Jazz Pharmaceuticals and Concert Pharmaceuticals Provide a Phase 1 Clinical Trial Update on JZP-386

July 21, 2014

DUBLIN & LEXINGTON, Mass.--(BUSINESS WIRE)--

Jazz Pharmaceuticals plc (JAZZ) and Concert Pharmaceuticals, Inc. (CNCE) today announced the initiation of the first Phase 1 clinical trial of JZP-386, a deuterium-containing analog of sodium oxybate—the active ingredient in Xyrem® (sodium oxybate) oral solution.

The Phase 1 clinical trial is designed to assess the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of JZP-386, and includes Xyrem as an active control. The study is expected to enroll up to 28 healthy subjects at a single center in Europe. The results of the study are intended to assess the PK/PD profile of JZP-386 to identify a safe and tolerable dose or doses of JZP-386 that could be used in subsequent clinical trials and to determine whether JZP-386 is suitable for once nightly dosing.

“Initiating this first-in-human Phase 1 study with JZP-386 is an important milestone in our development program and will provide valuable information on the potential benefit of this deuterium-containing analog of sodium oxybate. This study reflects our ongoing commitment to addressing the unmet medical needs of patients with narcolepsy and to further advancing our understanding of sodium oxybate.” said Jeffrey Tobias, M.D., executive vice president and chief medical officer of Jazz Pharmaceuticals.

“We are pleased to see JZP-386 advancing to clinical evaluation under our collaboration with Jazz Pharmaceuticals. We look forward to evaluating JZP-386 and seeing the results from this first-in-human clinical trial,” said Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals.

Under its 2013 agreement with Concert, Jazz Pharmaceuticals has worldwide rights to develop and commercialize JZP-386. Concert has the potential to realize milestone payments upon meeting development objectives and tiered royalties on any worldwide sales. Jazz Pharmaceuticals and Concert are working collaboratively on development of JZP-386, and Concert is responsible for conducting clinical activities for JZP-386 through Phase 1.

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 (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.

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.

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 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.

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 trial of JZP-386, 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 uncertainty of clinical trials and 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 March 31, 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 potential effectiveness of JZP-386, our plans and timelines for the clinical development of JZP-386, the Company's potential to realize milestone payments upon meeting development objectives 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 Annual Report on Form 10-Q filed with the Securities and Exchange Commission on May 14, 2014 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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- Health Care Industry
- Pharmaceuticals & Drug Trials
- clinical trials
- sodium oxybate
- Phase 1 clinical trial

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