Jazz Pharmaceuticals and Concert Pharmaceuticals Provide JZP-386 Program Update

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Phase 1 Results Support Further Evaluation of JZP-386

DUBLIN & LEXINGTON, Mass.--(BUSINESS WIRE)--May 7, 2015-- Jazz Pharmaceuticals plc (NASDAQ: JAZZ) and Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today announced results from the recently completed Phase 1 clinical study of JZP-386, a deuterium-containing analog of sodium oxybate. The Phase 1 study evaluated the safety, pharmacokinetics and pharmacodynamics (PD) of JZP-386 in 30 healthy volunteers.

Clinical data from this Phase 1 study demonstrated that JZP-386 provided favorable deuterium-related effects, including higher serum concentrations and correspondingly increased PD effects at clinically relevant time points compared to Xyrem® (sodium oxybate) oral solution. The safety profile of JZP-386 was similar to that observed with Xyrem. While the companies have determined that the deuterium-related effects observed in the Phase 1 studies do not support advancing into a later-stage clinical trial of JZP-386 at this time, the results indicate that further evaluation of JZP-386 is warranted. Accordingly, the companies intend to explore formulation options to enhance the positive effects observed in the studies to achieve an improved product profile for patients with narcolepsy.

Sodium oxybate is the active ingredient in Xyrem, a prescription medicine marketed in the United States by Jazz Pharmaceuticals to treat cataplexy and excessive daytime sleepiness (EDS) in patients with narcolepsy, a serious neurological disorder that affects approximately 1 in 2000 people in the United States.

About Jazz Pharmaceuticals plc
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 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.

About Concert Pharmaceuticals
Concert Pharmaceuticals is a clinical stage biopharmaceutical company focused on applying its DCE Platform® (deuterated chemical entity platform) to create novel small molecule drugs. This approach starts with approved drugs, advanced clinical candidates or previously studied compounds that have the potential to be improved with deuterium substitution to enhance clinical safety, tolerability and efficacy. The Company is developing a broad pipeline targeting CNS disorders, genetic diseases, renal disease, inflammatory diseases and cancer. For more information, please visit www.concertpharma.com.

About Xyrem
Xyrem® (sodium oxybate) oral solution, CIII, is indicated for the treatment of cataplexy in narcolepsy and for the treatment of EDS in narcolepsy. Xyrem may only be dispensed to patients enrolled in the Xyrem Success Program®. Xyrem was first approved in the United States in 2002.

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.

Jazz Pharmaceuticals plc "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 future evaluation of JZP-386 and exploration of formulation options to achieve an improved product profile for patients, 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 therapeutic potential of JZP-386 and the outcome of further evaluation and exploration of JZP-386; and those risks with respect to research and development and clinical trials 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 Annual Report on Form 10-K for the year ended December 31, 2014, and future filings and reports by Jazz Pharmaceuticals, including the Quarterly Report on Form 10-Q for the quarter ended March 31, 2015. 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.

Concert Pharmaceuticals Cautionary Note on Forward Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about the future evaluation of JZP-386, the potential effectiveness of JZP-386, our plans and timelines for the clinical development of JZP-386 and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals and other factors discussed in the " Risk Factors" section of our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission and in other filings that we make with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligation to update any forward-looking statements included in this press release.

Photos/Multimedia Gallery Available: http://www.businesswire.com/multimedia/home/20150507006370/en/

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