Jazz Pharmaceuticals to Present Advancements in Sleep Medicine at Psych Congress 2022

September 15, 2022

Seven abstracts emphasize Jazz's leadership in neuroscience and commitment to ongoing innovation

DUBLIN, Sept. 15, 2022 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the Company will present seven abstracts from across its neuroscience portfolio at the 35th annual Psych Congress 2022, being held September 17-20, 2022.

"Our presence at Psych Congress 2022 further reinforces Jazz's position as a pioneer in sleep medicine and therapies," said Kelvin Tan, MB BCh, MRCPCH, senior vice president and chief medical officer of Jazz Pharmaceuticals. "Jazz has long been at the forefront of providing therapies and support for our patients living with serious, debilitating sleep disorders, having launched the only U.S. Food and Drug Administration (FDA)-approved lower-sodium oxybate for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy and the only FDA-approved treatment for adults with idiopathic hypersomnia. We look forward to presenting these data at the meeting, as they provide another significant opportunity to share this important research with the greater sleep medicine community."

Highlights at Psych Congress 2022 include:

- New results from a post hoc analysis evaluating the efficacy of Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution in the open-label treatment phase of a study in idiopathic hypersomnia.
- Encore interim data from both the TENOR and SEGUE studies in narcolepsy patients transitioning from sodium oxybate to lower-sodium *Xywav*.

The Psych Congress 2022 presentations are available on-demand through the conference mobile application. A list of poster presentations follows below:

Presentation Title	**Lead Author**	**Date / Time (CT) / Session Title / Presentation Number**
Narcolepsy Data		
Dosing and Reasons for Transitioning From Sodium Oxybate to Lower-Sodium Oxybate in People With Narcolepsy: Data From the Real-World TENOR Study	AM Husain	Type: Poster Poster number: 170 Session dates/times: September 18, 2022 from 1:30-3:00PM; September 19, 2022 from 1:30-3:00PM
Effectiveness and Treatment Optimization Among Participants With Narcolepsy Switching From Sodium Oxybate to Lower-Sodium Oxybate: Interim Data From the SEGUE Study	EB Leary	Type: Poster Poster number: 156 Session dates/times: September 18, 2022 from 1:30-3:00PM; September 19, 2022 from 1:30-3:00PM
Efficacy and Safety in People With Narcolepsy Transitioning From Sodium Oxybate to Lower-Sodium Oxybate: Data From the Real-World TENOR Study	EB Leary	Type: Poster Poster number: 157 Session dates/times: September 18, 2022 from 1:30-3:00PM; September 19, 2022 from 1:30-3:00PM
Hypertension Onset Among Narcolepsy Patients Newly Treated with Sodium Oxybate	RH Ben-Joseph	Type: Poster Poster number: 128 Session dates/times: September 18, 2022 from 1:30-3:00PM; September 19, 2022 from 1:30-3:00PM
Idiopathic Hypersomnia Data		
Efficacy of Lower-Sodium Oxybate in the Treatment of Idiopathic Hypersomnia: Evaluation of Response, Based on the Epworth Sleepiness Scale Score	R Rosenberg	Type: Poster Poster number: 137 Session dates/times: September 18, 2022 from 1:30-3:00PM; September 19, 2022 from 1:30-3:00PM
Efficacy of Lower-Sodium Oxybate in the Treatment of Idiopathic Hypersomnia: Evaluation of Response Based on the Idiopathic Hypersomnia Severity Scale Score	Y Dauvilliers	Type: Poster Poster number: 138 Session dates/times: September 18, 2022 from 1:30-3:00PM; September 19, 2022 from 1:30-3:00PM
Efficacy of Lower-Sodium Oxybate in Participants With Idiopathic Hypersomnia: Results From the Open-label Treatment Phase of a Clinical Study	N Foldvary-Schaefer	Type: Poster Poster number: 171 Session dates/times: September 18, 2022 from 1:30-3:00PM; September 19, 2022 from 1:30-3:00PM

About Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution
Xywav 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 and for the treatment of idiopathic hypersomnia in adults. FDA recognized seven years of Orphan Drug Exclusivity for *Xywav* in June 2021 for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy, and in December 2021 for the treatment of idiopathic hypersomnia in adults. The Office of Orphan Product Development (OOPD) at FDA also published its summary of clinical superiority findings for *Xywav* for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy by means of greater cardiovascular safety compared to Xyrem® (sodium oxybate) oral solution. The decision of the OOPD is based on FDA findings that *Xywav* provides a greatly reduced chronic sodium burden compared to *Xyrem*. *Xywav* is comprised of a unique composition of cations resulting in 92% less sodium, or a reduction of 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.[1] The U.S. Drug Enforcement Agency (DEA) has designated *Xywav* as a Schedule III medicine. The DEA defines Schedule III drugs, substances, or chemicals as drugs with a moderate to low potential for physical and psychological dependence.[1,2] Because of the risks of CNS depression and abuse and misuse, *Xywav* is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XYWAV and XYREM REMS.

Important Safety Information for Xywav

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 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 this occurs.

The most common side effects of XYWAV in adults include nausea, headache, dizziness, anxiety, insomnia, decreased appetite, excessive sweating (hyperhidrosis), vomiting, diarrhea, dry mouth, 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), somnolence, fatigue, and tremor.

The most common side effects of XYREM (which also contains oxybate like XYWAV) in children include nausea, bedwetting, vomiting, headache, weight decrease, decreased appetite, dizziness, and sleepwalking.

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 see full Prescribing Information, including Boxed Warning, here: https://pp.jazzpharma.com/pi/xywav.en.USPI.pdf

About Xyrem® (sodium oxybate)

Xyrem oral solution, CIII, is a 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.[3] *Xyrem* may only be dispensed to patients enrolled in the XYWAV and XYREM REMS. *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 XYWAV and XYREM REMS 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) 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.

Media Contact:
Kristin Bhavnani
Head of Global Corporate Communications
Jazz Pharmaceuticals plc
CorporateAffairsMediaInfo@jazzpharma.com
Ireland +353 1 637 2141
U.S. +1 215 867 4948

Investors:
Andrea N. Flynn, Ph.D.
Vice President, Head, Investor Relations
Jazz Pharmaceuticals plc
InvestorInfo@jazzpharma.com
Ireland +353 1 634 3211
U.S. +1 650 496 2717

References:

1. Xywav (calcium, magnesium, potassium and sodium oxybates) oral solution. Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc. 2021.
2. United States Drug Enforcement Agency. Drug Scheduling. https://www.dea.gov/drug-scheduling. Accessed September 2022.
3. Xyrem (sodium oxybate) oral solution. Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc. 2022.

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