



Jazz Pharmaceuticals' LUVOX CR Is Now Available for Patients With Social Anxiety Disorder (SAD) and Obsessive Compulsive Disorder (OCD)

April 14, 2008

PALO ALTO, Calif., April 14 /PRNewswire-FirstCall/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced today that Once-A-Day LUVOX(R) CR (fluvoxamine maleate) Extended-Release Capsules is now available at pharmacies throughout the United States. LUVOX CR was recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of social anxiety disorder (SAD) and obsessive compulsive disorder (OCD) in adult patients. SAD and OCD are two difficult-to-treat, underdiagnosed and undertreated anxiety disorders.

(Photo: <http://www.newscom.com/cgi-bin/prnh/20080414/AQM046>)

Jazz Pharmaceuticals is dedicated to helping patients suffering from serious psychiatric and neurological disorders. Jazz Pharmaceuticals is supporting a number of programs and resources for SAD and OCD patients and for physicians. These efforts include education kits, disease education Web sites and diagnostic screening tools. The company is also introducing CT STEPS(TM), a novel, Internet-based cognitive behavioral therapy (CBT) program to help OCD patients.

Earlier this month, Jazz Pharmaceuticals' sales team began communicating with office-based psychiatrists and select primary care physicians about the unique attributes of LUVOX CR. These sales professionals will provide samples of LUVOX CR in 100 mg and 150 mg dose strengths that physicians may choose to distribute to their patients.

LUVOX CR incorporates Elan's proprietary SODAS(R) (Spheroidal Oral Drug Absorption System) technology, which is designed to minimize peak-to-trough fluctuations in plasma levels over a 24-hour period. In three Phase III trials, LUVOX CR was shown to provide tolerability in two common areas of concern to patients(1,2). In the trials, LUVOX CR demonstrated a weight-neutral profile with no significant weight gain or loss(3,4,5,6). In addition, patients taking LUVOX CR had a low incidence of sexual adverse events in the trials(4). Less than 1 percent of patients treated with LUVOX CR discontinued therapy due to any individual sexual adverse event(3-6).

"We are very excited about the introduction of LUVOX CR to the United States market. The availability of LUVOX CR provides physicians with a new and effective treatment option for the millions of adults in the United States suffering from SAD and OCD," said Samuel Saks, M.D., chief executive officer of Jazz Pharmaceuticals. "Through our educational efforts, we hope to provide physicians and their patients with important information about SAD and OCD. As part of our commitment to helping patients, their families and caregivers, we are working with advocacy organizations to increase awareness about these serious and underdiagnosed conditions."

Important Safety Information

The use of alosetron, tizanidine, thioridazine, or pimozide 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 WARNINGS and PRECAUTIONS). LUVOX CR Capsules are also contraindicated in patients with a history of hypersensitivity to fluvoxamine maleate or any of its excipients.

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 greater than or equal to 5 percent 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 greater than or equal to 5 percent and at least twice that of placebo) included abnormal ejaculation and anorgasmia.

Please see full prescribing information (<http://www.luvocr.com/LUVOX-CR-PI.pdf>), including boxed warning for LUVOX CR.

About LUVOX CR

Once-A-Day LUVOX(R) CR (fluvoxamine maleate) Extended-Release Capsules was approved by the U.S. Food and Drug Administration (FDA) in February 2008 on the basis of two pivotal trials in SAD and one pivotal trial in OCD.

LUVOX CR should be taken once-a-day at bedtime. It can be taken with or without food and is available in 100 mg and 150 mg dose strengths.

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 efficacy and safety study in patients with SAD. For more information about LUVOX CR, please visit <http://www.LUVOXCR.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(7). SAD affects an estimated 15 million American adults(8). For more information about SAD, please visit <http://www.socialanxietycenter.org>

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(7). OCD affects approximately 2.2 million American adults(8). For more information about OCD, please visit <http://www.ocdcenter.org>

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. For further information, please visit <http://www.JazzPharmaceuticals.com>.

(C)2008 Jazz Pharmaceuticals, Inc.

SODAS(R) is a registered trademark of Elan Pharma International Limited, Ireland, a subsidiary of Elan Corporation, plc (NYSE: ELN)

LUVOX(R) is a registered trademark of Solvay Pharmaceuticals, Inc.

(1) Hirschfeld RMA. Long-term side effects of SSRIs: sexual dysfunction and weight gain. *J Clin Psychiatry*. 2003;64(suppl 18):20-24.

(2) Bruce TJ, Saeed SA. Social anxiety disorder: a common, underrecognized mental disorder. *Am Fam Physician*. 1999;60:2311-2322.

(3) 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.

(4) LUVOX CR Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA; 2008.

(5) 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.

(6) 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 Psych*. 2003;64:640-647.

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

(8) 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.

CONTACT: Becky Lauer of MS&L, office, +1-212-468-4125, or cell, +1-917-304-6138, becky.lauer@mslpr.com, for Jazz Pharmaceuticals, Inc.