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Eisai gets USFDA nod for insomnia drug

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U.S. FDA Approves Eisai's DAYVIGOÃ¢â??Â¢ (lemborexant) for the Treatment of Insomnia in Adult Patients



Eisai has announced that the U.S. Food and Drug Administration (FDA) approved DAYVIGO™ (lemborexant) 5 mg and 10 mg for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. The approval was based on a robust clinical development program that included two pivotal Phase 3 studies, which evaluated DAYVIGO versus placebo for up to one month and DAYVIGO versus placebo for six months. The FDA has recommended that DAYVIGO be classified as a controlled substance, and this recommendation has been submitted to the U.S. Drug Enforcement Administration (DEA). DAYVIGO will be commercially available following scheduling by the DEA,

which is expected to occur within 90 days.

"Insomnia disorder is a chronic condition that has a variety of potential negative impacts and long-term consequences for health and well-being," said Russell Rosenberg, PhD, D.ABSM, a principal investigator in the DAYVIGO clinical studies and former Chairman of the Board of the National Sleep Foundation. "The clinical trials provide evidence that DAYVIGO may improve patients' ability to fall asleep and stay asleep."

The most common adverse reaction (reported in 5% or more of patients treated with DAYVIGO and at least twice the rate of placebo) in Study 1 (the first 30 days) and Study 2 was somnolence (DAYVIGO 10 mg, 10%; DAYVIGO 5 mg, 7%; placebo, 1.0%). The most common adverse reactions leading to discontinuation of DAYVIGO were somnolence (DAYVIGO 10 mg, 1.0%; DAYVIGO 5 mg, 0.7%; placebo, 0.4%) and nightmares (DAYVIGO 10 mg, 0.3%; DAYVIGO 5 mg, 0.3%; and placebo, 0%).

The FDA approval was based on findings from the lemborexant clinical development program, including two pivotal Phase 3 studies – Study 1 and Study 2. In 12-month and one-month controlled safety and efficacy trials (Studies 1 and 2, respectively), DAYVIGO was not associated with rebound insomnia following treatment discontinuation. Withdrawal effects were also assessed by the Tyrer Benzodiazepine Withdrawal Symptom Questionnaire following discontinuation from study drug in patients who received DAYVIGO 5 mg or 10 mg. There was no evidence of withdrawal effects following DAYVIGO discontinuation at either dose.

In addition to these pivotal trials, Eisai conducted a number of studies to further evaluate the safety of DAYVIGO, including a driving study and a study that assessed the effect of DAYVIGO on postural stability and memory performance.

We believe the approval of DAYVIGO is particularly exciting because it is the first FDA-approved medication to report safety data over a 12-month period along with sleep onset and sleep maintenance efficacy data over a six-month period in a pivotal clinical study," said Lynn Kramer, MD, Chief Clinical Officer, Neurology Business Group, Eisai. "We look forward to making this new therapeutic option available to the millions of patients who suffer with insomnia."

"DAYVIGO is an important addition to Eisai's rapidly growing neurology portfolio and underscores our leadership in neuroscience," said Ivan Cheung, Chairman and CEO, Eisai Inc. and Global President, Neurology Business Group, Eisai Co., Ltd. "Our commitment to patients and their families drives our relentless pursuit of innovative healthcare solutions."