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Eisai, Purdue Pharma declare positive results of SUNRISE 2

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The results of SUNRISE 2 are particularly encouraging for the many patients who suffer from chronic insomnia

Eisai Co., Ltd. and Purdue Pharma L.P. announced positive topline results from SUNRISE 2, a long-term Phase 3 efficacy and safety evaluation of lemborexant, an investigational agent for sleep-wake regulation currently being studied for the potential treatment of multiple sleep-wake disorders.

Topline results reported today are the primary and key secondary outcomes of the study from the six-month, placebo-controlled treatment period; the study is ongoing to 12 months. Eisai and Purdue Pharma plan to present full results from SUNRISE 2 at upcoming medical meetings in 2019.

SUNRISE 2 enrolled more than 900 adult patients (18 to 88 years of age) with insomnia disorder, characterized by difficulty falling asleep and/or staying asleep. The study met the pre-specified primary and a key secondary efficacy objective assessed by patient self-reports (sleep diaries).

At the end of the six-month, placebo-controlled treatment period, lemborexant 5 mg and 10 mg provided statistically significant improvement in subjective sleep onset latency compared to placebo, the study's primary endpoint.

Lemborexant 5 mg and 10 mg also provided statistically significant improvement in sleep maintenance variables of subjective sleep efficiency and subjective wake after sleep onset compared to placebo, which were the study's key secondary endpoints.

Daily functioning, as measured by the Insomnia Severity Index, was also improved by both lemborexant 5 mg and 10 mg compared to placebo. Overall discontinuation rates due to AEs were comparable between placebo and lemborexant 5 mg, and higher for lemborexant 10 mg.

"As a clinician and researcher treating patients with insomnia and other sleep-wake disorders for 30 years, for me, successful treatment means that patients fall asleep fast, sleep well, and wake well, without functional impairment, or loss of effect over time," said Russell Rosenberg, PhD, D.ABSM, a Principal Investigator in the lemborexant studies and former Chairman of the Board of the National Sleep Foundation. "The results of SUNRISE 2 are particularly encouraging for the many patients who suffer from chronic insomnia."

The results of SUNRISE 2 build on a growing body of knowledge supporting the development of lemborexant, including SUNRISE 1, a zolpidem tartrate extended release as well as key safety studies evaluating for impairment as assessed by the ability to maintain postural stability - a predictor of risk for falls - after middle-of-the-night and next morning awakening and next-morning driving performance.

Lemborexant appears to impact the underlying reason for a patient's inability to sleep 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.

Discovered by Eisai, lemborexant is being jointly developed by Eisai and Purdue Pharma.