Jazz Pharmaceuticals, Inc. Completes Enrollment in Second of Two Phase III Clinical Trials of Sodium Oxybate to Treat Fibromyalgia

January 13, 2009

PALO ALTO, Calif., Jan. 13 /PRNewswire-FirstCall/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) today announced completion of enrollment in the second of two Phase III pivotal clinical trials of JZP-6 (sodium oxybate) for the treatment of fibromyalgia.

"Completion of enrollment in this second trial is a meaningful milestone in the JZP-6 program in fibromyalgia. We expect to report top-line results from this trial in mid-2009," said Samuel Saks, M.D., Chief Executive Officer.

The JZP-6 Phase III clinical trial program includes two randomized, double blind, placebo-controlled studies. The first study was completed and positive top-line results were announced in November 2008. The second Phase III study has enrolled 575 patients at centers in the U.S. and Europe.

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 has the exclusive marketing and distribution rights to sodium oxybate for fibromyalgia in Europe and many other countries outside North America.

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.

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' 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, and risks related to Jazz Pharmaceuticals' need for additional funding. 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.

SOURCE Jazz Pharmaceuticals, Inc.

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