



Jazz Pharmaceuticals and Concert Pharmaceuticals Provide JZP-386 Program Update

December 09, 2014

DUBLIN & LEXINGTON, Mass.--(BUSINESS WIRE)--Dec. 9, 2014-- [Jazz Pharmaceuticals plc](#) (NASDAQ:JAZZ) and [Concert Pharmaceuticals, Inc.](#) (NASDAQ:CNCE) today announced that Phase 1 clinical data generated to date supports completing the Phase 1 evaluation of JZP-386 at the originally planned highest dose, which was not administered in the first Phase 1 trial due to a technical dosing issue. The existing Phase 1 clinical data was generated in a first-in-human trial evaluating the safety, pharmacokinetics, and pharmacodynamics of JZP-386; enrollment was completed in the third quarter. A second Phase 1 trial evaluating JZP-386 at the originally planned highest dose is expected to be initiated in the first quarter of 2015, with data expected in the second quarter of 2015.

JZP-386 is a deuterium-containing analog of sodium oxybate. The Phase 1 program is comparing JZP-386 to sodium oxybate versus placebo in healthy volunteers. The companies expect that the results from the upcoming Phase 1 trial will inform the next steps in the development program for JZP-386.

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 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 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 Erwinaze® and Defitelio® (defibrotide). 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, renal disease, inflammation 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. 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 amnesic 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.

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 events in the Phase 1 clinical program for JZP-386, the timing of the second Phase 1 clinical trial, the therapeutic potential of JZP-386 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 timing and conduct of clinical trials and the therapeutic value of JZP-386; the uncertainty of regulatory approval; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, and future filings and reports by Jazz Pharmaceuticals. 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 clinical development 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 Quarterly Report on Form 10-Q 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.

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Photos/Multimedia Gallery Available: <http://www.businesswire.com/multimedia/home/20141209005304/en/>

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