



FOR IMMEDIATE RELEASE

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EISAI INC. AND PURDUE PHARMA ENTER WORLDWIDE COLLABORATION TO DEVELOP AND COMMERCIALIZE LEMBOREXANT Companies to develop lemborexant for the potential treatment of insomnia and explore other future indications

Tokyo, Japan and Stamford, CT – August 31, 2015 – Eisai Co., Ltd. and Purdue Pharma L.P. announced today that Eisai Inc., the U.S. subsidiary of Eisai Co., Ltd., and Purdue Pharma have entered into a worldwide collaboration agreement for the development and commercialization of Eisai's clinical candidate lemborexant (development code: E2006), a dual orexin receptor antagonist entering Phase III clinical development for the treatment of insomnia.

Under the terms of the agreement, Eisai Inc. and Purdue Pharma will share the costs of lemborexant global clinical studies. While the potential indication for the product candidate is for the treatment of insomnia, the companies may also seek to develop other indications in the future. The two companies will form a joint steering committee to manage development and pursue marketing authorizations for lemborexant worldwide. Once approved, Eisai and Purdue Pharma will co-promote the product and share co-promotion costs and profits in the United States and other territories (to be agreed by the parties), which may include the European Union, China, Japan and Canada. Eisai will book sales in all co-promotion territories. In certain other countries, either Eisai or Purdue Pharma may solely commercialize lemborexant and pay the other party a royalty. Eisai Inc. will receive an upfront payment from Purdue Pharma, and is also eligible to receive certain other milestone payments that are contingent upon achieving regulatory approval and certain commercial milestones.

Insomnia is common worldwide; approximately 30% of adults report one or more symptoms of insomnia including difficulty initiating and or maintaining sleep¹. Insomnia is associated with impairments in daytime functioning, including difficulty with thinking and concentration, as well as altered mood².

Discovered by Eisai, lemborexant is a dual orexin receptor antagonist which competitively binds to the two subtypes of orexin receptors³. It is believed that the orexin system promotes wakefulness, and therefore, orexin receptor antagonists such as lemborexant have the potential to promote sleep⁴.

With the signing of this agreement, the Phase III clinical development program will commence immediately. The global trial program is designed to evaluate the efficacy of lemborexant on both objective and subjective measures of sleep. In addition, the development program will evaluate the impact of treatment of insomnia on daytime function. Safety and tolerability will also be evaluated during the clinical program.

"Eisai is excited about the significant and far-reaching potential of this compound as we commence Phase III clinical trials," said Lynn Kramer, MD, FAAN, President of the Neuroscience and General Medicine Product Creation Unit at Eisai. "We are looking forward to collaborating with Purdue Pharma, which brings deep expertise and proven successes in drug development and commercialization."

"This agreement reflects our strategy to diversify and grow our business through partnerships and business development," said Mark Timney, President and CEO, Purdue Pharma L.P. "We look forward to a productive relationship with Eisai and the prospects for growth this collaboration brings, as we seek to further expand our product portfolio with differentiated treatments."

<Notes to editors>

1. About lemborexant

Lemborexant, 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 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 has been developing lemborexant as a treatment for insomnia.

2. 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 Oncology and Neurology. For more information about Eisai Co., Ltd., please visit <u>www.eisai.com</u>

3. 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 <u>www.purduepharma.com</u>

¹ Thomas R. Insomnia: Definition, Prevalence, Etiology, and Consequences. *Journal of Clinical Sleep Med*, 2007; 3 (5 Suppl.) S7-10.

² Institute of Medicine (US) Committee on Sleep Medicine and Research. Extent and health consequences of chronic sleep loss and sleep disorders. In: Colten HR, Altevogt BM, eds. Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem. Washington (DC): National Academies Press (US); 2006.

³ Beuckmann, Carsten, et. al, Preclinical Pharmacological Characterization of E2006, a Novel Dual Orexin Receptor Antagonist for Insomnia Treatment, *Poster presented at Japanese Sleep Meeting* 2014.

⁴ Scammell TE, Winrow CJ. Orexin receptors: pharmacology and therapeutic opportunities. *Annu Rev Pharmacol Toxicol.* 2011;51:243-266.