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ASIA EDITION

FDA accepts NDA for Lemborexant to treat Insomnia

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Eisai Co., Ltd. and Imbrium Therapeutics L.P., a clinical-stage biopharmaceutical company and operating subsidiary of Purdue Pharma, L.P. have announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for lemborexant, an investigational agent being studied for the treatment of insomnia, a sleep-wake disorder. A Prescription Drug User Fee Act (PDUFA) date is set for December 27, 2019.

The NDA submission was based on data from the clinical development program including two pivotal Phase 3 studies of lemborexant - SUNRISE 1 (Study 304) and SUNRISE 2 (Study 303).

SUNRISE 1: a one-month Phase 3 clinical study to evaluate the efficacy and safety of lemborexant versus placebo and versus an active comparator (zolpidem tartrate extended release, "zolpidem ER") in 1,006 patients 55 years and older (45 percent of all patients were aged 65 years and older) with insomnia disorder. This study assessed sleep latency (using latency to persistent sleep; primary objective); sleep efficiency and wake after sleep onset (effect on maintaining sleep; key secondary objectives) objectively using polysomnography, and achieved its primary and key secondary objectives. The most common adverse events (AEs) reported in the lemborexant arms were headache and somnolence.

SUNRISE 2: in 949 adult patients (18 to 88 years of age) with insomnia disorder. This study evaluated subjective (patient-reported) sleep onset latency (primary objective), sleep efficiency, and wake after sleep onset (key secondary objectives) using sleep diaries, and achieved its pre-specified primary and key secondary efficacy objectives. The most common AEs reported in the lemborexant arms were somnolence, nasopharyngitis, headache, and influenza.

Eisai and Imbrium Therapeutics are striving to address new unmet medical needs and to improve the lives of patients and their families.