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Eisai Co., Ltd.

JAPANESE CLINICAL TRIALS CONFIRM SAFETY AND EFFICACY OF INSOMNIA TREATMENT SEP-190

EISAI PLANS TO SUBMIT MAA IN FISCAL 2010

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that clinical studies conducted in Japanese patients with insomnia have confirmed the efficacy and favorable safety profile of SEP-190 (generic name: eszopiclone). Based on these results, Eisai plans to submit a marketing authorization application in fiscal 2010 seeking approval of the agent to the Japan's Ministry of Health, Labour and Welfare.

A Phase II/III clinical study (Study 126) with SEP-190 was conducted in Japan in patients with primary insomnia, in addition to a Phase III study (Study 150) in patients with insomnia. Study 126 evaluated the efficacy of SEP-190 in 72 adult patients with primary insomnia through an overnight polysomnography (PSG) and subjective evaluation. Results showed that, compared with placebo, SEP-190 statistically significantly reduced latency to persistent sleep (LPS), as measured by a PSG, and sleep latency (SL), as measured by subjective evaluation, the study's two primary outcome measures. Study 150 evaluated the long term safety of SEP-190 in 325 adult and elderly patients with chronic insomnia caused by a variety of factors. Results of the study confirmed that the agent has a favorable safety profile.

SEP-190 is a non-benzodiazepine type $GABA_A$ agonist (non-benzodiazepine sedative hypnotic) discovered and developed by Sepracor Inc., the U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd. (Headquarters: Osaka, President & CEO: Masayo Tada). SEP-190 was approved in the United States by the U.S. Food and Drug Administration (FDA) in December 2004, and has been marketed by Sepracor under the brand name LUNESTA® since April 2005. Lunesta is approved for use in the United States to treat transient and chronic insomnia and studies of the product have shown that most patients using Lunesta over the long-term do not develop a resistance to it. Eisai obtained the exclusive rights to develop and market SEP-190 in Japan through a licensing agreement it concluded with Sepracor in July 2007.

In Japan, it is estimated that one out of every four or five people suffers from a sleep disorder. With this number expected to increase even further, 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 products in the neurology area.

[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). 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 resistance to it. In other words, its efficacy does not diminish over time.

2. About Study 126

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
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 *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 *latency to persistent sleep: the interval from "lights out" until sleep begins

3. About Study 150

Study Design:	Multicenter, randomized, double-blind, parallel-arm study
Eligibility:	Patients with chronic insomnia aged between 20 and 84 years
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