No. 12-16

April 17, 2012
Eisai Co., Ltd.

EISAI TO LAUNCH INSOMNIA TREATMENT LUNESTA® IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it will launch the insomnia treatment Lunesta® (eszopiclone) in Japan on April 18.

Lunesta, originally discovered and developed by Sunovion Pharmaceuticals Inc. ("Sunovion"; formerly Sepracor Inc.; currently a U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd.), is the first non-benzodiazepine type $GABA_A$ agonist to be launched in Japan in 12 years, and is believed to enhance GABA activity while exerting hypnotic and sedative effects. Results from clinical studies conducted in both Japan and overseas demonstrated that the agent is effective in treating those patients who have trouble falling asleep or wake up often during the night, two major symptoms of insomnia. Moreover, a distinctive feature of Lunesta is that patients do not experience clinically problematic issues such as dependency or carry-over effects, or develop a tolerance (experience diminished efficacy) with long-term use.

Marketed in the United States since April 2005, Lunesta was approved as the first insomnia treatment not to have restrictions placed on its length of use, and is widely used by individuals suffering from insomnia and is not typically taken by patients concomitantly with other insomnia treatments. Eisai has been pursuing the development of Lunesta since acquiring the exclusive rights to develop and market the product in Japan from Sunovion (at the time known as Sepracor). Lunesta received approval in Japan in January 2012, and was subsequently listed on the National Health Insurance (NHI) drug price list on April 17.

In a Phase II/III study (Study 126) conducted in Japan in patients with primary insomnia, patients treated with Lunesta demonstrated a statistically significantly improvement in Sleep Latency (SL)[1)], as measured by subjective evaluation, compared to placebo. Furthermore, Lunesta was shown to produce a statistically significant reduction (when measured against placebo) in Latency to Persistent Sleep (LPS), as objectively measured by an overnight polysomnography (PSG)[2)]. The effects of Lunesta on measures of SL and LPS were the two co-primary endpoints of Study 126. The favorable safety profile of Lunesta was also confirmed in a long-term study (Study 150) in patients with various forms of insomnia, including elderly adults and adults with insomnia associated with psychological disorders.

Insomnia is a condition that has a repeated negative effect on a person's ability to fall asleep, remain asleep or obtain quality of sleep despite having ample opportunity to sleep, and can interfere with everyday activities. In Japan, it is estimated that more than 20 million people suffer from some kind of sleep disorder, and this number expected to increase even further. By providing Lunesta as a new treatment for insomnia, Eisai seeks to make contributions to increase the benefits provided to patients.

[1)]Sleep latency (SL): the interval from "lights out" until sleep begins

[2)] Overnight polysomnography (PSG): a diagnostic tool that measures brain activity, eye movement and skeletal muscle activation to simultaneously record throughout the night the biophysical activity that occurs during sleep.

[Please refer to the following notes for a product outline, further information on Lunesta and Japan clinical studies, and a product photograph]

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[Notes to editors]

1. Product Outline

1) Product Name:

Lunesta® Tablets 1 mg, Lunesta® Tablets 2 mg, Lunesta® Tablets 3 mg

2) Generic Name:

eszopiclone

3) Indications and Usage:

Insomnia

4) Dosage and Administration:

The recommended dose of eszopiclone is 2 mg for non-elderly adults and 1mg for elderly adults taken orally immediately before bedtime. Dosage may be adjusted according the patients symptoms, however, it should not exceed 3 mg per dose for non-elderly adults or 2 mg per dose for elderly adults.

5) Price:

Lunesta Tablets 1 mg	49.60 yen
Lunesta Tablets 2 mg	78.70 yen
Lunesta Tablets 3 mg	99.80 yen

6) Packaging

Lunesta Tablets 1 mg	100 tablets (blister packaging/loose), 140 tablets (blister packaging)
Lunesta Tablets 2 mg	100 tablets (blister packaging), 140 tablets (blister packaging), 500 tablets (loose)
Lunesta Tablets 3 mg	100 tablets (blister packaging), 140 tablets (blister packaging), 500 tablets (loose)

2. About Lunesta®

Lunesta is a non-benzodiazepine type $GABA_A$ agonist (non-benzodiazepine sedative hypnotic) that was originally discovered and developed by Sunovion Pharmaceuticals Inc. (formerly Sepracor Inc.; a U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd.). The agent is an S-enantiomer obtained through optical resolution of the racemic compound (a mixture containing equal parts of the R- and S-enantiomers) zopiclone. Sleep is thought to be induced as a result of inhibition of (excitatory) neurotransmission in the brain's arousal system, with the neurogenic amino acid derivative GABA (γ-aminobutyric acid) serving as the chief inhibitory neurotransmitter. $GABA_A$ agonists are thought to enhance GABA effects and induce sleep by binding directly or allosterically to the ionotropic $GABA_A$ receptor complex. Clinical trials conducted overseas have confirmed that Lunesta is effective in treating transient and chronic insomnia and that it can be used over the long term without patients developing a tolerance to it. In other words, its efficacy does not diminish over time. The marketing authorization application submitted and approved in Japan was based on data from the following domestic clinical trials as well as data from trials conducted overseas.

3. Japan Clinical Trials

1) Study 126

Study Design: Multicenter, randomized, placebo-controlled, 5-way crossover, double-blind comparison

Eligibility: Chronic insomnia patients aged between 21 and 64 years old who had been diagnosed with primary insomnia (72 subjects)

Primary Objective: To investigate and evaluate the dose response of eszopiclone and its superiority relative to placebo

Treatment Arms: eszopiclone 1 mg, 2 mg, 3 mg, placebo, zolpidem tartrate 10 mg

Treatment Period: Five treatment phases for two consecutive nights, each separated by a washout period of four to six days

Co-primary Endpoints:

Latency to persistent sleep (LPS), as measured by an overnight polysomnography (PSG), and sleep latency (SL), as measured by subjective evaluation

2) Study150

Study Design: Multicenter, randomized, parallel-arm, double-blind comparison

Eligibility: Chronic insomnia patients aged between 20 and 84 years old (325 subjects)

Primary Objective: To evaluate the long-term safety of eszopiclone

Treatment Arms: Non-elderly adults: eszopiclone 2 mg, 3 mg; Elderly adults: eszopiclone 1 mg, 2 mg

Treatment Period: Once daily for a period of 24 weeks

Primary Endpoint: Adverse events

[Product Image]