Jazz Pharmaceuticals, Inc. Announces Final Patient Has Completed Phase III Clinical Trial of Sodium Oxybate to Treat Fibromyalgia

September 11, 2008

PALO ALTO, Calif., Sept. 11 /PRNewswire-FirstCall/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) today announced that the final patient has completed participation in the first Phase III pivotal clinical trial of JZP-6 (sodium oxybate) for the treatment of fibromyalgia.

The JZP-6 Phase III clinical trial program includes two randomized, double blind, placebo-controlled studies. The first study enrolled 550 fibromyalgia patients at 65 centers in the U.S. The second Phase III study is enrolling patients at sites in the U.S. and Europe. The primary endpoint for both studies is the change from baseline in pain based on the pain visual analog scale, which the U.S. Food and Drug Administration (FDA) and the European Medicines Agency have indicated is the appropriate primary endpoint.

"Completion of the final patient's participation in this trial is a key milestone in the JZP-6 program," said Samuel Saks, M.D., Chief Executive Officer. "The trial results remain blinded to the company, investigators, and patients. We will remain blinded as we conduct analysis of the extensive data set generated by this study. We anticipate releasing primary efficacy and safety data from the first Phase III clinical trial on schedule in the fourth quarter of this year, and we continue to plan for submission of a New Drug Application to the FDA by the end of 2009."

"We appreciate the dedication of the patients, clinical investigators and Jazz Pharmaceuticals employees who are taking part in this important program," Dr. Saks continued.

The JZP-6 clinical program also includes an open-label continuation trial to provide long-term safety data. Enrollment in this trial is ongoing, and the trial is open to patients who complete either of the two pivotal Phase III trials.

Sodium oxybate is the active ingredient in Xyrem(R), a Jazz Pharmaceuticals product approved by the FDA for the treatment of excessive daytime sleepiness and cataplexy (the sudden loss of muscle tone) in patients with narcolepsy. Sodium oxybate has not been approved for the treatment of fibromyalgia.

About Fibromyalgia

Fibromyalgia is a chronic pain syndrome defined by widespread pain lasting at least three months. According to the American College of Rheumatology, between two and four percent of the U.S. population suffers from fibromyalgia. Fibromyalgia is believed to be a central nervous system condition. In addition to pain, fibromyalgia patients often suffer from a combination of muscle stiffness, fatigue, disturbed sleep, restless legs syndrome and impaired memory and concentration. Although physicians do not understand the cause of fibromyalgia, it may be triggered by physical trauma, emotional stress or infection. The criteria established by the American College of Rheumatology for the classification of fibromyalgia require the application of pressure at 18 different points on the body and measurement of pain induced by such pressure. If at least 11 of the 18 points are painful and have been painful for three months, the patient is diagnosed with fibromyalgia.

About Jazz Pharmaceuticals, Inc.

Jazz Pharmaceuticals is a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. For further information see http://www.JazzPharmaceuticals.com.

"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 the continued development of Jazz Pharmaceuticals' JZP-6 product candidate for the treatment of fibromyalgia and the timing of the release of clinical study results 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 clinical trials of Jazz Pharmaceuticals' JZP-6 product candidate, including the risk that clinical trial results may require Jazz Pharmaceuticals to discontinue its development, risks related to our reliance on third parties to conduct the clinical trials for our product candidates, and risks that regulatory filings may not be made, or may be delayed, and that products 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 June 30, 2008 filed by Jazz Pharmaceuticals with the Securities and Exchange Commission on August 8, 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.

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