



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

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PALO ALTO, Calif., June 2 /PRNewswire-FirstCall/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) today announced completion of enrollment in the first of two Phase III pivotal clinical trials of JZP-6 (sodium oxybate) for the treatment of fibromyalgia.

"Completion of enrollment in this trial is a key milestone in the JZP-6 program. We expect to report top line results from this trial in the fourth quarter of 2008," 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 has completed enrollment of 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.

In a Phase II clinical trial completed in 2005, fibromyalgia patients taking sodium oxybate, the active ingredient in JZP-6, achieved a statistically significant improvement in pain compared to placebo based on the pain visual analog scale. These results need to be confirmed in the ongoing Phase III clinical trials.

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

Sodium oxybate is 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 and the timing of clinical study results. 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, and risks related to our reliance on third parties to conduct the clinical trials for our product candidates. These and other risk factors are discussed under "Risk Factors" in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 filed by Jazz Pharmaceuticals with the Securities and Exchange Commission on May 15, 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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