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Jazz pharma set to market Sunosi to control Excessive Daytime Sleepiness

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Sunosi is the first and only dual-acting dopamine and norepinephrine reuptake inhibitor approved by the FDA to improve wakefulness in adults living with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea

Jazz Pharmaceuticals plc 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.

Sunosi is expected to be commercially available in the U.S. following the final scheduling decision by the U.S. Drug Enforcement Administration (DEA), which is typically within 90 days of FDA approval.

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.

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 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.