BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Eisai, Purdue Pharma announce significant data of ph 3 clinical study

04 February 2019 | News

Six-month data show significant improvements in patient-reported measures of sleep onset and sleep maintenance for investigational agent lemborexant

Eisai Co., Ltd. and Purdue Pharma L.P. announced a six-month results from SUNRISE 2, a long-term Phase 3 clinical study evaluating the efficacy and safety of lemborexant, an investigational agent being developed for the treatment of insomnia, a sleep-wake disorder. Data were presented at the Sleep Research Society's Advances in Sleep and Circadian Science conference, taking place in Clearwater Beach, Florida, Feb. 1-4, 2019.

SUNRISE 2 was a 12-month multicentre, global, randomized, controlled, double-blind, parallel-group study of the efficacy and safety of lemborexant in 949 adult patients (18 to 88 years of age) with insomnia disorder, which was characterized by difficulty falling asleep and/or staying asleep. Approximately 28 percent of the patients randomized and treated were 65 years of age or older. During the first six months of the study, patients were randomized to receive either lemborexant 5 mg, lemborexant 10 mg, or placebo. The primary and key secondary efficacy objectives were assessed by patient self-reports via electronic sleep diaries.

"These findings add to the growing body of clinical data supporting the development of lemborexant for the treatment of insomnia, and we look forward to presenting 12-month results from the study in a future scientific forum," said Lynn Kramer, MD, Chief Clinical Officer and Chief Medical Officer, Neurology Business Group, Eisai. "It remains our aspiration to bring a medicine to physicians and patients that helps patients sleep well at night and wake well in the morning."

SUNRISE 2 is one of two Phase 3 safety and efficacy studies of lemborexant conducted by Eisai and Purdue Pharma. These studies supported the New Drug Application for lemborexant for the treatment of insomnia, filed with the U.S. Food and Drug Administration, on December 27, 2018. In Japan, an application is scheduled to be filed within fiscal 2018.

"The six-month findings from SUNRISE 2 are exciting, highlighting improvements in subjective measures of both sleep onset and sleep maintenance," said John Renger, PhD, Head of Research & Development and Regulatory Affairs, Purdue Pharma. "SUNRISE 2 was a robust Phase 3 clinical study in which the self-reported patient outcomes are encouraging as they reflect the patients' perception of lemborexant's impact on enabling the patient to both fall asleep faster and stay asleep longer."

Lemborexant, which 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, is being jointly developed by Eisai and Purdue Pharma

for the treatment of multiple sleep-wake disorders, including insomnia disorder. In addition to the treatment of insomnia disorder, a Phase 2 clinical study of lemborexant in patients with irregular sleep-wake rhythm disorder and mild to moderate Alzheimer's dementia is underway.