Jazz Pharmaceuticals Data to Showcase Ongoing Sleep Medicine Research at SLEEP 2019

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Fourteen abstracts highlight Jazz's breadth in sleep medicine research and commitment to developing treatment options for people living with debilitating sleep disorders

DUBLIN, May 9, 2019 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) announced today that 14 abstracts sponsored by Jazz Pharmaceuticals and one abstract from an investigator-sponsored trial will be presented at the 33rd Annual Meeting of the Associated Professional Sleep Societies, known as "SLEEP," in San Antonio from June 8-12, 2019.

"Jazz is committed to making meaningful strides in researching medicines that can improve the lives of people living with sleep disorders," said Jed Black, M.D., senior vice president, Sleep and CNS Medicine at Jazz Pharmaceuticals and adjunct professor, Stanford University Medical Center, Stanford Center for Sleep Sciences and Medicine. "There continue to be large unmet needs in these patient populations, and we are looking forward to presenting new data from our sleep portfolio, including our newest sleep medicine to be approved by FDA, solriamfetol."

On March 20, 2019, Jazz 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). *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.

Highlights at SLEEP will include the following poster presentations:

- Results from pooled analyses from 12-week randomized studies of solriamfetol for the treatment of excessive daytime sleepiness in patients with obstructive sleep apnea (OSA) or narcolepsy.
- Long-term effects of solriamfetol on quality of life in patients with excessive daytime sleepiness associated with narcolepsy or OSA.
- Treatment patterns among patients with narcolepsy treated with sodium oxybate.
- Physician prescribing patterns for patients with narcolepsy treated with sodium oxybate.
- Evaluation of cataplexy-free days in children/adolescents with narcolepsy with cataplexy treated with sodium oxybate.

A full list of Jazz-supported oral and poster presentations follows below:

Solriamfetol Poster Presentations

Presentation Title	Author	Date / Time / Abstract Number/ Location
Pooled Analyses from 12-Week Randomized, Controlled Studies of Solriamfetol in the Treatment Of Excessive Daytime Sleepiness In Participants With OSA Or Narcolepsy	Thorpy et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0616 Bridge Hall
Long-Term Effects of Solriamfetol on Quality of Life In Participants with Excessive Daytime Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea	Weaver et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0601 Bridge Hall
Dose Titration of Solriamfetol in Participants with Obstructive Sleep Apnea (OSA) from a 6-Week Randomized-Withdrawal Trial	Strollo et al.	Tuesday, June 11 5:15 p.m. – 7:15 p.m. 0570 Bridge Hall
Weight Change Associated with Solriamfetol Treatment of Excessive Daytime Sleepiness in Participants with Narcolepsy or Obstructive Sleep Apnea	Malhotra et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0618 Bridge Hall
Solriamfetol Treatment of Excessive Daytime Sleepiness in Parkinson's Disease: Results from a Phase 2 Proof-of-Concept Trial	Schweitzer et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0617 Bridge Hall
Incidence and Duration of Common Adverse Events in a Solriamfetol (JZP-110) Phase 3 Study for Treatment of Excessive Daytime Sleepiness in Obstructive Sleep Apnea	Rosenberg et al.	Tuesday, June 11 5:15 p.m. – 7:15 p.m. 0569 Bridge Hall

Sodium Oxybate Presentations

Presentation Title	Author	Date / Time / Session/ Presentation Number/ Location

Treatment Patterns among Patients with Narcolepsy Treated with Sodium Oxybate	Bae et al.	Poster presentation: Sunday, June 9 5:15 p.m. – 7:15 p.m. 0604 Bridge Hall Oral presentation: Tuesday, June 11 10:30 a.m. – 12:30 p.m. 0604 / Bridge Hall
Physician Prescribing Patterns for Patients with Narcolepsy Treated with Sodium Oxybate	Roy et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0608 Bridge Hall
Dosing, Titration, and Treatment Compliance to Sodium Oxybate Therapy in Pediatric Patients With Narcolepsy	Plazzi et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0765 Bridge Hall
Evaluation of Cataplexy-Free Days in Children/Adolescents with Narcolepsy with Cataplexy Treated with Sodium Oxybate	Mignot et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0766 Bridge Hall
Long-Term Safety of Sodium Oxybate in Pediatric Narcolepsy with Cataplexy: Open-Label Continuation Post 1-Year of Treatment	Strunc et al.	Poster presentation: Sunday, June 9 5:15 p.m. – 7:15 p.m. 0767 Bridge Hall Oral presentation: Tuesday, June 11 10:30 a.m. – 12:30 p.m. 0767 Bridge Hall
Sodium Oxybate Dosing Utilization Patterns in the Nexus Narcolepsy Registry	Ohayon et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0605 Bridge Hall

Patient Survey Poster Presentation

Presentation Title	**Author**	**Date / Time / Session/ Presentation Number/ Location**
Prevalence and Morbidity of Sleepiness in an Online Sleep Apnea Patient Cohort	Rottapel et al.	Tuesday, June 11 5:15 p.m. – 7:15 p.m. 0487 Bridge Hall

Narcolepsy Prevalence Poster Presentation

Presentation Title	**Author**	**Date / Time / Session/ Presentation Number/ Location**
Prevalence of Diagnosed Pediatric Narcolepsy in the United States	Morse et al.	Sunday, June 9 5:15 p.m. – 7:15 p.m. 0761 Bridge Hall

Additionally, data from the following investigator-sponsored trial focusing on sodium oxybate will be presented.

Presentation Title	**Author**	**Date / Time / Session/ Presentation Number/ Location**
Acute Total Sleep Deprivation Impairs the Ability to Manage Response Conflict	Salih et al.	Poster Presentation: Monday, June 10 5:15 PM - 7:15 PM 0213 Bridge Hall Oral Presentation: Tuesday, June 11 1:45 PM - 2:45 PM 0213 Bridge Hall

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 is not for use to treat the underlying cause of airway obstruction in people with OSA. SUNOSI does not take the place of using your continuous positive airway pressure (CPAP) machine or other devices that your healthcare provider has prescribed for the treatment of OSA. It is important that you continue to use these treatments as prescribed by your healthcare provider.

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.

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.
- 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: http://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

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 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 Erwinase®, 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 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 expected timing of the commercial availability of *Sunosi* 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: delays or problems in the supply or manufacture of *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'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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