Jazz Pharmaceuticals Announces FDA Acceptance of its New Drug Application for JZP-6 (sodium oxybate) for the Treatment of Fibromyalgia

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PALO ALTO, Calif., Feb 18, 2010 /PRNewswire via COMTEX/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for JZP-6 (sodium oxybate) for the treatment of fibromyalgia. Based on a standard 10-month review, the target date for the FDA to complete its review of the NDA under the Prescription Drug User Fee Act (PDUFA) is October 11, 2010.

The submission is based on a comprehensive clinical development program including results from two Phase III clinical trials. In both trials, sodium oxybate significantly decreased pain and fatigue as well as improved daily function, patient global impression of change, and sleep quality. Sodium oxybate was generally well tolerated, with the majority of adverse events reported being mild to moderate in nature and similar to those seen in previous trials with narcolepsy. Sodium oxybate has not been evaluated by regulators for the treatment of fibromyalgia and is not approved for this use.

Fibromyalgia is a complex musculoskeletal disorder clinically characterized by widespread pain usually accompanied by fatigue, insomnia, and dyscognition. According to the American College of Rheumatology (ACR), an estimated 6 million Americans suffer from fibromyalgia.

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) (sodium oxybate) oral solution, approved by the FDA and marketed by Jazz Pharmaceuticals in the U.S. for the treatment of excessive daytime sleepiness and cataplexy (the sudden loss of muscle tone) in adult patients with narcolepsy. The 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 is a chronic condition characterized by widespread pain. 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 (Nasdaq: JAZZ) is a specialty pharmaceutical company that identifies, develops and commercializes innovative treatments for important, underserved markets in neurology and psychiatry. For further information see www.JazzPharmaceuticals.com.

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