

Eisai's DAYVIGO gets approval in Japan to treat insomnia

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Japanese firm Eisai Co., Ltd has obtained the manufacturing and marketing approval in Japan for its in-house discovered orexin receptor antagonist DAYVIGOTM (2.5mg, 5mg, and 10mg tablets, lemborexant) for treatment of insomnia.

DAYVIGO is a dual orexin receptor antagonist that inhibits orexin neurotransmission regulating sleep-wake rhythm by binding competitively to the two subtypes of orexin receptors (OX1R and OX2R). Blocking the binding of wake-promoting neuropeptides orexin to orexin receptors is thought to suppress wake drive by balancing sleep-wake circuitry. DAYVIGO binds to orexin receptors OX1R and OX2R and acts as a competitive antagonist with stronger inhibition effect on OX2R.

This approval was mainly based on the results of two pivotal Phase 3 clinical studies in adult patients with insomnia, SUNRISE 2 and SUNRISE 1, enrolling approximately 2,000 patients. Approval was also based on important safety studies (Study108, Study106), which included assessment of residual next-morning effects via postural stability (falling prediction indicator) and memory after middle-of-the-night awakening.

In December 2019, the United States Food and Drug Administration (FDA) approved DAYVIGO for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. In the United States, DAYVIGO will be commercially available in 5 mg and 10 mg tablets following scheduling by the U.S. Drug Enforcement Administration (DEA), which is expected to occur within 90 days. In addition, Eisai submitted a new drug application seeking approval of DAYVIGO in Canada in August 2019.