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Eisai unveils new insomnia drug DAYVIGO

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Discovered at Eisai's Tsukuba Research Laboratories and developed in-house



Japan based Eisai Co., Ltd. has announced that its U.S. subsidiary Eisai Inc. has launched its in-house discovered orexin receptor antagonist DAYVIGO™ (lemborexant) CIV for the treatment of adults with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance in the U.S. on June 1, 2020.

Discovered at Eisai’s Tsukuba Research Laboratories and developed in-house, DAYVIGO is a small-molecule compound. The mechanism of action in the treatment of insomnia is presumed to be through antagonism of orexin receptors. The orexin neuropeptide signaling system plays a role in wakefulness.

Blocking the binding of wake-promoting neuropeptides orexin A and orexin B to orexin receptors OX1R and OX2R is thought to suppress wake drive. Lemborexant binds to orexin receptors OX1R and OX2R and acts as a competitive antagonist (IC50 values of 6.1 nM and 2.6 nM, respectively).

DAYVIGO was approved in the U.S. by the U.S. Food and Drug Administration (FDA) based on findings from the lemborexant clinical development program, which included two pivotal Phase 3 studies (SUNRISE 1 and SUNRISE 2) in nearly 2,000 adult patients with insomnia.

Analyses in both studies suggested DAYVIGO was not associated with rebound insomnia, and there was no evidence of withdrawal effects following treatment discontinuation, suggesting it does not produce physical dependence in those taking it for up to one year. DAYVIGO is the first FDA-approved insomnia medication with safety data over a 12-month treatment period and with sleep onset and sleep maintenance efficacy data over a six-month treatment period in a pivotal clinical study.

With the launch of DAYVIGO and through its continuing research and development efforts focusing on orexin biology, Eisai aspires to improve the lives of patients suffering from sleep disorders.