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Eisai Co., Ltd.

EISAI TO INITIATE PHASE II CLINICAL STUDY OF DUAL OREXIN RECEPTOR ANTAGONIST LEMBOREXANT IN PATIENTS WITH IRREGULAR SLEEP-WAKE RHYTHM DISORDER AND DEMENTIA

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today the initiation of a Phase II clinical study of its internally-discovered oral dual orexin receptor antagonist lemborexant (development code: E2006) in patients with Irregular Sleep-Wake Rhythm Disorder (ISWRD) and mild to moderate Alzheimer's disease (AD) dementia. Lemborexant is being jointly developed by Eisai and Purdue Pharma L.P. (Headquarters: Connecticut, United States, President and CEO: Mark Timney).

ISWRD is a type of circadian rhythm sleep disorder where the pattern of sleep and wakefulness that repeats itself over a 24 hour period in healthy individuals is broken down, and sleeping and waking occur instead at various times during the day and night. This is often observed in patients with neurodegenerative diseases such as AD. At the pre-investigational new drug meeting held with the U.S. Food and Drug Administration, it was confirmed ISWRD is different from general insomnia. There is no known treatment approved for an irregular sleep-wake pattern in patients, meaning this is a condition with high unmet medical need.

Study 202 is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study of the efficacy and safety of lemborexant in approximately 125 patients aged 65 to 90 with ISWRD and mild to moderate AD. The primary objective will be to evaluate the sleep efficiency and wake efficiency during the last seven nights of 4 weeks of treatment with lemborexant compared to placebo as measured using actigraphy. An actigraph is a non-invasive device worn on the wrist, and is used for assessing the circadian rhythm of sleep-wake patterns continuously over several weeks.

Regarding the development of lemborexant, a Phase III clinical study (Study 304) in patients with general insomnia is also in progress. Study 304 is a Phase III clinical study evaluating the efficacy and safety of lemborexant in approximately 950 participants, 55 years or older (at least 60% aged 65 years or older) with insomnia disorder. In addition to Study 304, three other Phase III studies are being planned.

Dr. Lynn Kramer, Chief Clinical Officer and Chief Medical Officer of Eisai's Neurology Business Group, commented "We are aiming to develop lemborexant as a first-in-class medicine for ISWRD to improve sleep and wake patterns for patients with dementia, and as a best-in-class medicine for insomnia disorder. We are striving to deliver lemborexant and contribute to increasing the benefit to patients around the world as soon as possible."

Eisai considers neurology a therapeutic area of focus and is committed to new drug development in this field. Through research and development on lemborexant, Eisai is striving to fulfill new unmet medical needs in ISWRD and dementia in addition to insomnia to further contribute to increasing the benefit for patients and their families.

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. About lemborexant

Lemborexant (development code: E2006), a dual orexin receptor antagonist, is an in-house discovered and developed small molecule compound by Eisai which inhibits orexin by binding competitively to two subtypes of orexin 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 facilitate the initiation and maintenance of sleep by interfering with orexin neurotransmission with lemborexant.

A Phase III study of lemborexant in insomnia is underway, and in addition, Eisai has announced the initiation of Phase II clinical studies of lemborexant in patients with irregular sleep-wake rhythm disorder (ISWRD) and mild to moderate Alzheimer's disease.

2. About ISWRD (Irregular Sleep-Wake Rhythm Disorder)

ISWRD is a type of circadian rhythm sleep disorder where the pattern of sleep and wakefulness that repeats itself over a 24 hour period in healthy individuals is broken down, and sleeping and waking occur instead at various times during the day and night. This is often observed in patients with dementia. Although referred to in this press release as ISWRD, the condition is also known as Circadian Rhythm Sleep Disorder (Irregular Sleep Wake Type).

3. About Study 202

Study 202 is a multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase II clinical study of the efficacy and safety of lemborexant in subjects with ISWRD and mild to moderate Alzheimer's disease dementia (AD) conducted in the United States and Japan. Patients with ISWRD associated with AD will be administered 2.5 mg, 5 mg, 10 mg or 15 mg of lemborexant or placebo for 4 weeks to determine whether at least one dose of lemborexant is superior to placebo on the change from baseline of mean sleep efficiency (ratio of time spent asleep to the total amount of time spent in bed) and wake efficiency (ratio of time spent awake to the total amount of time not asleep at night) during the last week of 4 weeks of treatment, as measured by actigraphy.

4. About Study 304

Study 304 is a multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase III clinical study of the efficacy and safety of lemborexant conducted in the United States and Europe. Approximately 950 patients 55 years and older (at least 60% aged 65 years or older) with insomnia disorder will be administered either lemborexant 10 mg or zolpidem tartrate extended release 6.25 mg. Regarding efficacy, polysomnography will be used to measure objective sleep maintenance in the second half of the sleep period after the last 2 nights of treatment.

5. About Purdue Pharma L.P.

Purdue Pharma L.P. and associated U.S. companies are privately-held pharmaceutical companies known for pioneering research in chronic pain. Purdue Pharma is engaged in the research, development, production and distribution of prescription and over-the-counter medicines, as well as hospital products. Purdue Pharma is committed to advancing the care of patients with quality products that make a positive impact on healthcare — and on lives. Purdue Pharma's headquarters are located in Stamford, Conn. For more information about Purdue Pharma, please visit www.purduepharma.com