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ASIA EDITION

Jazz Pharma gets U.S. FDA approval for a drug that improves wakefulness

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Jazz Pharmaceuticals plc has announced that the U.S. Food and Drug Administration (FDA) approved Sunosi (solriamfetol) to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). Once-daily Sunosi is approved with doses of 75 mg and 150 mg for patients with narcolepsy and doses of 37.5 mg, 75 mg, and 150 mg for patients with OSA. Sunosi is the first dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) approved to treat excessive daytime sleepiness in adults living with narcolepsy or OSA.

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"Excessive daytime sleepiness can negatively impact the daily lives of people living with narcolepsy or obstructive sleep apnea at work, at home or in daily activities. With this approval, a new, daytime medicine that can provide sustained wakefulness throughout the day will be available for patients," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "The FDA approval of *Sunosi* also represents an important milestone for Jazz as we continue to offer new treatment options that address unmet needs for people living with chronic, and often debilitating, sleep disorders."

At Week 12, 150 mg of *Sunosi* for narcolepsy patients and all doses for OSA patients demonstrated improvements in wakefulness compared to placebo as assessed in test sessions 1 (approximately one hour post-dose) through 5 (approximately nine hours post-dose) of the maintenance of wakefulness test (MWT).

The FDA's approval of *Sunosi* is based on data from the Treatment of Obstructive sleep apnea and Narcolepsy Excessive Sleepiness (TONES) Phase 3 clinical program, which included four randomized placebo-controlled studies that demonstrated the superiority of *Sunosi* relative to placebo. The most common adverse reactions (incidence ?5% and higher than placebo) reported in both the narcolepsy and OSA study populations were headache, nausea, decreased appetite, and anxiety.*Sunosi* was evaluated in more than 900 adults with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea and was shown to maintain its effect relative to placebo after six months of use.

"We're excited about this new therapeutic option for patients, and we are pleased with the information included in the*Sunosi* label as we believe it will give physicians the information needed to appropriately manage the vast majority of obstructive

sleep apnea and narcolepsy patients with excessive daytime sleepiness," said Daniel Swisher, president and chief operating officer of Jazz Pharmaceuticals.

In 12 week clinical studies, approximately 68-74% of people taking *Sunosi* at the 75 mg dose and 78-90% of people taking *Sunosi* at the 150 mg dose reported improvement in their overall clinical condition, as assessed by the Patient Global Impression of Change (PGIc) scale.

Although the exact mechanism of action is unknown, the effects of *Sunosi* are thought to be mediated through its activity as a DNRI.

"Sunosi is an effective treatment option with a novel mechanism of action as a dual-acting dopamine and norepinephrine reuptake inhibitor," said Richard K. Bogan, MD, FCCP, FAASM, Associate Clinical Professor at the University of South Carolina School of Medicine and Chief Medical Officer at SleepMed in Columbia, SC. "Excessive daytime sleepiness is the most common symptom for people with narcolepsy and a major complaint of people with obstructive sleep apnea. In some people with obstructive sleep apnea, excessive daytime sleepiness may persist despite using CPAP."

Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness in OSA. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is not a substitute for these modalities.

Jazz Pharmaceuticals plc, a global biopharmaceutical company, is dedicated to developing life-changing medicines for people with limited or no options. As a leader in sleep medicine and with a growing hematology/oncology portfolio, Jazz has a diverse portfolio of products and product candidates in development, and is focused on transforming biopharmaceutical discoveries into novel medicines.