No.18-56

July 2, 2018
Eisai Co., Ltd.

EISAI TO GIVE ORAL PRESENTATION ON RESULTS OF PHASE III HEAD-TO-HEAD CLINICAL STUDY OF LEMBOREXANT IN INSOMNIA DISORDER AT 43RD ANNUAL MEETING OF THE JAPAN SOCIETY OF SLEEP RESEARCH

AT "DRUG DISCOVERY RESEARCH FOR SLEEP MEDICINE" SYMPOSIUM

Eisai Co., Ltd. (CEO: Haruo Naito, "Eisai") today announced that the latest data from a Phase III clinical study (SUNRISE 1) on its investigational sleep-wake regulation agent lemborexant (development code: E2006), will be presented in an oral presentation at the 43rd Annual Meeting of the Japan Society of Sleep Research being held from July 11 to 13 in Sapporo, Japan. This presentation will be given at the symposium "Drug Discovery Research for Sleep Medicine".
The symposium will report on the latest data on lemborexant from non-clinical research and clinical studies relating to insomnia, including the results of SUNRISE 1. In addition to SUNRISE 1 in which the primary and key secondary objectives were achieved, non-clinical research data from the course of discovery of lemborexant, including medicinal chemistry and pharmacology, will also be highlighted at the symposium.

With a robust polysomnography (PSG) data set, SUNRISE 1 was a Phase III clinical study of the efficacy and safety of lemborexant versus placebo and an active comparator (zolpidem tartrate extended release, "zolpidem ER") in approximately 1,000 patients 55 years and older with insomnia disorder. The study evaluated change from baseline for both sleep onset (primary objective) and sleep maintenance variables (secondary objectives), including the time spent awake in the second half of the night, which is a common complaint, especially in older patients. The study used objective PSG to determine if 5 mg and 10 mg reduced time to sleep onset and prolonged sleep maintenance compared to zolpidem ER 6.25 mg and to placebo. In this study, lemborexant had rates of discontinuation due to adverse events (AEs) comparable to placebo, with the most common AEs in the lemborexant arms being headache and somnolence.

Discovered by Eisai, lemborexant is being jointly developed by Eisai and Purdue Pharma L.P. ("Purdue").

Lemborexant appears to impact an underlying reason for a patient's inability to sleep and wake well. 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.

Through research and development on lemborexant, Eisai and Purdue are striving to bring to patients with sleep-wake disorders a new treatment option for sleep-wake regulation that improves their ability to fall asleep and stay asleep, without impairing them the next morning.

Oral Presentation: Symposium 11 “Drug Discovery Research for Sleep Medicine”

Product, Presentation No.	**Presentation title and scheduled presentation date**
Lemborexant Presentation No.: S11-4	Development of Lemborexant: A Novel Dual Orexin Receptor Antagonist for the Treatment of Insomnia Oral Presentation: July 12 (Thursday) 8:30 – 10:30 / Venue B (Special Venue)

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