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Harmony Biosciences set to launch excessive daytime sleepiness drug

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WAKIX represents the first and only non-scheduled treatment approved for patients with narcolepsy

Harmony Biosciences, LLC (Harmony) has announced that the U.S. Food and Drug Administration (FDA) approved WAKIX® (pitolisant) for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy. WAKIX is the first and only treatment approved for patients with narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration (DEA).

“We are extremely proud to bring WAKIX to market for those living with narcolepsy, a chronic, debilitating, rare neurologic disorder,” said Harmony’s Chairman and Chief Executive Officer, John C. Jacobs. “At Harmony we share a vision to develop novel treatment options for people living with rare diseases, with a focus on those that affect the central nervous system. The approval of WAKIX strengthens our commitment to making that vision a reality.”

WAKIX, a first-in-class medication, is a selective histamine 3 (H?) receptor antagonist/inverse agonist that works through a novel mechanism of action to increase the synthesis and release of histamine, a wake-promoting neurotransmitter in the brain. WAKIX is administered orally once daily in the morning upon wakening.

“The approval of WAKIX provides healthcare professionals managing people living with narcolepsy a new and important treatment option for their patients,” said Harmony’s Chief Medical Officer, Jeffrey Dayno, M.D. “Additionally, WAKIX is the only non-scheduled treatment option approved for adult patients with narcolepsy, and it offers an important benefit/risk profile to address the unmet medical need that exists in people living with narcolepsy.”

WAKIX will be commercially available to healthcare professionals and appropriate patients in the U.S. in the fourth quarter of 2019.