Data Suggest Sodium Oxybate Significantly Improves Pain and the Core Symptoms of Fibromyalgia

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PALO ALTO, Calif., June 15, 2009 /PRNewswire-FirstCall via COMTEX/ -- Jazz Pharmaceuticals' (Nasdaq: JAZZ) sodium oxybate (JZP-6) demonstrated statistically significant and clinically meaningful improvement in pain and the core symptoms associated with fibromyalgia, according to Phase III data presented last week at the 2009 Associated Professional Sleep Societies meeting in Seattle, WA. These data have not been evaluated by the FDA or other regulatory authorities for use of sodium oxybate in the treatment of fibromyalgia.

Widespread chronic pain is the hallmark of fibromyalgia, but the vast majority of patients are also affected by a broader constellation of symptoms, including fatigue, sleep disturbances, cognitive dysfunction, and impaired physical function.

"The data showed that sodium oxybate improves the key symptoms of fibromyalgia: pain, fatigue, and sleep disturbances," said Dr. Todd Swick, one of the study's investigators and Medical Director of the Houston Sleep Center and Assistant Clinical Professor of Neurology at the University of Texas-Houston School of Medicine. "Millions of people are diagnosed with fibromyalgia and there is a continuing unmet need for therapies that address the constellation of symptoms that can have a significant impact on patients' quality of life."

The 14-week randomized, double-blind, placebo-controlled study included 548 adult patients with fibromyalgia randomized to one of three treatment arms: sodium oxybate 4.5 g/night, sodium oxybate 6 g/night or placebo. The primary outcome measure was the proportion of patients who achieved at least 30% reduction in pain from baseline to endpoint based on the Pain Visual Analog Scale (VAS).

At three months, 54.2% (p