News Release

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Eisai Co., Ltd.

Marketing Authorization Application for In-house Developed Insomnia Drug Lemborexant Accepted for Evaluation by the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA)

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the United Kingdom's (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA) has accepted for evaluation a marketing authorization application (MAA) for its in-house-discovered and developed orexin receptor antagonist lemborexant for the treatment of adult patients with insomnia, characterised by symptoms present for at least 3 months with considerable impact on daytime functioning.

Lemborexant is a dual orexin receptor antagonist (DORA) that inhibits orexin neurotransmission regulating sleep and wake states by binding competitively to the two subtypes of orexin receptors (OX1R and OX2R).[1] Lemborexant acts on the orexin neurotransmitter system, which regulates wakefulness. Lemborexant is believed to facilitate sleep onset and decrease wakefulness during the night by blocking the orexin receptors.[2]

Chronic insomnia is characterized by difficulty falling asleep, staying asleep, or both despite an adequate opportunity to sleep for at least three months, and which can lead to fatigue, difficulty concentrating and irritability.[3] In the U.K., chronic insomnia is reported to affect approximately 6.8–14.8% of adults and is recognized as an important health concern with a considerable impact on patients' quality of life and daily activities.[4] There is an increasing demand for treatment options that take into account their impact on daytime functioning.[5] If approved, lemborexant will represent another treatment option for insomnia patients in the U.K.

Eisai considers neurology, including sleep disorders, as a therapeutic area of focus. Eisai strives to create innovative products in therapeutic areas with high unmet medical needs as soon as possible. The Company will further contribute to addressing the diverse needs of and increasing the benefits provided to those living with neurological diseases and their families.

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[Notes to editors]

1. About lemborexant

Lemborexant, 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).[1] 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.[6] It has been approved for the treatment of insomnia in over 25 countries including Japan, the United States, Canada, Australia, and China, among others.[7]

1. Muehlan C, *et al*. The orexin story and orexin receptor antagonists for the treatment of insomnia. *J Sleep Res*. 2023 Dec;32(6):e13902.
2. Rosenberg R, *et al*. Comparison of Lemborexant With Placebo and Zolpidem Tartrate Extended Release for the Treatment of Older Adults With Insomnia Disorder: A Phase 3 Randomized Clinical Trial. *JAMA Netw Open*. 2019;2(12):e1918254.
3. Riemann, D, *et al*. (2023). The European Insomnia Guideline: An update on the diagnosis and treatment of insomnia 2023. *Journal of Sleep Research*, 32(6), e14035.
4. Hare A, *et al*. A modified Delphi consensus to reframe and prioritise the management of chronic insomnia in UK primary care. *BMJ Open*. 2025;15(11):e104341.
5. Beyer A, *et al*. Patient preferences for the benefits and risks of insomnia medication in a clinical trial and real-world setting. *Sleep Sci Pract.* 2025;9:36.
6. Beuckmann CT, *et al*. In Vitro and In Silico Characterization of Lemborexant (E2006), a Novel Dual Orexin Receptor Antagonist. *J Pharmacol Exp Ther*. 2017 Aug;362(2):287-295.
7. Eisai Global. 2025. Eisai Launches In-House Developed Anti-Insomnia Drug DAYVIGO® (Lemborexant) in China. Available at: https://www.eisai.com/news/2025/news202556.html. Last accessed: July 2026.