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EISAI AND PURDUE PHARMA ANNOUNCE POSITIVE TOPLINE RESULTS FROM KEY CLINICAL STUDIES OF LEMBOREXANT INCLUDING FIRST-EVER PHASE 3 HEAD-TO-HEAD SUPERIORITY COMPARISON VERSUS ZOLPIDEM ER IN PATIENTS WITH SLEEP DISORDER

Tokyo, Japan and Stamford, Conn., U.S. – March 7, 2018 – Eisai Co., Ltd. (CEO: Haruo Naito, "Eisai") and Purdue Pharma L.P. (President and CEO: Craig Landau, "Purdue Pharma") today announced positive topline results from multiple studies of lemborexant, an investigational agent for sleep and wake regulation currently being studied for the treatment of multiple sleep disorders.

The Phase 3 pivotal study, SUNRISE 1, achieved its primary and key secondary objectives versus placebo and versus an active comparator (zolpidem tartrate extended release, "zolpidem ER") in patients 55 years and older with difficulty staying asleep through the night. With a robust polysomnography (PSG) data set, this was the first-ever Phase 3 study with pre-specified endpoints versus zolpidem ER, measuring the change from baseline in both sleep onset and sleep maintenance variables, including the time spent awake in the second half of the night, which is a common complaint, especially in the elderly. The study used objective PSG to determine if 5 mg and 10 mg lemborexant were superior to zolpidem ER 6.25 mg and to placebo. In this study, lemborexant had rates of discontinuation due to adverse events (AEs) comparable to placebo, with the most common AEs in the lemborexant arms being headache and somnolence. Eisai and Purdue plan to present full results of SUNRISE 1 at an upcoming medical meeting in 2018.

In addition, a Phase 1 safety study (Study 108) assessed the ability to maintain postural stability, awaken to an auditory stimulus, and perform on tests of memory and attention in the middle of the night; the postural stability and tests of memory and attention were repeated in the morning shortly after awakening. The study also measured how quickly participants could return to sleep after being awakened. The study met its primary endpoint demonstrating that postural stability was clinically meaningfully worse for zolpidem ER 6.25 mg as compared with both treatment arms of lemborexant (5 mg and 10 mg), in healthy volunteers 55 years and older. In this study, the only AE observed in two or more people in the lemborexant arms was headache.

"As a clinician and researcher treating patients with sleep disruption issues for 30 years, for me, successful treatment means that they can both sleep well and wake well, without impairment. It's important for me to explain not only the benefits of a medication meant to help my patients fall asleep and stay asleep, but also any potential risks such as their next morning impairment," said Russell Rosenberg, PhD, D.ABSM, a Principal Investigator in lemborexant studies and former Chairman of the Board of the National Sleep Foundation. "These studies are particularly relevant to older patients for whom the ability to awaken unimpaired remains an ongoing issue."

These studies build on a growing body of knowledge regarding lemborexant, including another recently completed Phase 1 study (Study 106) that evaluated residual next morning effects via an on-road driving test, which also achieved its primary objective. This study was conducted versus placebo, with zopiclone included as a positive control, to evaluate potential next morning impairment by measuring adult and elderly participants' driving performance. In this study, the most common AEs observed in the lemborexant arms were somnolence and headache. Eisai and Purdue also plan to present the results of the Phase 1 studies at the upcoming 32nd Annual Meeting of the Associated Professional Sleep Societies (SLEEP 2018) on June 5 in Baltimore, Maryland, in the United States.

Lemborexant appears to impact an underlying reason for a patient's inability to sleep well. Lemborexant acts on the orexin neurotransmitter system and is believed to regulate sleep and wake by dampening wakefulness without impeding the ability to awaken to external stimuli.

"Our aspiration for lemborexant is to bring to patients suffering from sleep disorders a treatment for sleep and wake regulation that improves their ability to sleep through the night, but allows patients to function if they awaken during the night, or when they wake in the morning," said Lynn Kramer, MD, Chief Clinical Officer and Chief Medical Officer, Neurology Business Group, Eisai. "Knowing the unmet needs with respect to the risk of falls and motor vehicle collisions, especially among older patients, Eisai and Purdue scientists were challenged to discover a better option for treating sleep disorders."

"Our confidence in lemborexant as a potential treatment for patients living with sleep disorders is strengthened with these data," said Craig Landau, MD, President and CEO, Purdue Pharma. "We look forward to continuing to leverage our expertise in drug development and commercialization as we partner with Eisai to bring this new treatment to patients."

Discovered by Eisai, lemborexant is being jointly developed by Eisai and Purdue. Information about ongoing clinical studies is available at clinicaltrials.gov.

In addition to the studies described above, ongoing studies include a Phase 2 study for treatment of irregular sleep-wake rhythm disorder (ISWRD) in patients with Alzheimer's disease dementia.

Through research and development on lemborexant, Eisai and Purdue Pharma are striving to fulfill unmet medical needs of patients with ISWRD and Alzheimer's disease dementia in addition to insomnia to further contribute to increasing the benefit for patients and their families.

This release discusses investigational uses of agents in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such products will successfully complete clinical development or gain health authority approval.

<Notes to editors>

1. About lemborexant

Lemborexant, a dual orexin receptor antagonist, is Eisai's in-house discovered and developed small molecule compound that inhibits orexin neurotransmission by binding competitively to the two subtypes of orexin receptors (orexin receptor 1 and 2). In individuals with sleep disorders, it is possible that the orexin system that 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 and Purdue have been developing lemborexant as a treatment for multiple sleep disorders.

A Phase 2 clinical study of lemborexant in patients with irregular sleep-wake rhythm disorder (ISWRD) and mild to moderate Alzheimer's dementia is underway.

2. About Sleep Disorders

Population studies show that sleep disorders affect many more people worldwide than previously thought. Insomnia disorder is characterized by difficulty falling asleep, staying asleep or both, despite an adequate opportunity to sleep that can lead to fatigue, difficulty concentrating and irritability. Insomnia disorder is the most common sleep disorder, with persistent insomnia symptoms experienced by approximately 10%.[1,2,3]

Experimental studies in animals and humans provide evidence of associations between sleep and inflammatory markers,[4] and the association between sleep and mortality, as well as many diseases and disease risk factors, suggests an optimal sleep duration between seven and eight hours.[5] Women are 1.4 times more likely than men to suffer from insomnia.[6]

Older adults also have higher prevalence of insomnia; aging is often accompanied by changes in sleep patterns, including disrupted sleep, frequent waking and early waking, that can lead to insomnia.[5]

The causes of insomnia involve a combination of biological, psychological and social factors.[1] The cumulative effects of poor sleep have been associated with a wide range of health consequences including an increased risk of hypertension, diabetes, obesity, depression, heart attack and stroke, as well as adverse effects on mood and behavior.[4]

3. About SUNRISE 1 (Study 304)

SUNRISE 1 is a multicenter, randomized, double-blind, placebo-controlled, active comparator, parallel-group study of the efficacy and safety of lemborexant in approximately 1,000 patients 55 years and older (45% of all patients were aged 65 years and older) with insomnia disorder conducted in North America and Europe. In this study, patients were administered placebo or one of three treatment regimens (lemborexant 5 mg, lemborexant 10 mg, zolpidem ER 6.25 mg), and the primary endpoint was change from baseline in latency to persistent sleep of both lemborexant doses compared to placebo. Key secondary endpoints included change from baseline in sleep efficiency for both lemborexant doses compared to placebo, wake after sleep onset (WASO) for both lemborexant doses compared to placebo, and WASO in the second half of the night (WASO2H) for both lemborexant doses compared to zolpidem ER, after one month of treatment, measured objectively by polysomnography.

4. About Study 108

Study 108 was a randomized, double-blind, four period crossover study to evaluate the effect of lemborexant on postural stability, auditory awakening threshold, and cognitive performance in 56 healthy volunteers 55 years and older. Participants were administered a single dose of placebo, lemborexant 5 mg, lemborexant 10 mg, or zolpidem ER 6.25 mg. The primary endpoint was change from time-matched baseline in postural stability for lemborexant compared to zolpidem ER at approximately four hours post-dose.

5. About Study 106

Study 106 was a randomized, double-blind, placebo- and active-controlled, four period, crossover study to evaluate the effect of lemborexant in 48 healthy adult and elderly volunteers to evaluate on-road driving performance. Participants were treated at bedtime with two out of three dose levels of lemborexant (2.5, 5 or 10 mg) and placebo for eight consecutive days, and zopiclone 7.5 mg as an active control on days one and eight only, with placebo given for the six days in between. The primary endpoint was to evaluate change of standard deviation of lateral position (SDLP) during an on-road driving test on the mornings following the first and last dose of drug in each treatment period.

6. About Eisai Co., Ltd.

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our *human health care* (*hhc*) philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products in various therapeutic areas with high unmet medical needs, including Neurology and Oncology.

Furthermore, we invest and participate in several partnership-based initiatives to improve access to medicines in developing and emerging countries.

For more information about Eisai Co., Ltd., please visit www.eisai.com.

7. About Purdue Pharma L.P.

Purdue Pharma L.P. is a privately held pharmaceutical company headquartered in Stamford, Conn. Purdue Pharma is part of a network of independent associated companies dedicated to providing patients and providers with innovative medicines. The company's leadership and employees are committed to serving healthcare professionals, patients and caregivers by providing quality products and educational resources that make a positive impact on healthcare — and on lives.

For more information, please visit www.purduepharma.com.

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