Jazz Pharmaceuticals and UCB Announce Positive Phase III Results for Sodium Oxybate (JZP-6) in Fibromyalgia

November 20, 2008

PRELIMINARY TOP LINE RESULTS OF FIRST PHASE III TRIAL SHOW SIGNIFICANT DECREASES IN PAIN AND FATIGUE, AND IMPROVEMENT IN DAILY FUNCTION, IN FIBROMYALGIA PATIENTS

PALO ALTO, Calif., and BRUSSELS, Belgium, Nov. 20 /PRNewswire-FirstCall/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) and UCB (Euronext Brussels: UCB) announced today positive preliminary top-line results from the first of two Phase III pivotal clinical trials of sodium oxybate (JZP-6) for the treatment of fibromyalgia. The randomized, double-blind, placebo-controlled study achieved its primary endpoints, demonstrating that sodium oxybate significantly decreased pain and fatigue, and improved daily function, in patients with fibromyalgia.

"There is a significant unmet need in diagnosing and treating millions of patients with fibromyalgia. Potential new treatments that address the various symptoms can have a significant impact on patients' quality of life," said I. Jon Russell, M.D., Ph.D., the study's lead investigator and Associate Professor of Medicine, Division of Clinical Immunology and Rheumatology, and Director, University Clinical Research Center, University of Texas Health Science Center at San Antonio.

The 14-week study included 548 adult patients with fibromyalgia randomized to one of three treatment arms: sodium oxybate 4.5 g/night, sodium oxybate 6 g/night or placebo. The primary outcome measure, viewed by both U.S. and EU regulatory authorities as a clinically meaningful endpoint, was the proportion of patients who achieved at least 30 percent reduction in pain from baseline to endpoint based on the Pain Visual Analog Scale (VAS). In the EU it is also considered that Fibromyalgia Impact Questionnaire (FIQ) data is equally relevant. FIQ data are considered supportive data by U.S. regulators.

In the top-line results, a significant number of patients treated with sodium oxybate achieved 30 percent or greater improvement in their pain compared to patients treated with placebo. Of those patients receiving sodium oxybate treatment, 46.2 percent of patients on 4.5 g/night and 39.3 percent of patients on 6 g/night reported this level of pain relief, compared with 27.3 percent of patients on placebo. These results were highly statistically significant.

Patients' physical functioning and ability to perform daily tasks, as measured by the FIQ, were significantly different from placebo for the 4.5 g/night dose and approached significance for the 6 g/night dose.

Patients receiving sodium oxybate also reported significant improvement in fatigue, another common symptom of fibromyalgia, at both active dosage levels.

Adverse events were similar to those seen in previous experience with sodium oxybate. The most common adverse events, with incidence greater than or equal to 5 percent and at least twice the rate of placebo, were headache, nausea, dizziness, vomiting, diarrhea, anxiety, and sinusitis. Sodium oxybate was generally well tolerated, with the majority of adverse events reported being mild to moderate in nature.

"Achieving positive sodium oxybate (JZP-6) data in fibromyalgia from this Phase III clinical trial is an exciting milestone for Jazz Pharmaceuticals, and supports our commitment to developing products that can improve outcomes for patients with serious medical conditions," said Samuel Saks, M.D., Chief Executive Officer of Jazz Pharmaceuticals.

"As UCB continues to focus on serious diseases of the central nervous system and immunology, we are delighted to partner with Jazz Pharmaceuticals in bringing new hope for patients with this under-treated condition," said Roch Doliveux, Chief Executive Officer of UCB.

Only primary efficacy and safety data have been reviewed at this time. Further analyses will be undertaken to examine the full results, including secondary endpoints, in greater detail. The sodium oxybate Phase III clinical trial program also includes a second randomized, double blind, placebo-controlled study, which is continuing at sites in the U.S. and Europe. More than 90% of the subjects have been enrolled in this second Phase III trial. Jazz Pharmaceuticals anticipates submitting a New Drug Application for sodium oxybate to the U.S. Food and Drug Administration by the end of 2009. UCB anticipates filing in the EU shortly after. UCB has the exclusive marketing and distribution rights to sodium oxybate for fibromyalgia in Europe and some other countries outside North America and will manage registrations accordingly.

Jazz Pharmaceuticals will host an investor conference call and live audio webcast to discuss the preliminary top-line results from this clinical trial on November 20, 2008 commencing at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time. The live webcast may be accessed on Jazz Pharmaceuticals' website at http://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. An archived version of the webcast will be available through December 4, 2008. Investors may participate in the conference call by dialing 866-730-5765 in the U.S., or 857-350-1589 outside the U.S., and entering passcode 52336179. A replay of this call will be available until December 4, 2008 at 888-286-8010 or 617-801-6888 (international), using the passcode 46982308.

About Sodium Oxybate

Sodium oxybate is the sodium salt form of gamma-hydroxybutyrate, an endogenous neurotransmitter and metabolite of GABA. While the precise mechanism of action is unknown, the effects may be mediated in part through interaction with GABA(B) and GHB receptors. Sodium oxybate is the active ingredient in XYREM(R), approved by the FDA for the treatment of excessive daytime sleepiness (EDS) and cataplexy (the sudden loss of muscle tone) in adult patients with narcolepsy. The American Academy of Sleep Medicine recommends sodium oxybate as a standard of care for the U.S. Food and Drug Administration-approved indications. It is also approved by the European Medical Evaluation Agency (EMEA) for the treatment of narcolepsy with cataplexy in adult patients. Most commonly reported adverse drug reactions in narcolepsy patients are dizziness, nausea and headaches. Sodium oxybate has the potential to induce respiratory depression and neuropsychiatric events. Sodium oxybate has not been evaluated

by regulators for the treatment of fibromyalgia and is not approved for this use.

About Fibromyalgia

Fibromyalgia, a chronic condition characterized by widespread pain, affects 0.5% - 5% of adults worldwide. Fibromyalgia is believed to be a central nervous system condition, resulting from neurological changes in how the brain perceives and responds to pain. In addition to pain, the main symptoms are fatigue, disturbed sleep and morning stiffness.

The exact causes of fibromyalgia are unknown. It may be triggered by physical trauma, emotional stress, chronic pain or infection. Genetics, neurochemicals that affect pain modulation, neurohormones and sleep physiology abnormalities are thought to play a role. Research also has suggested a relationship between sleep and pain. Fibromyalgia patients experience a high prevalence of sleep problems, including a reduction in non-restorative or deep sleep.

About Jazz Pharmaceuticals, Inc.

Jazz Pharmaceuticals is a specialty pharmaceutical company that identifies, develops and commercializes innovative treatments for important, underserved markets in neurology and psychiatry. The Company has an unwavering commitment to improving care for patients with serious psychiatric and neurological conditions through innovative treatments and distinctive and valuable programs for patients and physicians. For further information see http://www.JazzPharmaceuticals.com.

About UCB

UCB (Brussels, Belgium, http://www.ucb-group.com) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on central nervous system and immunology disorders. Employing around 12,000 people in over 40 countries, UCB achieved revenue of EUR 3.6 billion in 2007. UCB is listed on Euronext Brussels (symbol: UCB).

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

This press release contains forward-looking statements related to the development of Jazz Pharmaceuticals' sodium oxybate (JZP-6) product candidate for the treatment of fibromyalgia, including the submission of a New Drug Application to the FDA. These forward-looking statements are based on the company's current expectations and inherently involve significant risks and uncertainties. Jazz Pharmaceuticals' 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, the risk that clinical trial results may require Jazz Pharmaceuticals to discontinue development of the sodium oxybate (JZP-6) product candidate, risks related to Jazz Pharmaceuticals' ability to obtain additional funds sufficient to support its operations, risks related to Jazz Pharmaceuticals' reliance on third parties to conduct the clinical trials for its product candidates, including the second Phase III clinical trial of the sodium oxybate (JZP-6) product candidate, and risks that regulatory filings may not be made, or may be delayed, and that the sodium oxybate (JZP-6) product candidate for the treatment of fibromyalgia may not be approved for marketing by regulatory authorities. These and other risk factors are discussed under "Risk Factors" in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 filed by Jazz Pharmaceuticals with the Securities and Exchange Commission on November 14, 2008. 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.

UCB Forward-looking Statement

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of employees.

SOURCE Jazz Pharmaceuticals, Inc.

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