Jazz Pharmaceuticals To Present Data On Compound In Sleep Pipeline During APSS Annual SLEEP Meeting

May 27, 2014

Phase 2b Data for JZP-110 in Adults with EDS in Narcolepsy Accepted as Late-Breaker Oral Presentation
Conference Call to be Held Monday, June 2 at 4:00 p.m. CDT / 10:00 p.m. IST

DUBLIN, May 27, 2014 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) announced today that new data for the investigational compound JZP-110 (previously ADX-N05) will be presented at the 28th Associated Professional Sleep Societies (APSS) Annual SLEEP Meeting, May 31 to June 4, 2014 in Minneapolis, Minn. The JZP-110 abstract was accepted as a late-breaker oral presentation.

The abstract titled "Efficacy and Safety of Oral ADX-N05 for the Treatment of Excessive Daytime Sleepiness in Adults with Narcolepsy: Results of a Randomized, Double-Blind, Placebo-Controlled Trial" will be presented during the Late-breaking Abstracts oral presentation session on Monday, June 2, 2014, from 1:25 p.m. – 1:40 p.m. CDT.

Company management will host a live audio webcast following the presentation at 4:00 p.m. CDT / 10:00 p.m. IST to discuss the data presented and provide an overview of JZP-110 and other clinical development programs in narcolepsy and sleep. Interested parties may access the live audio webcast via the Investors & Media section of the Jazz Pharmaceuticals website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary to listen to the webcast. A replay of the webcast will be archived on the website for one week.

Audio webcast/conference call:
U.S. Dial-In Number: +1 866 515 2912
International Dial-In Number: +1 617 399 5126
Passcode: 56517063

A replay of the conference call will be available through June 9, 2014 and accessible through one of the following telephone numbers and by entering the passcode:
Replay U.S. Dial-In Number: +1 888 286 8010
Replay International Dial-In Number: +1 617 801 6888
Passcode: 79173542

"As a company dedicated to improving the lives of people with severe sleep disorders, we look forward to presenting the JZP-110 Phase 2b data to the sleep community," said Jeffrey Tobias, M.D., executive vice president, research and development, and chief medical officer. "Given the robust alerting effect seen in this trial in adult patients with narcolepsy with excessive daytime sleepiness (EDS) and the consistency of the data with the Phase 2a study results, we are planning a Phase 3 clinical development program to further explore the potential of this novel compound."

Full details of the APSS annual meeting can be found here: http://www.aasmnet.org/resources/flipping/sleep2014finalprogram/

Jazz Pharmaceuticals Clinical Development Pipeline in Narcolepsy and Sleep
Jazz Pharmaceuticals continues to expand its clinical development pipeline in the areas of narcolepsy and sleep. Current clinical investigations include:

- **Xyrem® (sodium oxybate) oral solution in Children and Adolescents:** In working with the Food and Drug Administration (FDA), Jazz Pharmaceuticals has received a *Pediatric Written Request* from the FDA to study Xyrem in children and adolescents. The company is preparing to conduct a Phase 3 clinical trial to assess the safety and efficacy of sodium oxybate in children and adolescents aged seven to 17 years who have narcolepsy with cataplexy. The company plans to initiate clinical sites for this study in the second half of 2014.
- **JZP-110:** Jazz Pharmaceuticals is currently planning a Phase 3 clinical development program for this investigational compound for the treatment of EDS in adults with narcolepsy and for the treatment of EDS in adults with obstructive sleep apnea.
- **JZP-386**: Pre-clinical trials are underway with a deuterium-modified analog of sodium oxybate. Jazz Pharmaceuticals expects the first-in-human study to begin in Europe in 2014, subject to availability of clinical trial material.

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 to see the full Prescribing Information for Xyrem, including BOXED Warning.

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing differentiated products that address unmet medical needs. The company has a diverse portfolio of products and/or product candidates in the areas of sleep, hematology/oncology, pain and psychiatry. The company's U.S. marketed products in these areas include: Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase Erwinia chrysanthemi), Prialt® (ziconotide) intrathecal infusion, Versacloz™ (clozapine) oral suspension, FazaClo® (clozapine, USP) HD and FazaClo LD. Jazz Pharmaceuticals also has a number of products marketed outside the United States, including Erwinase® and Defitelio® (defibrotide). For more information, please visit www.jazzpharmaceuticals.com.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to Jazz Pharmaceuticals' planned clinical trials, the expected timing of those trials, and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' current expectations 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 the difficulty and uncertainty of pharmaceutical product development, including the timing thereof, the uncertainty of clinical success, such as the risk that results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, the risk that the company may not be able to obtain and supply sufficient product to meet requirements for clinical trial supplies, and the uncertainty of regulatory approval, and those other risks detailed 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 the Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 and future filings and reports by the company. Jazz Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events or changes in its expectations.

SOURCE Jazz Pharmaceuticals plc

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