Jazz Pharmaceuticals to Present New Data on Xywav™ (calcium, magnesium, potassium, and sodium oxybates) Oral Solution and Sunosi® (solriamfetol) at Virtual SLEEP 2020

August 27, 2020

10 new abstracts to showcase Jazz leadership and new data in sleep medicine research and therapies

DUBLIN, Aug. 27, 2020 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that 10 abstracts will be presented at Virtual SLEEP 2020, the 34th annual meeting of the Associated Professional Sleep Societies (APSS) from August 28-30. The presentations will debut data across Jazz's neuroscience therapeutic area, featuring important new insights into the company's ongoing sleep medicine research.

"At Jazz, we understand that sleep disorders can impact everyday life, which is why we are focused on identifying and developing innovative therapies for people with serious sleep disorders," said Robert Iannone, M.D., M.S.C.E., executive vice president, research and development of Jazz Pharmaceuticals. "Our goal is to think more holistically about patients' health so they can live fuller lives and our purpose is to innovate to transform the lives of patients. We are proud to present research at SLEEP on our meaningful therapeutic options for these patients with lifelong, chronic sleep disorders."

Highlights from Jazz at Virtual SLEEP 2020 will include the following presentations on Xywav™ (calcium, magnisium, potassium and sodium oxybate) oral solution (JZP-258), a lower sodium oxybate (LXB) indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy:

- Three poster presentations from the Phase 3, placebo-controlled, double-blind, randomized withdrawal study of JZP-258 in adults with narcolepsy with cataplexy
  - Abstract 0740: Analysis of patients' health-related quality of life
  - Abstract 0752: Findings on dose titration and transition from sodium oxybate
  - Abstract 0753: Cataplexy-free days analysis

The company will also feature two poster presentations on the effects of Sunosi® (solriamfetol) on driving performance in participants with excessive daytime sleepiness associated with obstructive sleep apnea or narcolepsy.

The Virtual SLEEP 2020 presentations and exhibit hall are available 24 hours a day for registered attendees from August 28-30 at www.sleepmeeting.org.

A full list of Jazz-supported poster presentations are below:

Xywav ™(calcium, magnesium, potassium, and sodium oxybates) oral solution (JZP-258) Poster Presentations

Presentation Title	Author	Abstract Number
Quality of Life in a Phase 3, Placebo-Controlled, Double-Blind, Randomized Withdrawal Study of JZP-258 in Adults With Narcolepsy With Cataplexy	Foldvary-Schaefer et al.	0740
JZP-258 Dose Titration and Transition From Sodium Oxybate in a Placebo-Controlled, Double-Blind, Randomized Withdrawal Study in Adult Participants With Narcolepsy With Cataplexy	Foldvary-Schaefer et al.	0752
Cataplexy-Free Days in a Phase 3, Placebo-Controlled, Double-Blind, Randomized Withdrawal Study of JZP-258 in Adults With Narcolepsy With Cataplexy	Dauvilliers et al.	0753

Xyrem® (sodium oxybate) oral solution Poster Presentation

Presentation Title	Author	Abstract Number
Effects of Sodium Oxybate (SXB) on Body Mass Index (BMI) in Pediatric Patients With Narcolepsy	Dauvilliers et al.	0950

Sunosi® (solriamfetol) Poster Presentations

Presentation Title	Author	Abstract or Presentation Number
Effects of Weight Loss During Long-Term Solriamfetol Treatment on Cardiometabolic Indices	Malhotra et al.	0641

Effects of Solriamfetol on Driving Performance in Participants With Excessive Daytime Sleepiness Associated With Obstructive Sleep Apnea	Vinckenbosch et al.	0673
Effects of Solriamfetol on 24-Hour Blood Pressure Patterns in Participants with Excessive Daytime Sleepiness Associated With Obstructive Sleep Apnea	Strollo et al.	0693
Epworth Sleepiness Scale Test-Retest Reliability Analysis in Solriamfetol Studies	Rosenberg et al.	0751
Effects of Solriamfetol on Driving Performance in Participants With Narcolepsy	Vinckenbosch et al.	0763
Effects of Solriamfetol on 24-Hour Blood Pressure Patterns in Participants with Excessive Daytime Sleepiness Associated With Narcolepsy	Strollo et al.	0772

About Xywav ™(calcium, magnesium, potassium, and sodium oxybates) oral solution
Xywav, also known as JZP-258, is 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 also being studied for the treatment of idiopathic hypersomnia in adult patients. *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 dosage range of 6 to 9 grams. *Xywav* has the same oxybate concentration as sodium oxybate and includes a mix of calcium, magnesium, potassium and sodium cations. 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.[1]

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, and other abnormal sleep-related events), diarrhea, excessive sweating (hyperhidrosis), anxiety and vomiting.

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

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.

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

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 Xyrem®
Xyrem® (sodium oxybate) oral solution, CIII, is the only product approved by the U.S. Food and Drug Administration (FDA) for both cataplexy and excessive daytime sleepiness in narcolepsy in adult and pediatric patients ages 7 and older. Xyrem may only be dispensed to patients enrolled in the Xyrem REMS Program. Xyrem was first approved in the U.S. in 2002, based on clinical trial data in adults.

Important Safety Information for Xyrem

WARNING: Taking XYREM with other 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), dizziness (syncope), and death.

XYREM 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.

Because of these risks, you have to go through the XYREM REMS Program to have your or your child's prescription for XYREM filled.

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

Keep XYREM in a safe place to prevent abuse and misuse. Selling or giving away XYREM 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 XYREM 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 XYREM. Those activities should not be done until you know how XYREM affects you or your child.

XYREM 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 XYREM.
- **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, or thoughts of killing yourself or trying to kill yourself. Tell your doctor if you or your child have or had depression or have tried to harm yourself. Call your doctor right away if you have or your child has symptoms of mental health problems.**
- **Sleepwalking. Sleepwalking can cause injuries. Call your doctor if you or your child starts sleepwalking**. Your doctor should check you or your child.

Tell your doctor if you are or your child is on a salt-restricted diet or if you have or your child has high blood pressure, heart failure, or kidney problems. XYREM contains a lot of sodium (salt) and may not be right for you or your child.

The most common side effects of XYREM include nausea, sleepiness, dizziness, vomiting, bedwetting, and tremor (in adults). In pediatric patients, headache, decreased appetite, and weight decrease were also common. Your side effects may increase when you take higher doses of XYREM. XYREM 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 XYREM.

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: http://pp.jazzpharma.com/pi/xyrem.en.USPI.pdf

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharmaceutical company dedicated to developing and commercializing life-changing medicines that transform the lives of patients with serious diseases - often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep and movement disorders, and in oncology, including hematologic malignancies and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in more than 90 countries. For more information, please visit www.jazzpharmaceuticals.com and follow @JazzPharma on Twitter.

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References:

1. Xywav (calcium, magnesium, potassium and sodium oxybates) oral solution Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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