



FDA Approves LUVOX(R) CR (Fluvoxamine Maleate) Extended-Release Capsules for the Treatment of Social Anxiety Disorder (SAD) and Obsessive Compulsive Disorder (OCD)

February 28, 2008

PALO ALTO, Calif., February 28, 2008 - Today, Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced that the U.S. Food and Drug Administration (FDA) has approved Once-A-Day LUVOX CR (fluvoxamine maleate) Extended-Release Capsules for the treatment of social anxiety disorder (SAD) and obsessive compulsive disorder (OCD) in adults. LUVOX CR is a selective serotonin reuptake inhibitor (SSRI) that incorporates Elan's proprietary SODAS® (Spheroidal Oral Drug Absorption System) technology designed to minimize peak-to-trough plasma level fluctuations over a 24-hour period.

In clinical trials at the primary endpoint of 12 weeks, Once-A-Day LUVOX CR provided statistically significant improvement vs. placebo in SAD symptoms as measured by the LSAS (Liebowitz Social Anxiety Scale) and statistically significant improvement vs. placebo in OCD symptoms as measured by the Y-BOCS (Yale-Brown Obsessive Compulsive Scale)

"We are pleased to have FDA approval of this new, effective treatment option for patients in the United States with SAD and OCD and our proceeding towards launch by the end of this quarter," said Samuel Saks, M.D., chief executive officer of Jazz Pharmaceuticals. "As part of our commitment to patients with these two serious and widely under-recognized anxiety disorders, we are working with patient advocacy organizations to raise awareness about these conditions and encourage patients to get accurately diagnosed."

"The approval of Once-A-Day LUVOX CR (fluvoxamine maleate) Extended-Release Capsules for social anxiety disorder and obsessive compulsive disorder is important for the 15 million Americans with SAD and the 2.2 million Americans with OCD, two underdiagnosed and undertreated anxiety disorders," said John H. Greist, M.D., distinguished senior scientist, Madison Institute of Medicine and clinical professor of psychiatry, University of Wisconsin Medical School. "Physicians have been using immediate-release fluvoxamine for years to treat OCD patients. Now having Once-A-Day LUVOX CR (fluvoxamine maleate) Extended-Release Capsules offers patients with SAD and OCD an additional option."

The FDA evaluated a data package involving approximately 600 patients worldwide that included three clinical trials with positive outcomes evaluating the efficacy and safety of LUVOX CR. These studies were:

Social Anxiety Disorder

- Davidson, Jonathan, et al. Fluvoxamine-controlled release formulation for the treatment of generalized social anxiety disorder. *J Clin Psychopharmacol* 2004; 24:118-125.
- Westenberg, Herman, et al. A double-blind, placebo-controlled study of controlled-release fluvoxamine for the treatment of generalized social anxiety disorder. *J Clin Psychopharmacol*. 2004; 24:49-55.

Obsessive Compulsive Disorder

- Hollander, Eric, et al. A double-blind, placebo-controlled study of the efficacy and safety of controlled-release fluvoxamine in patients with obsessive-compulsive disorder. *J Clin Psychiatry*. 2003; 64:640-647.

"SAD and OCD are serious, yet treatable conditions," said Jerilyn Ross, M.A., L.I.C.S.W., president and CEO, Anxiety Disorders Association of America (ADAA). "We're excited about new treatment options - both medications and psychological - to help patients with these chronic and undertreated anxiety disorders. Having treatment options benefits the patient, and that's what is most important."

LUVOX CR will be available in 100 mg and 150 mg dose strengths. Over the next several weeks, Jazz Pharmaceuticals will continue to work closely with Elan on the manufacturing of LUVOX CR for commercial launch.

In January 2007, Jazz Pharmaceuticals licensed the right to market Once-A-Day LUVOX CR (fluvoxamine maleate) Extended-Release Capsules in the U.S. from Solvay Pharmaceuticals. The license agreement provides for Jazz Pharmaceuticals to pay Solvay Pharmaceuticals \$20 million as a result of the approval of LUVOX CR for both SAD and OCD and the approved expiry dating of the product.

The approval of LUVOX CR includes a post marketing commitment to conduct a safety and efficacy study in adolescent patients with SAD and a long-term safety and efficacy study in patients with SAD. The NDA for LUVOX CR is being transferred to Jazz Pharmaceuticals.

For more information about LUVOX CR, please visit www.JazzPharmaceuticals.com

Social Anxiety Disorder

SAD or social phobia is characterized by the fear and avoidance of social or performance situations where patients feel that others may scrutinize them and they may embarrass themselves. Patients experience physical symptoms of anxiety, including blushing, sweating, trembling and nausea. SAD affects an estimated 15 million American adults.

Obsessive Compulsive Disorder

OCD is a chronic and debilitating anxiety disorder that is characterized by recurrent, unwanted thoughts (obsessions) and/or repetitive behaviors (compulsions) that are severe enough to cause significant impairment. Patients are compelled to perform repetitive behaviors such as hand washing, counting, checking or cleaning with the goal of preventing obsessive thoughts or making them go away.⁵ OCD affects approximately 2.2 million American adults.⁶

Important Safety Information

Antidepressants can increase suicidal thoughts and behaviors in children, adolescents and young adults. Patients should call their doctor right away if they experience new or worsening depression symptoms, unusual changes in behavior, or thoughts of suicide.

In clinical trials, the most commonly observed adverse events with an incidence of $\leq 5\%$ and at least twice that of placebo were nausea, somnolence, asthenia, diarrhea, anorexia, tremor, and sweating. Overall, these side effects were mild to moderate in severity and transient in nature. Other common adverse events with an incidence of $\leq 5\%$ and at least twice that of placebo included abnormal ejaculation and anorgasmia.

The use of alosetron, tizanidine, thioridazine, or pimozone with LUVOX CR Capsules is contraindicated. The use of MAO inhibitors in combination with LUVOX CR Capsules or within 14 days of discontinuing treatment with LUVOX CR Capsules is contraindicated. (see CONTRAINDICATIONS, WARNINGS and PRECAUTIONS in full prescribing information.) LUVOX CR Capsules are also contraindicated in patients with a history of hypersensitivity to fluvoxamine maleate or any of its excipients.

Clinical Measures

LSAS: A clinician-rated, 24-item scale used to assess the range of difficulties in social interaction (11 questions) and performance situations (13 questions) that a patient with SAD may have.

Y-BOCS: A clinician-rated, 10-item scale used to rate the severity of obsessive compulsive symptoms and to monitor improvement during treatment.

About Jazz Pharmaceuticals, Inc.

Jazz Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Jazz Pharmaceuticals will host an Investor Day on March 13, 2008 beginning at 10:00 a.m. Eastern Time/7:00 a.m. Pacific Time. The event will be available by live audio webcast, and the accompanying presentation materials will also be available on the investor relations section of Jazz Pharmaceuticals' website. For further information, please visit 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 planned commercial launch of LUVOX CR and Jazz Pharmaceuticals' continuing efforts, including manufacturing to prepare for commercial launch. Words and phrases such as "will," "are proceeding" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Jazz Pharmaceuticals' current expectations. Forward-looking statements 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 when or whether commercial launch of LUVOX CR will occur, Jazz Pharmaceuticals' ability to attain market acceptance of LUVOX CR by physicians, patients and third party payors, Jazz Pharmaceuticals' dependence on single source suppliers and manufacturers, and scaling up manufacturing of LUVOX CR to commercial capacity. These and other risk factors are discussed under "Risk Factors," in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 filed by Jazz Pharmaceuticals with the Securities and Exchange Commission on November 9, 2007. 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.

¹ Davidson J, Yaryura-Tobias J, DuPont R, et al. Fluvoxamine-controlled release formulation for the treatment of generalized social anxiety disorder. *J Clin Psychopharmacol*. 2004;24:118-125.

² Hollander E, Koran LM, Goodman WK, et al. A double-blind, placebo-controlled study of the efficacy and safety of controlled-release fluvoxamine in patients with obsessive-compulsive disorder. *J Clin Psychiatry*. 2003;64:640-647.

³ LUVOX CR Prescribing Information. Jazz Pharmaceuticals, Inc., Palo Alto, CA;2008.

⁴ Westenberg HGM, Stein DJ, Yang H, et al. A double-blind placebo-controlled study of controlled release fluvoxamine for the treatment of generalized social anxiety disorder. *J Clin Psychopharmacol*. 2004;24:49-55.

⁵ American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, 4th ed, revised. Washington, DC: American Psychiatric Association; 2000.

⁶ Kessler RC, et al. *Arch Gen Psychiatry*. 2005; 62:593-602/ NIMH Website: <http://www.nimh.nih.gov/health/publications/the-numbers-count-mental-disorders-in-america.shtml#Anxiety>, Date accessed December 14, 2007.

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