Jazz Pharmaceuticals to Present Abstracts from Ongoing Evaluations of Xyrem® (sodium oxybate) at SLEEP 2015

June 4, 2015

DUBLIN, June 4, 2015 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) will present abstracts related to the ongoing clinical evaluation of Xyrem® (sodium oxybate) oral solution, a U.S. Food and Drug Administration (FDA) approved treatment for both excessive daytime sleepiness (EDS) and cataplexy in narcolepsy, at the 29th Annual SLEEP Meeting of the Associated Professional Sleep Societies (APSS), June 6-10, 2015 in Seattle, Washington.

"Xyrem is used to treat two common symptoms of narcolepsy -- cataplexy and EDS. The abstracts to be presented at SLEEP 2015 demonstrate Jazz's commitment to continuing clinical research that will help increase the sleep community's scientific and clinical understanding of the role of Xyrem in the treatment of patients with narcolepsy," said Jed Black, M.D., vice president, Sleep Medicine, Jazz Pharmaceuticals, and consulting associate professor, Stanford University Medical Center, Stanford Center for Sleep Sciences and Medicine.

Highlights from four Jazz-sponsored abstracts to be presented as posters in the Narcolepsy and Hypersomnia (P26) and in the Sleep Disorders, Other Than Sleep Disordered Breathing, in Children (P08) sessions follow:

- **Evaluation of Quality-of-Life in Patients with Narcolepsy Treated with Sodium Oxybate: Use of the 36-Item Short-Form Health Survey in a Clinical Trial** [Abstract # 0764, Poster # 252, Tuesday June 9, 4-6 PM, Washington State Convention Center Exhibit Hall 4AB] Richard K. Bogan, M.D., will present previously unpublished quality-of-life data from a 36-item Short-Form Health Survey (SF-36) used to measure the impact of Xyrem on key quality of life measures in patients with narcolepsy. Dr. Bogan is Associate Clinical Professor at the University of South Carolina School of Medicine and Chief Medical Officer of SleepMed Inc.
- **Sodium Oxybate Treatment in Patients with Narcolepsy Stratified by the Presence of Cataplexy: Retrospective Subgroup Analysis of a Randomized Clinical Trial** [Abstract # 0765, Poster # 253, Tuesday June 9, 4-6 PM, Washington State Convention Center Exhibit Hall 4AB] Dr. Jed Black will present a retrospective analysis of data from a Phase 3 study of Xyrem given alone or in combination with modafinil in patients with narcolepsy with and without cataplexy.
- **Design of the First Study Evaluating Efficacy, Safety, and Pharmacokinetics of Sodium Oxybate for the Treatment of Pediatric Patients with Narcolepsy with Cataplexy** [Abstract # 1098, Poster # 151, Monday June 8, 4-6 PM, Washington State Convention Center Exhibit Hall 4AB] Y. Grace Wang, M.D., will present the design of the ongoing Phase 3 study of Xyrem in children and adolescents with narcolepsy with cataplexy. This study is currently enrolling patients and is registered at www.clinicaltrials.gov (NCT 02221869). Dr. Wang is Sr. Director, Clinical Development at Jazz Pharmaceuticals.
- **Developing Outcome Measures for Assessing Narcolepsy with Cataplexy in Children and Adolescents** [Abstract # 1097, Poster # 150, Monday June 8, 4-6 PM, Washington State Convention Center Exhibit Hall 4AB] Dr. Wang will share results of an evaluation of the adequacy of the current measures of cataplexy and EDS in a pediatric population. This evaluation helped inform how to measure an effective response to treatment among a pediatric population in the ongoing Phase 3 study of Xyrem in children and adolescents with narcolepsy with cataplexy.

SLEEP 2015 is the largest gathering of sleep medicine physicians, sleep and circadian researchers, and allied health professionals in the sleep field. More details about SLEEP 2015, including abstracts, are available at http://www.sleepmeeting.org/

About Narcolepsy

Narcolepsy is a sleep disorder that involves the brain's inability to regulate sleep-wake cycles normally. It affects an estimated 1 in 2,000 people in the United States (U.S.), with symptoms typically appearing in early adulthood. It is estimated that 50 percent or more patients with narcolepsy have not been diagnosed. Studies have shown it may take 10 years or more for people with narcolepsy to receive a correct diagnosis. EDS is the primary symptom of narcolepsy and is present in all people with the disorder. EDS is characterized by the inability to stay awake and alert during the day resulting in unplanned lapses into sleep or drowsiness.

About Xyrem

Xyrem® (sodium oxybate) oral solution, CIII, is indicated for the treatment of cataplexy in narcolepsy and for the treatment of excessive daytime sleepiness (EDS) in narcolepsy. Xyrem may only be dispensed to patients enrolled in the Xyrem Success Program®. Xyrem was first approved in the U.S. in 2002. Safety and effectiveness in pediatric patients have not been established.

IMPORTANT SAFETY INFORMATION

Xyrem is a Central Nervous System (CNS) depressant. In clinical trials at recommended doses, obtundation and clinically significant respiratory depression occurred in Xyrem-treated patients. Almost all of the patients who received Xyrem during clinical trials in narcolepsy were receiving CNS stimulants.

Xyrem is the sodium salt of gamma hydroxybutyrate (GHB). Abuse of GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.

Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the Xyrem Success Program®, using a centralized pharmacy. Prescribers and patients must enroll in the program. For further information go to www.XYREM.com or call 1-866-XYREM88® (1-866-997-3688).

Xyrem is contraindicated in combination with sedative hypnotics or alcohol and in patients with succinic semialdehyde dehydrogenase deficiency. Use caution when considering the concurrent use of Xyrem with other CNS depressants. Healthcare providers should caution patients against hazardous activities requiring complete mental alertness or motor coordination within the first 6 hours of dosing or after first initiating treatment until certain that Xyrem does not affect them adversely. Xyrem is a Schedule III controlled substance. The rapid onset of sedation, coupled with the amnestic features of Xyrem, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (e.g. assault victim). Monitor patients for emergent or increased depression and suicidality and for impaired motor/cognitive function. Episodes of sleepwalking should be fully evaluated and appropriate interventions considered. Consider the amount of daily sodium intake in each dose of Xyrem in patients sensitive to salt intake.

In three controlled clinical trials, the most common adverse reactions (incidence ≥5% and twice the rate of placebo) in Xyrem-treated patients were nausea (20%), dizziness (15%), vomiting (11%), somnolence (8%), enuresis (7%), and tremor (5%).

Please click here [http://www.xyrem.com/safety-information] **to see the full Prescribing Information for Xyrem, including BOXED Warning.**

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and/or product candidates with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase *Erwinia chrysanthemi*) in the U.S., and markets Erwinase® and Defitelio® (defibrotide) in Europe and other countries outside the U.S. For more information, please visit www.jazzpharmaceuticals.com.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/jazz-pharmaceuticals-to-present-abstracts-from-ongoing-evaluations-of-xyrem-sodium-oxybate-at-sleep-2015-300094019.html

SOURCE Jazz Pharmaceuticals plc

Jazz Pharmaceuticals Contacts: Investors:Kathee Littrell, Vice President, Investor Relations, Ireland, +353 1 634 7887, U.S., +1 650 496 2717; Media: Laurie Hurley, Vice President, Corporate Affairs, Ireland, +353 1 634 7894, U.S., +1 650 496 2796