sleep disorder, and the number of patients being examined at medical institutions continues to increase. Eisai is striving to address new unmet medical needs and contribute to further increasing the benefits for patients and their families.