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Eisai Co., Ltd.

Marketing Authorization Application for In-house Developed Insomnia Drug Lemborexant Accepted for Evaluation by European Medicines Agency (EMA)

Eisai Co., Ltd. announced today that the European Medicines Agency (EMA) has accepted for evaluation a marketing authorization application (MAA) for its in-house-discovered and developed orexin receptor antagonist lemborexant (generic name) for the treatment of adult patients with chronic insomnia.

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 Europe, chronic insomnia is reported to affect approximately 4.7–22.1% of adults and is recognized as an important health concern with a considerable impact on patients' quality of life and daily activities.[4] In the current treatment of insomnia in Europe, medications that relatively broadly suppress (sedate) central nervous system activity are widely used. There is an increasing demand for treatment options that take into account their impact on daytime functioning.[5] If approved, lemborexant will represent a new treatment option for insomnia patients in Europe.

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.

References

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