Jazz Pharmaceuticals Announces Xywav® (calcium, magnesium, potassium, and sodium oxybates) Investor Webcast on October 13, 2021

September 13, 2021

DUBLIN, Sept. 13, 2021 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the company will host a webcast on Wednesday, October 13, 2021 at 4:30 p.m. ET / 9:30 p.m. IST to provide an update on Xywav® (calcium, magnesium, potassium and sodium oxybates), the first and only U.S. Food and Drug Administration-approved treatment for idiopathic hypersomnia (IH) in adults, which was approved on August 12, 2021.

Jazz senior management will provide an overview of *Xywav* and commercial launch plans in IH, and Richard Bogan, M.D., FCCP, FAASM, president of Bogan Sleep Consultants, LLC and associate clinical professor, University of South Carolina School of Medicine and Medical University of South Carolina, Charleston, S.C., will discuss IH.

Audio webcast/conference call:
U.S. Dial-In Number: +1 (855) 353-7924
International Dial-In Number: +1 (503) 343-6056
Passcode: 2789509

The live webcast may be accessed from the Investors section of the Jazz Pharmaceuticals website at www.jazzpharmaceuticals.com. A replay of the webcast will be archived on the website for at least one week.

Replay U.S. Dial-In Number: +1 (855) 859-2056
Replay International Dial-In Number: +1 (404) 537-3406
Passcode: 2789509

About Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution
Xywav, also known as JZP258, 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. In June 2021, the FDA recognized seven years of Orphan Drug Exclusivity for *Xywav* for the treatment of cataplexy or excessive daytime sleepiness 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 excessive daytime sleepiness in patients 7 years of age and older with narcolepsy by means of greater 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*. There are no head-to-head data for *Xywav* and *Xyrem*. *Xywav* is comprised of a unique composition of cations resulting in 92 percent 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. 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.

Please see the full Prescribing Information, including Boxed Warning, and Medication Guide available here: http://pp.jazzpharma.com/pi/xywav.en.USPI.pdf.

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.** 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.

About Jazz Pharmaceuticals
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. We actively explore new options for patients including novel compounds, small molecules and biologics, and through cannabinoid science and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. For more information, please visit www.jazzpharma.com and follow @JazzPharma on Twitter.

Jazz Pharmaceuticals Contacts:

Investors:	***Media:***
Andrea N. Flynn, Ph.D.	Kristin Bhavnani
Vice President, Head, Investor Relations	Head of Global Corporate Communications
Jazz Pharmaceuticals plc	Jazz Pharmaceuticals plc
investorinfo@jazzpharma.com	CorporateAffairsMediaInfo@jazzpharma.com
Ireland, +353 1 634 3211	Ireland, +353 1 697 2141
U.S., +1 650 496 2717	U.S., +1 215 867 4948

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