Jazz Pharmaceuticals plc and Concert Pharmaceuticals Announce Worldwide Licensing Agreement to Develop and Commercialize Deuterium-Modified Sodium Oxybate

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DUBLIN and LEXINGTON, Mass.--(BUSINESS WIRE)--Feb. 26, 2013-- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and Concert Pharmaceuticals, Inc. today announced an exclusive license agreement that provides Jazz Pharmaceuticals worldwide rights to develop and commercialize Concert's deuterium-modified sodium oxybate (D-SXB) compounds, including C-10323.

Sodium oxybate is the active ingredient in Xyrem®, a prescription medicine marketed in the United States by Jazz Pharmaceuticals to treat two of the key symptoms of narcolepsy, a serious neurological disorder that affects approximately 157,000 people in the United States.

Under the agreement, Jazz Pharmaceuticals will have worldwide commercial rights to C-10323, as well as principal responsibility for ongoing development activities. Concert will receive an upfront payment and is eligible to receive additional milestone payments as well as tiered royalties based on potential worldwide sales of any D-SXB products.

"This collaboration reflects our deep commitment to patients with narcolepsy and to improving their care with safe and effective treatment options," said Jeffrey Tobias, MD, executive vice president of research and development and chief medical officer of Jazz Pharmaceuticals. "Our agreement with Concert on the D-SXB program provides an excellent opportunity for us to explore the potential of deuterium technology in this important area. We look forward to advancing this program into clinical testing in order to further evaluate its potential to provide benefits for patients with narcolepsy."

"Preclinical data indicate that selective deuterium incorporation can stabilize sodium oxybate *in vivo* and we are eager to see how this improvement in metabolic properties is reflected in the clinical performance of D-SXB," said Roger Tung, Ph.D., president and chief executive officer of Concert Pharmaceuticals. "This collaboration with Jazz Pharmaceuticals allows us to progress our deuterium-modified sodium oxybate program with a partner that has extensive development and commercial experience and is a leader in the narcolepsy field."

Through Concert's DCE Platform® (Deuterated Chemical Entity), Concert has developed a number of deuterium-containing analogs of sodium oxybate. C-10323 has emerged as the lead compound based on *in vivo* preclinical testing that demonstrated prolonged pharmacokinetic profile and reduced variability as a result of its specific deuterium modification pattern. The companies plan to submit an investigational new drug (IND) application for C-10323 later this year.

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc is a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing innovative products that address unmet medical needs. The company has a diverse portfolio of products in the areas of narcolepsy, 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, Luvox CR® (fluvoxamine maleate), FazaClo® (clozapine, USP) HD and FazaClo LD. Outside of the U.S., Jazz Pharmaceuticals also has a number of products marketed by its EUSA Pharma division. For further information, see www.jazzpharmaceuticals.com.

About Concert Pharmaceuticals

Concert Pharmaceuticals is a clinical stage biotechnology company focused on applying the company's DCE Platform® (deuterated chemical entity platform) to create novel and differentiated small molecule drugs. Concert's approach leverages decades of pharmaceutical and clinical experience to reduce the time, risk and expense needed to create important new medicines. The company has a broad research pipeline addressing renal disease, hematologic disorders, CNS disorders and other therapeutic areas. Founded in 2006, Concert has raised more than $110 million of venture and institutional capital. For more information on Concert Pharmaceuticals, please visit www.concertpharma.com.

About Xyrem

Xyrem® (sodium oxybate) oral solution is indicated for the treatment of cataplexy and excessive daytime sleepiness (EDS) in patients with narcolepsy and may be dispensed only to patients enrolled in the Xyrem Success Program®. Xyrem is the only product approved by the FDA for the treatment of cataplexy and EDS in narcolepsy, a serious neurological disorder. Xyrem was first approved in the U.S. in 2002. The Xyrem Success Program is a proprietary program to ensure the safe use of Xyrem and minimize the risk of abuse, misuse, and diversion of sodium oxybate. Xyrem is available only by prescription from physicians enrolled in the Xyrem Success Program and is distributed through a single central pharmacy directly to patients. The labeling for Xyrem contains a boxed warning about CNS depression, abuse, and misuse. In controlled clinical trials, the most common adverse reactions seen (incidence ≥ 5% and twice the rate seen with placebo) in Xyrem-treated patients were nausea, dizziness, vomiting, somnolence, enuresis, and tremor.

"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' future exploration of the deuterium-modified sodium oxybate (D-SXB) technology and development of D-SXB compounds, including C-10323, the future clinical testing of D-SXB to evaluate the compounds' therapeutic and commercial potential, and the plan to submit an investigational new drug application for C-10323. 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 results of the exploration of the D-SXB technology; the companies' ability to file an IND for C-10323 as currently contemplated; the uncertainty of clinical success and therapeutic value of

D-SXB compounds, including C-10323; the uncertainty of regulatory approval; the difficulty in integrating the D-SXB products into the company's product portfolio and the possibility that the company may fail to realize the anticipated benefits (commercial or otherwise) from this license; 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' Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 and future filings and reports by the company, including the Annual Report on Form 10-K for the year ended December 31, 2012. Jazz Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

Photos/Multimedia Gallery Available: http://www.businesswire.com/multimedia/home/20130226006806/en/

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