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Eisai Co., Ltd.

New Drug Approval for In-House Developed Anti-Insomnia Drug DAYVIGO® (Lemborexant) in China

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the in-house-discovered and developed orexin receptor antagonist DAYVIGO® (brand name in China: "达卫可®" generic name: lemborexant) has been approved in China for the treatment of adults with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Eisai plans to launch this medicine in China in the second quarter of fiscal year 2025.

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). DAYVIGO acts on the orexin neurotransmitter system and is believed to facilitate sleep onset, sleep maintenance, and wake by regulating sleep-wake rhythm. DAYVIGO binds to orexin receptors OX1R and OX2R and acts as a competitive antagonist with stronger inhibition effect on OX2R, which suppresses both REM and non-REM sleep drive, such that DAYVIGO may provide faster sleep onset and better sleep maintenance to patients.

Eisai submitted an application for approval, which was accepted in January 2024, based on the outcome of two pivotal Phase 3 clinical studies (SUNRISE 1: NCT02783729 and SUNRISE 2: NCT02952820) conducted globally in a total of approximately 2,000 adult patients with insomnia, as well as the outcome of a Phase 3 clinical study (Study 311: NCT04549168) conducted in China.

Insomnia is characterized by difficulty falling asleep, staying asleep, or both despite an adequate opportunity to sleep, that has occured at least three times a week for at least one month, and which can lead to fatigue, difficulty concentrating and irritability [1,2]. The prevalence of insomnia among adults in China is reported to be 15.0% [3], with approximately 172.5 million people thought to suffer from insomnia. [4]

DAYVIGO has been approved for the treatment of insomnia in 22 countries and regions, including Japan and the United States, Canada, Australia and countries in Asia.

Eisai will continue its efforts to deliver DAYVIGO as a new treatment option to insomnia patients across the world with the hope of contributing to restoration of daytime function and recovery for patients with insomnia by potentially delivering an active daytime life through fast sleep onset and good quality sleep.

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[Notes to editors]

1. About DAYVIGO (Generic Name: Lemborexant)

DAYVIGO, an orexin receptor antagonist, is Eisai's in-house discovered and developed small molecule that inhibits orexin neurotransmission by binding competitively to the two subtypes of orexin receptors (orexin receptor 1 and 2). Fast on/off receptor kinetics of lemborexant to orexin receptors may influence lemborexant's potential to facilitate improvements in sleep onset and maintenance with minimal morning residual effects. It has been approved for the treatment of insomnia in 22 countries including Japan, the United States, Canada, Australia and countries in Asia.

References

1. Ferrie JE, et al. Sleep epidemiology – a rapidly growing field. *Int J Epidemiol.* 2011;40(6):1431–1437.
2. Roth T. Insomnia: definition, prevalence, etiology and consequences. *J Clin Sleep Med.* 2007;3(5 Suppl):S7–S10.
3. Cao X-L, et al. The prevalence of insomnia in the general population in China: A meta-analysis. *PLoS ONE* 2017,12(2): e0170772.
4. Internal estimate