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Eisai’s DAYVIGO gets approval in Japan to treat insomnia

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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)

Japanese firm Eisai Co., Ltd has obtained the manufacturing and marketing approval in Japan for its in-house discovered orexin receptor antagonist DAYVIGO™ (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.