



## Jazz Pharmaceuticals Announces U.S. FDA Approval of Sunosi™ (solriamfetol) for Excessive Daytime Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea

March 20, 2019

**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**

DUBLIN, March 20, 2019 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today 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.

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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  $\geq 5\%$  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.

**More information about *Sunosi*, including Full Prescribing Information and Medication Guide, is available [here](#).**

### About Sunosi™ (solriamfetol)

*Sunosi* is a dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adults living with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea (OSA). In 2014, Jazz Pharmaceuticals acquired a license to develop and commercialize *Sunosi* from Aerial Biopharma. Jazz Pharmaceuticals has worldwide development, manufacturing, and commercialization rights to *Sunosi*, excluding certain jurisdictions in Asia. SK Biopharmaceuticals, the discoverer of the compound, maintains rights in 12 Asian markets, including Korea, China and Japan. *Sunosi* has orphan drug designation for narcolepsy in the United States.

### Important Safety Information

**SUNOSI can be a target for people who abuse prescription medicines or street drugs.** Keep SUNOSI in a safe place to protect it from theft. Never give your SUNOSI to anyone else, because it may cause death or harm them. Selling or giving away SUNOSI may harm others and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

**Do not take SUNOSI** if you are taking or have stopped taking within the past 14 days a medicine used to treat depression called a monoamine

oxidase inhibitor (MAOI).

**Before taking SUNOSI, tell your doctor about all of your medical conditions, including if you:**

- have heart problems, high blood pressure, kidney problems, diabetes, or high cholesterol
- have had a heart attack or a stroke
- have kidney problems or diabetes
- have a history of mental health problems, (including psychosis and bipolar disorders), or of drug or alcohol abuse or addiction
- are pregnant or planning to become pregnant. It is not known if SUNOSI will harm your unborn baby.
  - **Pregnancy Registry:** There is a pregnancy registry for women who take SUNOSI during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. It is not known if SUNOSI passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take SUNOSI.

**Especially tell your healthcare provider** if you take a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

**What are the possible side effects of SUNOSI?**

**SUNOSI may cause serious side effects, including:**

- **Increased blood pressure and heart rate.** SUNOSI can cause blood pressure and heart rate increases that can increase the risk of heart attack, stroke, heart failure and death. Your doctor should check your blood pressure before you start and during treatment with SUNOSI. Your doctor may decrease your dose or tell you to stop taking SUNOSI if you develop high blood pressure that does not go away during treatment with SUNOSI.
- **Mental (psychiatric) symptoms including anxiety, problems sleeping (insomnia), irritability and agitation.** Tell your doctor if you develop anxiety, problems sleeping, irritability, agitation. Your doctor may change your dose or tell you to stop taking SUNOSI if you develop side effects during treatment with SUNOSI.

The most common side effects of SUNOSI include:

- headache
- nausea
- decreased appetite
- anxiety
- problems sleeping

These are not all the possible side effects of SUNOSI. Call your doctor for advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

#### **About Obstructive Sleep Apnea and Excessive Daytime Sleepiness**

Obstructive sleep apnea, commonly referred to as sleep apnea, is a highly prevalent disease (as high as 14% in men and 5% in women) in which excessive daytime sleepiness is a major presenting complaint in many cases.<sup>1-4</sup> Positive Airway Pressure (PAP) therapy, with its most common form being Continuous Positive Airway Pressure (CPAP), has been shown to be an effective therapy for sleep apnea that frequently results in improvement in excessive daytime sleepiness in many patients; however, not all patients tolerate CPAP therapy and among those who tolerate CPAP, usage is highly variable. Excessive daytime sleepiness may persist in people with sleep apnea despite using CPAP.

#### **About Narcolepsy**

Narcolepsy is a chronic, debilitating neurological disorder characterized by excessive daytime sleepiness, and the inability to regulate sleep-wake cycles normally.<sup>5</sup> It affects an estimated one in 2,000 people in the United States, with symptoms typically appearing in childhood. It is estimated that more than 50% of patients with narcolepsy have not been diagnosed.<sup>6</sup> Studies have shown it may take 10 years or more for people with narcolepsy to receive a diagnosis.<sup>7</sup> Excessive daytime sleepiness is the primary symptom of narcolepsy and is present in all people with the disorder.<sup>8</sup> Excessive daytime sleepiness is characterized by the inability to stay awake and alert during the day resulting in unplanned lapses into sleep or drowsiness.<sup>6,8,9</sup> There are five primary symptoms of narcolepsy, including excessive daytime sleepiness, cataplexy, sleep-related hallucinations, sleep paralysis and sleep disruption. While all patients with narcolepsy experience excessive daytime sleepiness, they may not experience all five symptoms.

#### **About Jazz Pharmaceuticals plc**

Jazz Pharmaceuticals plc (Nasdaq: JAZZ), 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. Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Defitelio® (defibrotide sodium) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinaze®, Defitelio® (defibrotide) and Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion in countries outside the U.S. For country-specific product information, please visit <https://www.jazzpharma.com/medicines>. For more information, please visit [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) and follow us on Twitter at [@JazzPharma](https://twitter.com/JazzPharma).

## "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of *Sunosi*, the expected timing of the commercial launch of *Sunosi* in the U.S., the company's belief that the *Sunosi* label will give physicians the information needed to appropriately manage the vast majority of OSA and narcolepsy patients with excessive daytime sleepiness, and other statements that are not historical facts. These forward-looking statements are based on the company's current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: the company's ability to effectively commercialize *Sunosi* in the U.S.; delays or problems in the supply or manufacture of *Sunosi*; obtaining and maintaining appropriate pricing and reimbursement for *Sunosi*; complying with applicable U.S. regulatory requirements; any delays in, or the outcome of, DEA scheduling for *Sunosi*; and other risks and uncertainties affecting the company, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Annual Report on Form 10-K for the year ended December 31, 2018 and future filings and reports by the company. Other risks and uncertainties of which the company is not currently aware may also affect the company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by the company on its website or otherwise. The company undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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