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Eisai Co., Ltd.

# EISAI SUBMITS MARKETING AUTHORIZATION APPLICATION IN JAPAN FOR INSOMNIA TREATMENT SEP-190

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that it has submitted a Marketing Authorization Application (MAA) to the Japanese Ministry of Health, Labour and Welfare seeking approval for SEP-190 (generic name: eszopiclone), a product the company has been developing in Japan, as a treatment for insomnia.

SEP-190 is a non-benzodiazepine type $GABA_A$ agonist (non-benzodiazepine sedative hypnotic) that is effective in treating transient and chronic insomnia and that can be used over the long-term without patients developing a tolerance resistance to it. Originally discovered and developed by Sunovion Pharmaceuticals Inc. (“Sunovion”; formerly Sepracor Inc.), the U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd. (Headquarters: Osaka, President & CEO: Masayo Tada), SEP-190 has been marketed in the United States by Sunovion since April 2005 under the brand name LUNESTA® and is widely used by patients with various forms of insomnia who have difficulty falling asleep and/or who wake up frequently during the night. Eisai obtained the exclusive rights to develop and market SEP-190 in Japan in a licensing agreement it concluded with Sunovion (known as Sepracor Inc. at time of signing) in July 2007.

The MAA is based primarily on two pivotal clinical studies conducted with SEP-190 in Japan, namely a Phase II/III (Study 126) clinical study in patients with primary insomnia and a Phase III study (Study 150) in patients with insomnia. Study 126 demonstrated that, compared to placebo, SEP-190 statistically significantly reduced latency to persistent sleep (LPS), as measured by an overnight polysomnography (PSG), and sleep latency (SL), as measured by subjective evaluation, in adult Japanese patients with primary insomnia. Study 150 confirmed the favorable long-term safety profile of the agent in adult and elderly Japanese insomnia patients.

In Japan, it is estimated that one out of every four or five people suffers from some kind of sleep disorder, and this number is expected to continue to increase even further. Insomnia is a condition that repeatedly affects a person’s ability to fall asleep, remain asleep or obtain quality sleep, and that interferes with everyday activities.

Eisai is committed to expediting the approval of SEP-190 in Japan, and seeks to make contributions to increasing the benefits provided to patients living with insomnia by further expanding its lineup of neurology products.

**[Please refer to the following notes for further information on SEP-190, Study 126 and Study 150]**

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**[Notes to editors]**

**1. About SEP-190**

Generic Name: eszopiclone

SEP-190 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.). It 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 SEP-190 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.

**2. About Study 126**

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| Study Design: | Multicenter, randomized, placebo-controlled, double-blind, 5-way crossover study |
| Eligibility: | Patients with chronic insomnia aged between 21 and 64 years who have been diagnosed with primary insomnia (72 subjects) |
| Primary Objective: | To investigate and evaluate the dose-response of SEP-190 and its superiority relative to placebo |
| Treatment Arms: | SEP-190: 1 mg, 2 mg, 3 mg, placebo, zolpidem tartrate 10 mg |
| Treatment Period: | Five treatment phases for two consecutive nights, each phase separated by a washout period of 4 to 6 days |
| Primary Endpoints: | Latency to persistent sleep (LPS), as measured by an overnight polysomnography (PSG), and sleep latency (SL), as measured by subjective evaluation<br>*overnight polysomnography (PSG): a diagnostic tool that uses an EEG (measures brain activity), EOG (measures eye movement), and EMG (measures skeletal muscle activation) to simultaneously record throughout the night the biophysical activity that occurs during sleep<br>*latency to persistent sleep: the interval from "lights out" until sleep begins |

**3. About Study 150**

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| Study Design: | Multicenter, randomized, double-blind, parallel-arm study |
| Eligibility: | Patients with chronic insomnia aged between 20 and 84 years (325 subjects) |
| Primary Objective: | To evaluate the long-term safety of SEP-190 |
| Treatment Arms: | Non-elderly patients: SEP-190: 2 mg, 3 mg; Elderly patients: SEP-190: 1 mg, 2 mg |
| Treatment Period: | Once daily for a period of 24 weeks |
| Primary Endpoint: | Adverse events |