Jazz Pharmaceuticals to Present New Data at SLEEP 2022 Reinforcing Leadership in Sleep Medicine

June 01, 2022

Seventeen abstracts debut new data across narcolepsy and idiopathic hypersomnia

DUBLIN, June 1, 2022 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the Company and its partners will present 17 new abstracts from across its neuroscience portfolio at SLEEP 2022, the 36th annual meeting of the Associated Professional Sleep Societies (APSS) being held June 4-8, 2022.

"Our latest research being presented at SLEEP 2022 provides important insights that benefit people living with complex and severe sleep disorders, deepening our understanding of these debilitating conditions and their overarching effects on patients," said Kelvin Tan, MB BCh, MRCPCH, senior vice president and chief medical officer of Jazz Pharmaceuticals. "We continue to be pioneers in sleep medicine, building on the extensive data we've generated in narcolepsy and idiopathic hypersomnia. The breadth of data Jazz is presenting reinforces our passion for advancing research, elevating patient voices and addressing unmet needs through our transformational medicines."

Highlights at SLEEP 2022 include:

- Two poster presentations sharing responder analyses from the Phase 3 idiopathic hypersomnia trial evaluating the efficacy and safety of Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution as a treatment for adults with idiopathic hypersomnia.
- Interim data from both the TENOR and SEGUE studies in narcolepsy patients transitioning from sodium oxybate to lower-sodium *Xywav*.
- Results from two online surveys of U.S. patients and physicians providing meaningful perspectives on idiopathic hypersomnia, including the assessment of physician familiarity, symptoms, patient impact and disease management.

The SLEEP 2022 presentations and exhibit hall are available here. A list of poster presentations follows below:

Presentation Title	**Presenting Author**	**Date / Time (EST) / Session Title / Presentation Number**
Narcolepsy Data		
External Validation of an Enhanced Machine Learning Algorithm: Polysomnography-Based Narcolepsy-Like Feature Assessment and Clinician Notification in Routine Sleep Medicine Clinics	H Moore	Type: Poster Abstract ID: 082 Poster number: 53 Session date/time: June 7, 2022 at 5:15-7:15PM
Long-term Safety During a Clinical Trial of Lower-Sodium Oxybate in Participants With Narcolepsy With Cataplexy	RK Bogan	Type: Poster Abstract ID: 386 Poster number: 131 Session date/time: June 5, 2022 at 5:15-7:15PM
Dosing and Reasons for Transitioning From Sodium Oxybate to Lower-Sodium Oxybate in People With Narcolepsy: Data From the Real-World TENOR Study	A Husain	Type: Poster Abstract ID: 388 Poster number: 133 Session date/time: June 5, 2022 at 5:15-7:15PM
Weight Changes During Treatment With Lower-Sodium Oxybate in a Phase 3 Clinical Study in Patients With Narcolepsy	N Foldvary-Schaefer	Type: Poster Abstract ID: 393 Poster number: 136 Session date/time: June 5, 2022 at 5:15-7:15PM
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 Abstract ID: 394 Poster number: 137 Session date/time: June 5, 2022 at 5:15-7:15PM
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 Abstract ID: 395 Poster number: 138 Session date/time: June 5, 2022 at 5:15-7:15PM

A Narcolepsy Detection Paradigm: Automated Nocturnal Detection and Notification of Sleep Onset Rapid Eye Movement Periods	A Cairns	Type: Poster Abstract ID: 408 Poster number: 151 Session date/time: June 5, 2022 at 5:15-7:15PM
Children, Adolescents, and Their Providers: The Narcolepsy Assessment Partnership (CATNAP™) Pediatric Narcolepsy Registry: Baseline Demographics	W Macfadden	Type: Poster Abstract ID: 385 Poster number: 176 Session date/time: June 6, 2022 at 5:15-7:15PM
Idiopathic Hypersomnia Data		
Weight Changes During Treatment With Lower-Sodium Oxybate in a Phase 3 Clinical Study in Patients With Idiopathic Hypersomnia	Y Dauvilliers	Type: Poster Abstract ID: 387 Poster number: 132 Session date/time: June 5, 2022 at 5:15-7:15PM
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 Abstract ID: 389 Poster number: 134 Session date/time: June 5, 2022 at 5:15-7:15PM
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 Abstract ID: 390 Poster number: 135 Session date/time: June 5, 2022 at 5:15-7:15PM
Physician Perspective on Idiopathic Hypersomnia: Awareness, Diagnosis, and Impact on Patients	M Whalen	Type: Poster Abstract ID: 391 Poster number: 156 Session date/time: June 5, 2022 at 5:15-7:15PM
Patient Perspective on Idiopathic Hypersomnia: Impact on Quality of Life and Satisfaction With the Diagnostic Process and Management	M Whalen	Type: Poster Abstract ID: 392 Poster number: 157 Session date/time: June 5, 2022 at 5:15-7:15PM
Characteristics and Disease Burden of Patients With Idiopathic Hypersomnia With and Without Long Sleep Time: The Real-World Idiopathic Hypersomnia Outcomes Study (ARISE)	L Schneider	Type: Poster Abstract ID: 396 Poster number: 158 Session date/time: June 5, 2022 at 5:15-7:15PM
Investigator Sponsored Trials		
Prevalence of Idiopathic Hypersomnia in the Wisconsin Sleep Cohort	PE Peppard	Type: Poster Abstract ID: 414 Poster number: 161 Session date/time: June 5, 2022 at 5:15-7:15PM
The Impact of Idiopathic Hypersomnia in Social and Romantic Relationships for Young Adults	R Davidson	Type: Poster Abstract ID: 416 Poster number: 163 Session date/time: June 5, 2022 at 5:15-7:15PM

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). 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

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 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 December 2021.

View original content to download multimedia:https://www.prnewswire.com/news-releases/jazz-pharmaceuticals-to-present-new-data-at-sleep-2022-reinforcing-leadership-in-sleep-medicine-301558804.html

SOURCE Jazz Pharmaceuticals plc