

NEW DRUG APPROVAL FOR IN-HOUSE DEVELOPED ANTI-INSOMNIA DRUG DAYVIGO® (LEMBOREXANT) IN HONG KONG

FIRST DRUG APPROVAL FOR DAYVIGO IN ASIA OUTSIDE OF JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its Hong Kong subsidiary Eisai (Hong Kong) Co., Ltd. has obtained approval for the in-house-discovered and developed orexin receptor antagonist DAYVIGO® (generic name: lemborexant) for the treatment of adults with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. This approval is the first approval for DAYVIGO in Asia outside of Japan.

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.

In June 2020, DAYVIGO was launched in the U.S. for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance; and in July 2020, DAYVIGO was launched in Japan for the treatment of insomnia. In addition, DAYVIGO has been approved in Canada, and an application for approval has been submitted in Australia. In Asia, Eisai has currently submitted applications to the respective regulatory authorities in India, Indonesia, Malaysia, the Philippines, Singapore, Taiwan and Thailand, and plans to further expand submissions of applications for approval in other countries.

Insomnia is characterized by difficulty falling asleep, staying asleep or both, despite an adequate opportunity to sleep, that can lead to daytime consequences, such as fatigue, difficulty concentrating and irritability.^{1,2} Insomnia is one of the most common sleep-wake disorders. Approximately 30% of adults worldwide have symptoms of insomnia.^{3,4} In Hong Kong, over 35% of adults are reported to have symptoms of insomnia.⁵ In particular, older adults also have a higher prevalence rate with many experiencing insomnia symptoms for months to years. As a result, insomnia causes various social losses, such as long absences and reduced productivity. It can increase the risk of falls in older adults.⁶

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 is Eisai's in-house discovered and developed small molecule that binds to orexin receptors, OX1R and OX2R, and acts as a competitive antagonist (IC₅₀ values of 6.1 nM and 2.6 nM, respectively). The mechanism of action of DAYVIGO in the treatment of insomnia is presumed to be through antagonism of orexin receptors. The orexin neuropeptide signaling system plays a role in wakefulness. Blocking the binding of wake-promoting neuropeptides orexin to receptors OX1R and OX2R is thought to suppress wake drive (Ki values of 8.1 nM and 0.48 nM, respectively). Higher affinity and faster on/off receptor kinetics of DAYVIGO to orexin receptor 2, which also suppresses non-REM sleep, indicates its potential to facilitate non-sedative onset and maintenance of sleep.

In addition to the indication of insomnia, a clinical study of DAYVIGO in the treatment of Irregular Sleep Wake Rhythm Disorder (ISWRD) associated with mild-to-moderate Alzheimer's dementia is underway.

2. About Sleep-Wake Disorders and Insomnia

Sleep-wake disorders consist of disease categories such as insomnia, ISWRD, hypersomnia and breathing-related sleep disorders. Among the sleep-wake disorders, insomnia is the most common with persistent insomnia symptoms experienced by approximately 30% of the adult population worldwide.^{3,4} Insomnia disorder is characterized by difficulty falling asleep, staying asleep or both, despite an adequate opportunity to sleep, which can lead to daytime consequences, such as fatigue, difficulty concentrating and irritability.^{1,2}

Sleeping well is essential for good health, including brain health.⁷ Studies suggest an optimal sleep duration between seven and eight hours.⁸ Poor sleep is associated with a wide range of health consequences, including an increased risk of hypertension, accidental injury, diabetes, obesity, depression, heart attack, stroke, dementia and adverse effects on mood and behavior.^{1,8}

Women are 1.4 times more likely than men to suffer from insomnia.⁹ Older adults also have higher prevalence of insomnia as aging is often accompanied by changes in sleep patterns, including disrupted sleep, frequent waking, and early waking, that can lead to less sleep time.¹⁰

3. About the Anti-Insomnia Drug Market in Hong Kong

The anti-insomnia drug market in Hong Kong as of 2019 valued at approximately 7.6 million USD, comprising nearly 8% of the insomnia drug market in Asia (Hong Kong, India, Indonesia, Korea, Malaysia, the Philippines, Singapore, Taiwan, Thailand).¹¹

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