Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that it has presented data from a Phase II clinical study (Study 201) on its in-house-developed investigational dual orexin receptor antagonist (DORA) E2006 in patients with insomnia disorder at the 53rd American College of Neuropsychopharmacology (ACNP) Annual Meeting held from December 7 through 11, 2014, in Phoenix, Arizona in the United States. In the study

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[Notes to editors]

1. About E2006

E2006, a dual orexin receptor antagonist (DORA), is an in-house discovered and developed small molecule compound by Eisai which inhibits orexin by binding competitively to two subtypes of orexin neuron receptors (orexin receptor 1 and 2). In individuals with insomnia disorder, it is possible that the orexin system which regulates sleep and wakefulness is not functioning normally. During normal periods of sleep, orexin system activity is suppressed, suggesting it is possible to purposefully counteract inappropriate wakefulness and facilitate the initiation and maintenance of sleep by interfering with orexin neurotransmission. Therefore Eisai is developing E2006 as a treatment for insomnia.

2. About Study 201

Study Design:	Multi-center (within the U.S.), randomized, double-blind, placebo-controlled, parallel-group, Bayesian adaptive, dose response study
Eligibility:	Patients between 18 and 80 years old, inclusive, with chronic insomnia as defined by the DSM-5 criteria for insomnia disorder (difficulty sleeping at least 3 times per week for a period of at least 3 months), 291 subjects
Primary Objective:	Identify an optimal dose of E2006 that balances sleep efficiency and next-day residual sleepiness
Treatment Method:	Patients were given a dose of either E2006 at 1 mg, 2.5 mg, 5 mg, 10 mg, 15 mg, 25 mg or placebo prior to sleep
Treatment Duration:	Screening period to determine eligibility and establish baseline sleep parameters, 15 days (nights), followed by 2 days (nights) of placebo to assess rebound insomnia (occurrence of insomnia worse than at baseline after stopping treatment)
Primary Endpoints:	Sleep efficiency (SE) as measured by objective polysomnography (PSG) and next-day residual sleepiness as measured by the Karolinska Sleepiness Scale (KSS)
Secondary Endpoints:	Latency to persistent sleep (LPS), wake after sleep onset (WASO), Sleep Diary measures of efficacy, objective measures of next-day residual sleepiness, etc.

*Bayesian adaptive design: A multi-stage study that optimally changes (adapts) treatment allocation based on the results of interim analyses

*PSG: A sleep assessment method that records the biophysiological changes that occur during sleep by monitoring designated parameters such as brainwaves, eye movements and skeletal muscle activation

*SE: Total sleep time as a proportion of time in bed

*LPS: Time from lights off to entering persistent sleep

*WASO: Total time spent awake after falling asleep

*KSS: Subjective sleepiness assessment scale developed by the Karolinska Institute