Jazz Pharmaceuticals Receives Schedule IV Designation from DEA for Sunosi™ (solriamfetol)

June 17, 2019

Sunosi expected to be commercially available in the U.S. July 2019
Investor webcast planned for July 2, 2019

DUBLIN, June 17, 2019 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the U.S. Drug Enforcement Agency (DEA) has designated solriamfetol, also known as *Sunosi*, as a Schedule IV medicine. With U.S. Food and Drug Administration (FDA) approval on March 20, 2019, *Sunosi* is the first and only dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) approved to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

"Jazz Pharmaceuticals focuses on doing what is best for patients and we are committed to the safe and appropriate use of our medicines for debilitating conditions like excessive daytime sleepiness associated with narcolepsy or OSA," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "We are pleased that *Sunosi* has received a Schedule IV designation that aligns with our research demonstrating this medicine's relatively low potential for abuse and risk of dependence."

Beginning early July, once-daily *Sunosi* will be commercially available in the U.S. in 75 mg and 150 mg tablets.

"Excessive daytime sleepiness can have a significant impact on the lives of people with narcolepsy or OSA. With this scheduling decision, we move closer to commercial availability of *Sunosi*, which can improve wakefulness throughout the day in these patients," said Daniel Swisher, president and chief operating officer of Jazz Pharmaceuticals. "*Sunosi* is the first medicine that Jazz has taken through Phase 3 development to commercialization, further evidence of the success of our growing research and development capabilities."

Investor Webcast Details

Jazz Pharmaceuticals will host an investor webcast for a discussion of the narcolepsy and OSA treatment landscape and a *Sunosi* U.S.launch overview from the company's senior executive management on Tuesday, July 2, 2019. Additional details regarding the investor webcast will be communicated in a future press release.

*Sunos*i 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*. *Sunosi* is not a substitute for these modalities, and the treatment of the underlying airway obstruction should be continued.

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 (solriamfetol) is available in 75 mg and 150 mg tablets and is a federally controlled substance (C-IV) because it contains solriamfetol that 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 or sell your SUNOSI to anyone else, because it may cause death or harm them and it is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

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 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
- 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.

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 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 any of these symptoms. 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
- decreased appetite
- problems sleeping
- nausea
- anxiety

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, 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.[1-4] 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.[5] 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.[6] Studies have shown it may take 10 years or more for people with narcolepsy to receive a diagnosis.[7] Excessive daytime sleepiness is the primary symptom of narcolepsy and is present in all people with the disorder.[8] Excessive daytime sleepiness is characterized by the inability to stay awake and alert during the day resulting in unplanned lapses into sleep or drowsiness.[6,8,9] 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 Sunosi™ (solriamfetol), Xyrem® (sodium oxybate) oral solution, Defitelio® (defibrotide sodium), Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Defitelio® (defibrotide), Erwinase® 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 and follow us on Twitter at @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 commercial availability of *Sunosi* in the U.S., 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; 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'sSecurities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 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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