

Jazz Pharmaceuticals to Showcase Expansive Neuroscience Portfolio at American Academy of Neurology Annual Meeting

April 10, 2024

Two oral presentations share results of real-world impact of idiopathic hypersomnia and long-term effectiveness of Epidiolex® (cannabidiol) in treatment-resistant epilepsies

Thirteen abstracts underscore Jazz's diverse neuroscience portfolio and pioneering efforts to continue advancing the treatment of serious sleep disorders, rare epilepsy syndromes and movement disorders

DUBLIN, April 10, 2024 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that 13 abstracts from across its neuroscience portfolio and pipeline, including two oral presentations, will be featured at the 76th Annual American Academy of Neurology Meeting (AAN) being held April 13-18, 2024, in Denver.

Two encore datasets were selected for oral presentations, including results from a real-world claims analysis that demonstrated the increased risk of comorbid conditions, such as stroke or cardiovascular disease, in individuals living with idiopathic hypersomnia compared to those without the condition. Additional data being presented include a post-hoc analysis from the Epidiolex[®] (cannabidiol) oral solution Expanded Access Program (EAP) that explores the long-term effectiveness of *Epidiolex* on reduction of treatment-resistant focal-onset seizures.

"Jazz's presentations at the 2024 AAN Annual Meeting reflect our leadership in sleep and rare epilepsies, as well as our commitment to developing therapies for debilitating, and often overlooked, neurological disorders," said Rob Iannone, MD, MSCE, executive vice president and global head of research and development of Jazz Pharmaceuticals. "We remain committed to expanding our knowledge of the patient experience, including the real-world impact and effectiveness of our products, in order to achieve our purpose of transforming the lives of patients and their families."

Highlights at the 2024 AAN Annual Meeting include:

- An oral presentation showcasing results from the Real-World Idiopathic Hypersomnia Total Health Model (RHYTHM) study which, using claims data, compared the comorbid conditions of individuals diagnosed with idiopathic hypersomnia with those experienced by individuals without idiopathic hypersomnia. Results revealed that individuals with idiopathic hypersomnia experienced higher odds of comorbid conditions across multiple clinical categories, including cardiovascular conditions, reaffirming the importance of considering the patient's full clinical profile when evaluating treatment options for patients living with idiopathic hypersomnia.
- A second oral presentation focusing on a post-hoc analysis that examined the real-world outcomes and long-term effectiveness of *Epidiolex* in treatment-resistant focal-onset seizures in individuals who participated in the EAP. Findings showed that *Epidiolex* was associated with a reduction in focal seizures through 144 weeks, with an acceptable safety profile.
- Two posters assessing the impact of Xywav[®] (calcium, magnesium, potassium, and sodium oxybates) oral solution, the first and only low-sodium oxybate, on sleep inertia in individuals living with idiopathic hypersomnia, including results from a Phase 3 trial.
- One poster reporting the final results from the SEGUE study of adults with narcolepsy transitioning from Xyrem[®] (sodium oxybate) oral solution, a high-sodium oxybate, to *Xywav*, showing that participants switched from high-sodium to low-sodium oxybate with minimal adjustments to their dosing.
- A poster reviewing key data from five clinical studies evaluating the impact of all once- and twice-nightly high-sodium oxybates on sleep quality, sleep architecture and measures of disrupted nighttime sleep in narcolepsy. The review found that oxybate was effective in improving measures of sleep architecture and disrupted nighttime sleep in patients with narcolepsy. *Xyrem* is indicated for the treatment of cataplexy and/or excessive daytime sleepiness (EDS) in narcolepsy patients.
- Five posters examining real-world treatment patterns, effectiveness and caregiver experiences with *Epidiolex*. Notable presentations include updated interim results of seizure and non-seizure outcomes from the cross-sectional BEhavior, COgnition, and More with *Epidiolex* (BECOME) tuberous sclerosis complex (TSC) caregiver survey, where the majority of caregivers reported improvements in patient seizure and non-seizure outcomes, including cognition, emotional and communication domains. Additionally, a post-hoc analysis demonstrated long term effectiveness of *Epidiolex* across all focal seizure subtypes in patients with TSC in GWPCARE6 Open Label Extension trial.
- Two posters featuring Jazz's research with investigational suvecaltamide (also known as JZP385) in essential tremor (ET) and Parkinson's disease (PD) tremor. Presentations include insights from a systematic review of existing literature on the epidemiology and treatment patterns of patients with ET, emphasizing the need for additional research in the space, and a study design overview of the ongoing Phase 2, proof-of-concept study evaluating the efficacy and safety of suvecaltamide on the functional impact of tremor in PD.

The 2024 AAN Annual Meeting abstracts are available online at https://index.mirasmart.com/AAN2024/.

A full list of Jazz-sponsored presentations follows:

Presentation Title	Presenting Author	Date / Time (MDT) / Session Title / Presentation Number
Idiopathic Hypersomnia Data		
Real-World Idiopathic Hypersomnia Total Health Model (RHYTHM): Clinical Burden of Patients Diagnosed With Idiopathic Hypersomnia	J Black	Type: Oral Session Name: S36: Sleep Neurology Highlights Code: S36.009 Session Date/Time: Wednesday, April 17, 5:06PM
Minimal Clinically Important Difference for the Visual Analog Scale for Sleep Inertia Using Data From a Phase 3 Trial of Low-Sodium Oxybate for Idiopathic Hypersomnia	L Schneider	Type: Poster Session Name: P10: Sleep 3 Code: P10.005 Session Date/Time: Wednesday, April 17, 11:45AM – 12:45PM
Efficacy of Low-Sodium Oxybate by Baseline Sleep Inertia in a Phase 3 Clinical Study in Participants with Idiopathic Hypersomnia	M Whalen	Type: Poster Session Name: P10: Sleep 3 Code: P10.003 Session Date/Time: Wednesday, April 17, 11:45AM – 12:45PM
Narcolepsy Data		
Effectiveness and Optimization of Low-Sodium Oxybate in Participants with Narcolepsy Switching From Sodium Oxybate: Final Data From the Substitution of Equal Grams of Uninterrupted Xyrem to Xywav (SEGUE) Study	D Fuller	Type: Poster Session Name: P10: Sleep 3 Code: P10.001 Session Date/Time: Wednesday, April 17, 11:45AM – 12:45PM
Effects of Oxybate on Sleep, Sleep Architecture, and Disrupted Nighttime Sleep	J Black	Type: Poster Session Name: P10: Sleep 3 Code: P10.006 Session Date/Time: Wednesday, April 17, 11:45AM – 12:45PM
Epilepsy Data	•	
Long-term Effectiveness of Cannabidiol (CBD) Against Focal-Onset Seizures in Treatment-Resistant Epilepsies (TRE): Experience from the Expanded Access Program (EAP)	YD Park	Type: Oral Session Name: S29: Epilepsy Diagnostics and Therapeutic Code: S29.005 Session Date/Time: Wednesday, April 17, 1:48PM
Real-World Treatment Patterns of Patients with Dravet Syndrome (DS) and Lennox-Gastaut Syndrome (LGS) in the United States (U.S.)	SV Kothare	Type: Poster Session Name: P1: Epilepsy / Clinical Neurophysiology (EEG): Pediatric Epilepsy 1 Code: P1.005 Session Date/Time: Sunday, April 14, 8:00AM – 9:00AM
Real-world Safety and Effectiveness of Cannabidiol (CBD) in Adults with Treatment-Resistant Epilepsies (TREs): Long-term Results From the United States Expanded Access Program (EAP)	JP Szaflarski	Type: Poster Session Name: P8: Epilepsy / Clinical Neurophysiology (EEG): Anti-seizure Medications: Clinical Trials and Outcomes Code: P8.002 Session Date/Time: Tuesday, April 16, 5:30PM – 6:30PM
Caregiver-Reported Seizure Outcomes with Real-World Use of Cannabidiol (CBD) in Tuberous Sclerosis Complex (TSC): Interim Results from the BECOME-TSC Survey	MK Koenig	Type: Poster Session Name: P8: Epilepsy / Clinical Neurophysiology (EEG): Anti-seizure Medications: Clinical Trials and Outcomes Code: P8.005 Session Date/Time: Tuesday, April 16, 5:30PM – 6:30PM

Caregiver-Reported Nonseizure Outcomes with Real-World Use of Cannabidiol (CBD) in Tuberous Sclerosis Complex (TSC): Interim Results From the BECOME-TSC Survey	S Wilson	Type: Poster Session Name: P8: Epilepsy / Clinical Neurophysiology (EEG): Anti-seizure Medications: Clinical Trials and Outcomes Code: P8.010 Session Date/Time: Tuesday, April 16, 5:30PM – 6:30PM
Long-Term Effectiveness of Cannabidiol (CBD) Against Focal Seizures in Tuberous Sclerosis Complex (TSC): Results From the GWPCARE6 Open-Label Extension (OLE) Trial	JY Wu	Type: Poster Session Name: P8: Epilepsy / Clinical Neurophysiology (EEG): Anti-seizure Medications: Clinical Trials and Outcomes Code: P8.001 Session Date/Time: Tuesday, April 16, 5:30PM – 6:30PM
Suvecaltamide Data		
Epidemiology and Treatment Patterns in Essential Tremor: A Systematic Review	J Lin	Type: Poster Session Name: P3: Movement Disorders: Essential Tremor and Other Tremor Disorders Code: P3.005 Session Date/Time: Sunday, April 14, 5:30PM – 6:30PM
Design of a Phase 2 Study of Suvecaltamide in Moderate to Severe Parkinson's Disease Tremor	T Skarpaas	Type: Poster Session Name: P9: Movement Disorders: Parkinson's Disease Clinical Trials Code: P9.009 Session Date/Time: Wednesday, April 17, 8:00AM – 9:00AM

About Xywav[®] (calcium, magnesium, potassium, and sodium oxybates) oral solution

Xywav is a low-sodium oxybate approved by the U.S. Food and Drug Administration (FDA) for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. The FDA recognized seven years of Orphan Drug Exclusivity for *Xywav* for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy. The Office of Orphan Product Development (OOPD) at the FDA also published its summary of clinical superiority findings for *Xywav* for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy. The Office of Orphan Product Development (OOPD) at the FDA also published its summary of clinical superiority findings for *Xywav* for the treatment of cataplexy or EDS 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 the FDA findings that *Xywav* provides a greatly reduced chronic sodium burden compared to *Xyrem. Xywav* has 131 mg of sodium at the maximum recommended nightly dose. *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. *Xywav* is the only low-sodium oxybate therapy approved by the FDA, and the only oxybate that does not carry a warning in the label related to use in patients sensitive to high sodium intake.

Xywav is also the first and only U.S. FDA-approved treatment option for idiopathic hypersomnia in adults. The FDA recognized seven years of Orphan Drug Exclusivity for *Xywav* for the treatment of idiopathic hypersomnia in adults. *Xywav* is the only FDA-approved treatment studied across the multiple symptoms of idiopathic hypersomnia, such as EDS, sleep inertia (severe grogginess or confusion when waking up), long sleep duration and cognitive impairment. *Xywav* can be administered as a twice- or once-nightly regimen for the treatment of idiopathic hypersomnia in adults.

The exact mechanism of action of Xywav in the treatment of adults with idiopathic hypersomnia and of cataplexy and EDS in narcolepsy is unknown. It is hypothesized that the therapeutic effects of Xywav are mediated through GABAB actions during sleep at noradrenergic and dopaminergic neurons,

as well as 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 central nervous system (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. XYWAV can cause sleepwalking, which 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/xyway.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 Epidiolex[®]/Epidyolex[®] (cannabidiol)

Epidiolex/Epidyolex is a prescription, plant-derived cannabis-based medicine administered as an oral solution which contains highly purified cannabidiol (CBD). Cannabidiol, the active ingredient in *Epidiolex*, is a cannabinoid that naturally occurs in the *Cannabis sativa* L. plant. The precise mechanisms by which EPIDIOLEX exerts its anticonvulsant effect in humans are unknown. *Epidiolex* was approved by the U.S. Food and Drug Administration (FDA) for use in the U.S., the European Commission (EC) for use in Europe, the Medicines and Healthcare products Regulatory Agency (MHRA) for use in Great Britain, the Therapeutic Goods Administration for use in Australia, Swissmedic for use in Switzerland, the Food & Nutrition Services of the Israel Ministry of Health for use in Israel, and the New Zealand Medicines and Medical Devices Safety Authority for use in New Zealand, is an oral solution which contains highly purified cannabidiol (CBD). In the U.S., *Epidiolex* is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or tuberous sclerosis complex (TSC) in patients one year of age and older. *Epidiolex* has received approval in the European Union under the tradename *Epidyolex* for adjunctive use in conjunction with clobazam to treat seizures associated with LGS and DS in patients two years and older, and for adjunctive use to treat seizures associated with TSC, in patients two years of age and older. *Epidiolex* has received Orphan Drug Designation (ODD) from the U.S. FDA for the treatment of seizures associated with LGS, DS, and TSC. Similarly, *Epidyolex* received ODD from the European Medicines Agency (EMA) for the same indications.

Important Safety Information & Indications

CONTRAINDICATION: HYPERSENSITIVITY

EPIDIOLEX (cannabidiol) oral solution is contraindicated in patients with a history of hypersensitivity to cannabidiol or any ingredients in the product.

WARNINGS & PRECAUTIONS

Hepatic Injury:

EPIDIOLEX can cause dose-related transaminase elevations. Concomitant use of valproate and elevated transaminase levels at baseline increase this risk. Obtain transaminase and bilirubin levels prior to starting treatment, at 1, 3, and 6 months after initiation of treatment, and periodically thereafter, or as clinically indicated. Resolution of transaminase elevations occurred with discontinuation of EPIDIOLEX, reduction of EPIDIOLEX and/or concomitant valproate, or without dose reduction. For patients with elevated transaminase levels, consider dose reduction or discontinuation of EPIDIOLEX or concomitant medications known to affect the liver (e.g., valproate or clobazam). Dose adjustment and slower dose titration is recommended in patients with moderate or severe hepatic impairment. Consider not initiating EPIDIOLEX in patients with evidence of significant liver injury. There have been postmarketing reports of cholestatic or mixed patterns of liver injury. Elevated ammonia levels were reported in some patients with transaminase elevations; most taking concomitant valproate, clobazam, or both. Consider discontinuation or dose adjustment of valproate or clobazam if ammonia is elevated.

Somnolence and Sedation:

EPIDIOLEX can cause somnolence and sedation that generally occurs early in treatment and may diminish over time; these effects occur more commonly in patients using clobazam and may be potentiated by other CNS depressants.

Suicidal Behavior and Ideation:

Antiepileptic drugs (AEDs), including EPIDIOLEX, increase the risk of suicidal thoughts or behavior. Inform patients, caregivers, and families of the risk and advise them to monitor and report any signs of depression, suicidal thoughts or behavior, or unusual changes in mood or behavior. If these symptoms occur, consider if they are related to the AED or the underlying illness.

Withdrawal of Antiepileptic Drugs:

As with most AEDs, EPIDIOLEX should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

ADVERSE REACTIONS:

The most common adverse reactions in patients receiving EPIDIOLEX (≥10% and greater than placebo) include transaminase elevations; somnolence; decreased appetite; diarrhea; pyrexia; vomiting; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor-quality sleep; and infections. Hematologic abnormalities were also observed.

PREGNANCY:

EPIDIOLEX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Encourage women who are taking EPIDIOLEX during pregnancy to enroll in the EPIDIOLEX Pregnancy Surveillance Program and the North American Antiepileptic Drug (NAAED) Pregnancy Registry.

DRUG INTERACTIONS:

Strong inducers of CYP3A4 and CYP2C19 may affect EPIDIOLEX exposure. EPIDIOLEX may affect exposure to CYP2C19 substrates (e.g., clobazam, diazepam, stiripentol), orally administered P-gp substrates, or other substrates (see full Prescribing Information). Consider dose reduction of orally administered everolimus, with appropriate therapeutic drug monitoring, when everolimus is combined with EPIDIOLEX. A lower starting dose of everolimus is recommended when added to EPIDIOLEX therapy. Concomitant use of EPIDIOLEX and valproate increases the incidence of liver enzyme elevations. Pneumonia was observed more frequently with concomitant use of EPIDIOLEX and clobazam. Dosage adjustment of EPIDIOLEX

or other concomitant medications may be necessary.

INDICATIONS:

EPIDIOLEX (cannabidiol) oral solution is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

Please read the EPIDIOLEX full Prescribing Information for additional important information here.

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, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience. Jazz is headquartered in Dublin, Ireland with research and development laboratories, manufacturing facilities and employees in multiple countries committed to serving patients worldwide. Please visit <u>www.jazzpharmaceuticals.com</u> for more information.

Caution Concerning Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to advancing the treatment of serious sleep disorders, rare epilepsy syndromes and movement disorders and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' 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 pharmaceutical product development, and other risks and uncertainties affecting Jazz Pharmaceuticals and its development programs, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including Jazz Pharmaceuticals' Annual Report on Form 10-K for the year ended December 31, 2023, and future filings and reports by Jazz Pharmaceuticals. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect Jazz Pharmaceuticals' 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 Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals 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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References:

- 1. Xywav (calcium, magnesium, potassium and sodium oxybates) oral solution. Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc. 2021.
- United States Drug Enforcement Agency. Drug Scheduling. <u>https://www.dea.gov/drug-information/drug-scheduling</u>. Accessed February 2024.
- 3. Xyrem (sodium oxybate) oral solution. Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc. 2022.



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