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Eisai, Purdue to present latest Clinical Data on Lemborexant

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Lemborexant appears to impact an underlying reason for a patient's inability to sleep well

Eisai Co., Ltd. and Purdue Pharma L.P. announced they will present the latest data from two key Phase I clinical studies (Study 108 and Study 106) of investigational sleep/wake regulation agent lemborexant, including a comparison versus zolpidem tartrate extended release (zolpidem ER) and placebo on middle of the night awakening and next-morning effects, in poster presentations at the 32nd Annual Meeting of the Associated Professional Sleep Societies (SLEEP 2018) from June 2 to 6 in Baltimore, Maryland in the United States.

Of note, Eisai and Purdue Pharma will present data on a Phase I safety study (Study 108) that assessed the ability to awaken to an auditory stimulus and maintain postural stability (a predictor of risk for falls) and perform on tests of memory and attention in the middle of the night and the next morning.

The study demonstrated that postural stability was statistically significantly worse for zolpidem ER 6.25 mg compared with both lemborexant 5 mg and 10 mg in healthy volunteers age 55 and older, and the primary endpoint was achieved. In this study, headache was the only adverse event (AE) observed in two or more people taking lemborexant.

Another Phase I study (Study 106), which evaluated residual next-morning effects via an on-road driving test, also achieved its primary objective, demonstrating no significant difference in next-morning driving performance versus placebo.

This study was conducted versus placebo, with zopiclone included as a positive control, to evaluate potential next-morning

impairment by measuring healthy adult and elderly participants' driving performance.

In this study, the most common AEs observed in the lemborexant arms were somnolence, headache, and dry mouth.

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 excessive arousal or wakefulness without impeding the ability to awaken to external stimuli.