Jazz Pharmaceuticals Presents 18 Abstracts in Sleep Medicine at SLEEP 2021

June 9, 2021

Jazz shares results from sleep medicine research and the development of novel therapeutic options for people living with sleep disorders

DUBLIN, June 9, 2021 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that 13 abstracts sponsored by Jazz Pharmaceuticals and five abstracts from investigator-sponsored trials will be presented at SLEEP 2021, the 35th annual meeting of the Associated Professional Sleep Societies (APSS) from June 10-13, 2021.

"Jazz continues to be committed to deepening our understanding of sleep disorders and delivering transformational medicines to those with lifelong and chronic sleep conditions," said Robert Iannone, M.D., M.S.C.E., executive vice president, research and development and chief medical officer of Jazz Pharmaceuticals. "There remains a large unmet need for people living with sleep disorders, including narcolepsy and idiopathic hypersomnia, and we look forward to showcasing the latest research and results from our portfolio during SLEEP 2021 as we work to help people with sleep disorders live fuller lives."

Highlights from Jazz at SLEEP 2021 will include the following presentations:

- A late-breaking abstract poster presentation on June 13 on a sub-group analysis of Xywav™ (calcium, magnesium, potassium and sodium oxybates) oral solution compared to placebo in adults with idiopathic hypersomnia with long sleep time (n=25) and without long sleep time (n=91), and the importance of treatment effects on those two groups
- Additional data results from the Phase 3, placebo-controlled, double-blind, randomized withdrawal study of *Xywav* in adults with idiopathic hypersomnia including an oral presentation of the correlation of the idiopathic hypersomnia severity scale score with other measures of sleep parameters
- Results from a real-world study of the cardiovascular burden of narcolepsy
- Data results from the titration and administration (START) study of Sunosi® (solriamfetol) in patients with narcolepsy

Xywav is not currently approved by regulatory authorities for the treatment of idiopathic hypersomnia.

The SLEEP 2021 presentations and exhibit hall are available for registered attendees through November 30, 2021 at www.sleepmeeting.org.

Find a full list of Jazz-supported data below:

Xywav™ (calcium, magnesium, potassium, and sodium oxybates) oral solution Oral Presentation and Posters

Presentation Title	**Author**	**Presentation Date / Time (EDT) & Number**
Correlation of the Idiopathic Hypersomnia Severity Scale Score With Other Measures of Sleep Parameters in a Phase 3 Trial	Dauvilliers et al.	**Oral Presentation** Sunday, June 13 12:41-12:52 PM **Abstract ID:** 500
Placebo-Controlled, Double-Blind, Randomized Withdrawal Study of Lower-Sodium Oxybate in Adults With Idiopathic Hypersomnia	Dauvilliers et al.	**ePoster Presentation Abstract ID:** 494
Efficacy and Safety of Lower-Sodium Oxybate in Adults With Idiopathic Hypersomnia: With and Without Long Sleep Time	Bogan et al.	**ePoster Presentation Abstract ID:** LBA070
Effect of Lower-Sodium Oxybate on Sleep Inertia in Idiopathic Hypersomnia in a Double-Blind, Randomized Withdrawal Study	Bogan et al.	**ePoster Presentation Abstract ID:** 487
Efficacy and Safety of Once- and Twice-Nightly Dosing of Lower-Sodium Oxybate in Adults With Idiopathic Hypersomnia	Arnulf et al.	**ePoster Presentation Abstract ID:** 485
Efficacy of Lower-Sodium Oxybate on Idiopathic Hypersomnia, Measured by the Idiopathic Hypersomnia Severity Scale	Foldvary-Schaefer et al.	**ePoster Presentation Abstract ID:** 495
Clinical Presentation Prior to Idiopathic Hypersomnia Diagnosis Among US Adults: A Retrospective, Real-World Claims Analysis	Saad et al.	**ePoster Presentation Abstract ID:** 497
Utilization of Diagnostic Sleep Testing Prior to Idiopathic Hypersomnia Diagnosis Among US Adults: A Real-World Claims Analysis	Saad et al.	**ePoster Presentation Abstract ID:** 499
Timing and Duration of Adverse Events in a Clinical Trial of Lower-Sodium Oxybate in Participants With Narcolepsy With Cataplexy	Bogan et al.	**ePoster Presentation Abstract ID**: 486
Cardio-Vascular Burden of Narcolepsy Disease (CV-BOND): A Real-World Evidence Study	Ben-Joseph et al.	**ePoster Presentation Abstract ID:** 503

Sunosi® (solriamfetol) Poster Presentations

Presentation Title	**Author**	**Presentation Number**

Solriamfetol Titration & Administration (START): Characteristics of Patients With Narcolepsy and Solriamfetol Prescriber Rationale	Thorpy et al.	**ePoster Presentation Abstract ID:** 481
Solriamfetol Titration & Administration (START): Dosing and Titration Strategies in Patients With Narcolepsy Starting Solriamfetol	Thorpy et al.	**ePoster Presentation Abstract ID:** 482
Solriamfetol Titration & Administration (START): Physician Titration Strategies in a Hypothetical Patient With Narcolepsy	Singh et al.	**ePoster Presentation Abstract ID:** 484

Additionally, data from the following investigator-sponsored trials will be presented as poster presentations:

Presentation Title	Author	Presentation Number
Impact of A Single Sleep Education Session on Beliefs and Attitudes Among People with Excessive Daytime Sleepiness: A Pilot Study	Grandner et al.	**ePoster Presentation Abstract ID:** 089
Strategies for Dealing with or Ameliorating Excessive Sleepiness: Beliefs and Attitudes of People with Daytime Sleepiness	Grandner et al.	**ePoster Presentation Abstract ID:** 090
Seeking Treatment for Daytime Sleepiness: Beliefs and Attitudes Among People with Excessive Daytime Sleepiness	Grandner et al.	**ePoster Presentation Abstract ID:** 120
It Makes Relationships Harder: The Role of Narcolepsy in Social and Romantic Relationships in Young Adults	Zhou et al.	**ePoster Presentation Abstract ID:** 498
The Effect of Sodium Oxybate on Cataplexy in Orexin -/- Mice	Hamieh et al	**ePoster Presentation Abstract ID:** 006

More information about Xywav, including Full Prescribing Information and Medication Guide, is available here. http://pp.jazzpharma.com/pi/xywav.en.USPI.pdf

About Xywav™ (calcium, magnesium, potassium, and sodium oxybates) oral solution
Xywav, also known as JZP258, is a lower-sodium oxybate approved by the U.S. Food and Drug Administration (FDA) for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy. It is an investigational product being evaluated for the treatment of adult patients with idiopathic hypersomnia. *Xywav* is comprised of a unique composition of cations resulting in 92 percent less sodium, or approximately 1,000 to 1,500 mg/night, than sodium oxybate at the recommended adult dosage range of 6 to 9 grams. While the exact mechanism of action of *Xywav* is unknown, it is hypothesized that the therapeutic effects of *Xywav* on cataplexy and excessive daytime sleepiness are mediated through $GABA_B$ actions during sleep at noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons. *Xywav* received Fast Track designation by the FDA in September 2020 for the treatment of idiopathic hypersomnia. The FDA recently accepted for filing and granted Priority Review the supplemental New Drug Application (sNDA) for this indication and the PDUFA date is set for August 12, 2021.

Important Safety Information

WARNING: Taking XYWAV with other central nervous system (CNS) depressants such as medicines used to make you or your child fall asleep, including opioid analgesics, benzodiazepines, sedating antidepressants, antipsychotics, sedating anti-epileptic medicines, general anesthetics, muscle relaxants, alcohol, or street drugs, may cause serious medical problems, including trouble breathing (respiratory depression), low blood pressure (hypotension), changes in alertness (drowsiness), fainting (syncope), and death.

The active ingredient of XYWAV is a form of gamma hydroxybutyrate (GHB). Abuse or misuse of illegal GHB alone or with other drugs that cause changes in alertness (or consciousness) has caused serious side effects. These effects include seizures, trouble breathing (respiratory depression), changes in alertness (drowsiness), coma, and death. Call your doctor right away if you or your child has any of these serious side effects. Because of these risks, you have to go through the XYWAV and XYREM REMS Program to have your or your child's prescription for XYWAV filled.

Do not take XYWAV if you take or your child takes other sleep medicines or sedatives (medicines that cause sleepiness), drinks alcohol, or has a rare problem called succinic semialdehyde dehydrogenase deficiency.

Keep XYWAV in a safe place to prevent abuse and misuse. Selling or giving away XYWAV 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.

Anyone who takes XYWAV should not do anything that requires them to be fully awake or is dangerous, including driving a car, using heavy machinery, or flying an airplane, for at least 6 hours after taking XYWAV. Those activities should not be done until you know how XYWAV affects you or your child.

XYWAV can cause serious side effects, including the following:

- **Breathing problems, including** slower breathing, trouble breathing, and/or short periods of not breathing while sleeping (sleep apnea). People who already have breathing or lung problems have a higher chance of having breathing problems when they use XYWAV.
- **Mental health problems, including** confusion, seeing or hearing things that are not real (hallucinations), unusual or disturbing thoughts (abnormal thinking), feeling anxious or upset, depression, thoughts of killing yourself or trying to kill yourself, increased tiredness, feelings of guilt or worthlessness, or difficulty concentrating. Tell your doctor if you or your child have or had depression or have tried to harm yourself or themselves. **Call your doctor right away if you have or your child has symptoms of mental health problems or a change in weight or appetite.**
- **Sleepwalking**. Sleepwalking can cause injuries. Call your doctor if you or your child starts sleepwalking. Your doctor should check you or your child.

The most common side effects of XYWAV in adults include headache, nausea, dizziness, decreased appetite, parasomnia (a sleep disorder that can

include abnormal dreams, abnormal rapid eye movement (REM) sleep, sleep paralysis, sleep talking, sleep terror, sleep-related eating disorder, sleep walking [somnambulism], and abnormal sleep-related events), diarrhea, excessive sweating (hyperhidrosis), anxiety and vomiting.

The most common side effects of XYWAV in children include bedwetting (enuresis), nausea, headache, vomiting, weight decrease, decreased appetite dizziness and sleep walking.

XYWAV can cause physical dependence and craving for the medicine when it is not taken as directed. These are not all the possible side effects of XYWAV.

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 Sunosi® (solriamfetol)
Sunosi is a dual-acting dopamine and norepinephrine reuptake inhibitor shown to improve wakefulness in adults living with excessive daytime sleepiness (EDS) due to narcolepsy or obstructive sleep apnea (OSA). *Sunosi* received U.S. Food and Drug Administration approval on March 20, 2019 to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA and was designated a Schedule IV medicine by the U.S. Drug Enforcement Agency on June 17, 2019. In 2014, Jazz Pharmaceuticals acquired a license to develop and commercialize solriamfetol from Aerial Biopharma LLC. Jazz Pharmaceuticals has worldwide development, manufacturing, and commercialization rights to solriamfetol, excluding certain jurisdictions in Asia. SK Biopharmaceuticals Co., Ltd., 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 for Sunosi

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.

Please find full prescribing information here: https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf

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. We actively explore new options for patients including novel compounds, small molecules and biologics, and through cannabinoid science and innovative delivery technologies. 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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