No.26-10

February 16, 2026
Eisai Co., Ltd.

Ministry of Health, Labour and Welfare Grants Orphan Drug Designation in Japan to Novel Orexin Receptor Agonist E2086 for Narcolepsy

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has received an orphan drug designation for its in-house discovered and developed novel selective orexin 2 receptor agonist E2086, with prospective indication for narcolepsy, from the Ministry of Health, Labour and Welfare (MHLW).

Narcolepsy is a chronic sleep disorder that is characterized by excessive daytime sleepiness (EDS). Due to problems with fatigue, cognition, and persistence of residual symptoms despite treatment, disease burden for narcolepsy is high,[1] and narcolepsy remains a disease with high unmet medical needs. While estimates vary depending on the study data, a 2025 report estimates the narcolepsy patient population in Japan to be approximately 46,000.[2] Narcolepsy is classified into two subtypes, type 1 (narcolepsy with cataplexy) and type 2 (narcolepsy without cataplexy). The pathogenesis of narcolepsy type 1 is thought to involve a deficiency of orexin due to autoimmune destruction of orexin-producing neurons located in the hypothalamus. Although the pathogenesis of narcolepsy type 2 remains unknown, it has been suggested that a reduction in orexin neurotransmission may also be involved.[3]

Orexin is a neurotransmitter that plays a central role in regulating sleep and wakefulness. Inhibiting orexinergic neurons is believed to promote a natural transition from wakefulness to sleep. Conversely, activating orexinergic neurons is believed to help maintain a more stable state of wakefulness. From the perspective of inhibiting orexinergic neuron activity, Eisai has developed the insomnia treatment DAYVIGO® (generic name: lemborexant), an orexin receptor antagonist that is approved in more than 25 countries and regions worldwide. Furthermore, leveraging the unique orexin platform established through the development of DAYVIGO, Eisai has created E2086, a selective orexin 2 receptor agonist that activates orexinergic neurons. E2086 has the potential to improve patients' symptoms by enhancing orexin receptor activity and acting on the pathophysiology of narcolepsy. Eisai presented data from a Phase Ib clinical study in patients with narcolepsy type 1, which suggests that E2086 has the potential to improve daytime wakefulness, at the World Sleep 2025 congress.[4]

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

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. About Orphan Drug Designation System in Japan

The orphan drug designation system in Japan aims to support the development of drugs for diseases for which the number of patients is small, and research and development is not progressing, despite high unmet medical need. As the requirement for designation based on Article 77-2 of the Pharmaceutical and Medical Device Act (PMD Act) of Japan, a drug must meet the following conditions in order to be considered for orphan drug designation in Japan: the number of people expected to use the drug for its intended use is fewer than 50,000 people in Japan; there is no suitable alternative drug or treatments in Japan, or the proposed drug is expected to be significantly more effective or safer than drugs already available on the Japanese market; there is a scientific rationale to support the necessity of the drug for the target disease, and the development plan for the drug is appropriate. Specific measures to support the development of orphan drugs include giving prioritized consultation regarding clinical development and conducting priority examinations, reducing application fees, extension of re-examination period, granting subsidies for research and development expenditures, and tax incentives.

2. About narcolepsy

Narcolepsy is a chronic sleep disorder and classified into two subtypes, type 1 (narcolepsy with cataplexy) and type 2 (narcolepsy without cataplexy). The pathogenesis of narcolepsy type 1 is thought to be the autoimmune destruction of orexin-producing neurons located in the hypothalamus. Individuals with a deficiency of orexin demonstrate a loss of orexinergic neurons, and low cerebrospinal fluid (CSF) orexin levels and demonstrate excessive daytime sleepiness (EDS). Although the pathogenesis of narcolepsy type 2 remains unknown, it has been suggested that a reduction in orexin neurotransmission may also be involved.[3]

While estimates vary depending on the study data, according to a study using the JMDC Inc. insurance payer database, the number of narcolepsy patients in Japan is estimated at approximately 23,000, based on the criteria of medical claims made for two consecutive months during the study period.[5] Meanwhile, the number is estimated to be 46,000 when including patients with two or more medical claims over a 12-months period.[2]

3. About E2086

E2086 is Eisai's in-house discovered novel selective orexin 2 receptor agonist. Nonclinical studies have demonstrated statistically significant increases in time spent awake and significant reductions in rates of cataplexy. Furthermore, in a Phase Ib clinical trial with patients with narcolepsy type 1, the agent demonstrated a statistically significant reduction in excessive daytime sleepiness compared to placebo or the existing drug (modafinil).[4]

References

1. Maski. K, et.al. Listening to the Patient Voice in Narcolepsy: Diagnostic Delay, Disease Burden, and Treatment Efficacy. *J. Clinical Sleep Medicine*. 2017, 13 (3) p419-,https://jcsm.aasm.org/doi/pdf/10.5664/jcsm.6494
2. Kadotani H, Matsuo M, Tran L, Parsons VL, Maguire A, Crawford S, Ghosh S, Dave S. Epidemiology of narcolepsy and idiopathic hypersomnia in Japan: A retrospective analysis of health insurance claims from the Japan Medical Data Center. *Sleep Med*. 2025; 126: 25–31.
3. Thannickal TC, Nienhuis R, Siegel JM. Localized loss of hypocretin (orexin) cells in narcolepsy without cataplexy. *Sleep*. 2009; 32: 993–8.
4. Highlights from oral presentation on E2086 at World Sleep 2025 – September 11, 2025 https://www.eisai.com/ir/library/presentations/pdf/e4523_250911.pdf
5. Imanishi A, Kamada Y, Shibata K, Sakata Y, Munakata H, Ishii M. Prevalence, incidence, and medications of narcolepsy in Japan: a descriptive observational study using a health insurance claims database. *Sleep Biol Rhythms. 2022; 20: 585–94.*