Jazz Pharmaceuticals Announces Health Canada Approval of Sunosi® (solriamfetol) for Excessive Daytime Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea

August 31, 2021

DUBLIN, Aug. 31, 2021 /CNW/ - Jazz Pharmaceuticals plc (NASDAQ: JAZZ) today announced the Health Canada approval and availability of Sunosi® (solriamfetol) for the treatment of excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA) in adult patients. Once-daily *Sunosi* is approved with doses of 75 mg and 150 mg.[1]

Sunosi is the first dopamine and norepinephrine reuptake inhibitor (DNRI) approved to treat EDS in adults living with narcolepsy or OSA.[1]

EDS is characterized by the inability to stay awake and alert during the day resulting in unplanned lapses into sleep or drowsiness.[11,13,16] Major contributors to EDS are narcolepsy, a chronic, debilitating neurological disorder characterized by the inability to regulate sleep-wake cycles normally[2,3,4], and OSA, a condition where a person's breathing stops for brief periods of time when they sleep.[1]

The approval of *Sunosi* is based on data from the **T**reatment of **O**bstructive Sleep Apnea and **N**arcolepsy **E**xcessive **S**leepiness (TONES) Phase 3 clinical program which enrolled over 1,500 adults in four randomized placebo-controlled studies. Data from the studies in the TONES program demonstrated the superiority of solriamfetol relative to placebo. The efficacy of *Sunosi* in reducing EDS in patients with narcolepsy or OSA was assessed in the pivotal studies, two randomized, 12-week, placebo-controlled studies, Study 14-002 (TONES 2, narcolepsy patients) and Study 14-003 (TONES 3, OSA patients). At Week 12 of these trials, 150 mg of solriamfetol for narcolepsy patients and both 75 mg and 150 mg doses for OSA patients demonstrated significant improvements in wakefulness and reduced sleepiness compared to placebo as assessed via the Maintenance of Wakefulness Test (MWT) and Epworth Sleepiness Scale respectively (ESS). Furthermore, the increase in the MWT sleep latency was maintained through nine-hours from morning dosing. Up to 78% of the narcolepsy patients and up to 90% of the OSA patients taking 150 mg reported feeling better as measured by the Patient Global Impression of Change (PGIc) scale. The efficacy of *Sunosi* was shown be maintained for at least 6 months in a long-term open label follow up study (TONES 5).

In TONES 2 and 3, the most common treatment emergent adverse events reported in patients treated with *Sunosi* (incidence ≥5% and greater than placebo) in either the narcolepsy or OSA populations were headache, nausea, decreased appetite, anxiety and insomnia.

"The Health Canada approval of *Sunosi* represents an important advancement for Canadians living with chronic, and often debilitating, sleep disorders. Excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea is a serious condition with limited treatment options available," said Paul Petrelli, general manager, Jazz Pharmaceuticals Canada Inc. "Jazz is proud to introduce this new therapeutic option to the Canadian market as we continue innovating to transform the lives of patients and their families."

About Sunosi® (solriamfetol)

Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated for the treatment of excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea in adult patients. *Sunosi* is not indicated to treat the underlying causes of airway obstruction in OSA.[1] It is important that the underlying airway obstruction is treated with a Continuous Positive Airway Pressure (CPAP) machine or other device prescribed by a doctor during treatment with *Sunosi* for excessive daytime sleepiness in OSA.[1] Modalities to treat the underlying airway obstruction should be continued. *Sunosi* is not a substitute for these modalities.

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.

Important Safety Information for Canada

Sunosi should not be taken by those who:

- Are allergic to this drug or to any ingredient in the formulation including any nonmedicinal ingredient, or component of the container'
- Are taking a monoamine oxidase inhibitor (MAOI) for depression or for Parkinson's Disease, or who have taken MAOI within the last 14 days.
- Have or have had the following in the past one year: myocardial infarction, also known as a heart attack, chest pain (angina), high blood pressure that is not under control, irregular heartbeat (arrhythmias), or other serious heart conditions.
- Have had kidney problems or end stage kidney failure.

For more information, please refer to the product monograph for *Sunosi* in Canada located here.

About Obstructive Sleep Apnea and Excessive Daytime Sleepiness

Obstructive sleep apnea, commonly referred to as sleep apnea, is a highly prevalent disease in which excessive daytime sleepiness is a major presenting complaint in many cases. A consistent finding is that OSA affects more men than women. [5, 6] In 2016 and 2017, 6.4% of Canadians had reported they had been diagnosed for sleep apnea by a health care professional[7] which was higher than results from a 2009 survey which found that the prevalence of self-reported sleep apnea was only 3% among adults 18 years and older.[8]

Positive Airway Pressure therapy, with its most common form being 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.[9,10]

About Narcolepsy

Narcolepsy is a chronic, debilitating neurological disorder characterized by excessive daytime sleepiness, and the inability to regulate sleep-wake cycles normally.[11] Narcolepsy, although uncommon, is not a rare disorder, with symptoms typically appearing in childhood. The estimated prevalence is about 1 in 2000 individuals in the US and Europe,[12,13] a figure that would extrapolate to about 15,000 patients in Canada.[14] It is estimated that more than 50% of patients with narcolepsy have not been diagnosed[15]. Studies have shown it may take 10 years or more for people with narcolepsy to receive a diagnosis[16]. Excessive daytime sleepiness is the primary symptom of narcolepsy and is present in all people with the disorder[17]. Excessive daytime sleepiness is characterized by the inability to stay awake and alert during the day resulting in unplanned lapses into sleep or drowsiness.[11,13,18] There are five primary symptoms of narcolepsy, including excessive daytime sleepiness, cataplexy (when muscles suddenly go limp), sleep-related hallucinations, sleep paralysis and sleep disruption.[19] While all patients with narcolepsy experience excessive daytime sleepiness, they may not experience all five symptoms. [15]

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (NASDAQ: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases—often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. For more information, please visit www.jazzpharmaceuticals.com and follow @JazzPharma on Twitter.

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