



## Data from Jazz Pharmaceuticals' First Phase III Study of Sodium Oxybate in Patients With Fibromyalgia to be Presented at Upcoming Conferences

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PALO ALTO, Calif., Oct. 14 /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 next week during the American College of Rheumatology 2009 Annual Meeting (ACR) in Philadelphia, Pennsylvania and also in November during the US Psychiatric and Mental Health Congress (US Psych Congress) in Las Vegas, Nevada.

-- At ACR on October 20, 2009, I. Jon Russell, MD, PhD, Associate Professor of Medicine in the Division of Clinical Immunology and Rheumatology and Director, University Clinical Research Center at The University of Texas Health Science Center at San Antonio, will present a poster entitled, "Effect of Sodium Oxybate on Pain, Functionality, PGlc, & Composite Scores in Fibromyalgia - Results from a Phase 3 Controlled Trial". The poster will be presented in the 9:00 am - 11:00 am poster session.

-- Also at ACR on October 20, 2009, Philip J. Mease, MD, Clinical Professor at the University of Washington School of Medicine in Seattle and Chief of Rheumatology Clinical Research at the Swedish Hospital Medical Center, will present a poster entitled, "Sodium Oxybate Improves Fatigue, Sleep Disturbance, and PGlc in Fibromyalgia - Results from a Phase 3, 14-Week Controlled Trial". The poster will be presented in the 9:00 am - 11:00 am poster session.

-- At US Psych Congress on November 2, 2009, Stephen S. Flitman, MD, Medical Director at 21st Century Neurology, a division of Xenoscience, will present a poster entitled, "Efficacy and Safety of Sodium Oxybate in Fibromyalgia: A 14-week, Randomized, Double-blind, Controlled Trial". The poster will be presented in the 3:45 pm - 6:45 pm poster session.

Jazz Pharmaceuticals has completed two Phase III pivotal clinical trials of JZP-6, with positive results in both studies. Jazz Pharmaceuticals is working to submit 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®, 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 [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com).

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