Jazz Pharmaceuticals to Present Data From First Phase III Study of Sodium Oxybate in Patients With Fibromyalgia

June 9, 2009

PALO ALTO, Calif., June 9 /PRNewswire-FirstCall/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced today that data from the company's first Phase III clinical trial of sodium oxybate (JZP-6) for the treatment of fibromyalgia will be presented this week during the Associated Professional Sleep Societies (APSS) 2009 Annual Meeting in Seattle, Washington and also during the European League Against Rheumatism (EULAR) Congress in Copenhagen, Denmark.

Following are the details on each of these data presentations.

-- At APSS on June 10, 2009, Dr. Todd Swick will be presenting a poster entitled "Impaired Sleep and Daytime Functioning at Baseline in Subjects with Fibromyalgia: a 14-week Randomized, Double-blind, Placebo-controlled Trial of Sodium Oxybate" in the 10:15 am-12:15 pm poster session.

-- At APSS on June 11, 2009 at 9:00 am in Ballroom 6E, Dr. Swick will also deliver an oral presentation entitled "Sodium Oxybate Improves Pain, Fatigue, and Sleep in Fibromyalgia: Results from a 14-week Randomized, Double-blind, Placebo-controlled Study."

-- At EULAR on June 12, 2009, in Room C2 from 5:30-7:00 pm, Dr. I. Jon Russell will be presenting "Sodium Oxybate in the Treatment of Fibromyalgia" at a UCB-sponsored Symposium entitled: "Fibromyalgia: How Much More than Pain?" The symposium will be chaired by Dr. Ernest Choy and also features Dr. Gilles Lavigne and Dr. Michael Spaeth as speakers.

Jazz Pharmaceuticals has completed a second Phase III pivotal clinical trial of JZP-6 and expects to announce top-line results from that study in mid-2009. Assuming positive results in the second study, the company anticipates submitting a New Drug Application for sodium oxybate for the treatment of fibromyalgia to the U.S. Food and Drug Administration by the end of 2009.

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 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 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. For further information please 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 timing of results from the second Phase III pivotal clinical trial and 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, risks related to the outcomes of the company's second Phase III clinical study of sodium oxybate for the treatment of fibromyalgia and the timing of the announcement of clinical results, and risks that a New Drug Application may not be submitted, or may be delayed, and that sodium oxybate 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 March 31, 2009 filed by Jazz Pharmaceuticals with the Securities and Exchange Commission on May 7, 2009. 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.

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