

News Release: February 23, 2006

## Study Finds That Xyrem(R) (Sodium Oxybate) Relieves Pain in Patients With Fibromyalgia

### Data Presented Today at the American Academy of Pain Management Annual Meeting

SAN DIEGO, Feb. 23 -- Patients with fibromyalgia syndrome taking Xyrem® (sodium oxybate) in a Phase II clinical trial experienced significant pain relief, according to data presented today at the annual meeting of the American Academy of Pain Management in San Diego.

"The pain of fibromyalgia is notoriously difficult to treat," said Patrick B. Wood, MD, of the Louisiana State University Health Sciences Center in Shreveport, Louisiana. "The results from this trial are quite encouraging, and further study is warranted."

The 8-week randomized, double-blind, placebo-controlled study examined two dosages of Xyrem (4.5g per day or 6g per day) taken in two equally divided doses (the first at bedtime and the second 2.5 to 4 hours later). The intent-to-treat population included 188 patients [randomized to Xyrem 4.5g, n=58; Xyrem 6g, n=66 or placebo, n=64], of whom 147 [78%] completed the trial.

The primary outcome variable [POV] was a composite of changes from baseline in three co-primary, self-reported measures: Pain Visual Analog Scale [PVAS], captured with electronic diaries; Fibromyalgia Impact Questionnaire total score [FIQ]; and Patient Global Impression of Change [PGIC].

In the intent-to-treat analysis, a statistically significant benefit in the POV was seen in both doses of Xyrem compared with placebo [4.5g, p=0.005 and 6g, p=0.048]. Patient response rates in the POV were 34.5% [4.5g] and 27.3% [6g] compared to 12.5% in the placebo group. In the PVAS, both doses of Xyrem resulted in significantly greater improvement than placebo [4.5g, p=0.04 and 6g, p=0.03].

In this study, Xyrem was generally well tolerated and no treatment-related serious adverse events were reported. The most commonly reported adverse events included nausea and dizziness and were dose-related [4.5g, 15% and 6.7% respectively; 6g, 28.4% and 13.4% respectively; placebo, 9.2% and 1.5% respectively]. Most adverse events were mild to moderate in severity and transient in duration.

### About Fibromyalgia

Fibromyalgia syndrome is a chronic pain illness which is characterized by widespread musculoskeletal aches, pains and stiffness, soft tissue tenderness, general fatigue and sleep disturbances. The most common sites of pain include the neck, back, shoulders, pelvic girdle and hands, but any body part can be involved.

Published data estimate that approximately 4 million Americans are affected by the condition. Fibromyalgia affects women three times more often than men.

### About Xyrem

Xyrem was approved by the U.S. Food and Drug Administration (FDA) in July 2002 as the first and only treatment for cataplexy (sudden loss of muscle tone) in patients with narcolepsy. In November 2005, the FDA approved an expanded indication for Xyrem as a treatment for excessive daytime sleepiness associated with narcolepsy. Xyrem is not approved for the treatment of fibromyalgia syndrome. Additional clinical study of the use of Xyrem to treat fibromyalgia syndrome would be required before marketing approval could be sought.

In clinical trials with Xyrem, frequently reported adverse reactions included dizziness, headache, nausea, pain, somnolence and pharyngitis. Less common side effects include vomiting, sleepwalking, urinary incontinence, depression and confusion. Xyrem is a central nervous system and respiratory depressant. Therefore, the use of other CNS depressants or alcohol is contraindicated in patients receiving Xyrem.

Sodium oxybate, the active ingredient in Xyrem, is a sodium salt of gamma- hydroxybutyrate, a substance with a history of abuse when acquired illicitly and used illegally. Abuse of illicit gamma-hydroxybutyrate has been associated with adverse CNS events including seizures, respiratory depression and profound decreases in level of consciousness, with instances of coma and death.

Xyrem is a Schedule III drug under the Controlled Substances Act and is only available through a restricted distribution system called the Xyrem Success Program®. Please refer to the Xyrem package insert for full prescribing information.

About Jazz Pharmaceuticals, Inc.

Jazz Pharmaceuticals is focused on helping patients by meeting unmet medical needs in neurology and psychiatry with important and innovative therapeutic products. Jazz Pharmaceuticals is aggressively building its product portfolio through a combination of commercialization and development activities. Based in Palo Alto, California, the company is committed to working closely with patients, patient advocacy groups and healthcare professionals. For further information, please visit <http://www.JazzPharmaceuticals.com> .

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