



## **Jazz Pharmaceuticals, Inc. Announces Submission of Complete Responses to FDA Approvable Letters for Luvox(R) CR and Luvox(R)**

August 2, 2007

PALO ALTO, Calif., Aug 02, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the submission of the complete response by Solvay Pharmaceuticals, Inc. to the FDA approvable letter for Luvox(R) CR (fluvoxamine maleate) extended-release capsules. The PDUFA action date is December 22, 2007.

The NDA for Luvox CR seeks marketing approval for the treatment of obsessions and compulsions in patients with obsessive compulsive disorder (OCD) and for the treatment of social anxiety disorder (SAD). Luvox CR is an extended-release formulation of fluvoxamine maleate, a selective serotonin reuptake inhibitor.

The FDA has also accepted the submission of the complete response by Solvay Pharmaceuticals to the FDA approvable letter for Luvox (fluvoxamine maleate) immediate release tablets. The PDUFA action date is December 21, 2007.

In January 2007, Jazz Pharmaceuticals licensed from Solvay Pharmaceuticals the right to market Luvox CR and Luvox in the United States. Solvay Pharmaceuticals retains the right to market both products in other territories around the world. Subject to receipt of FDA approval, Jazz Pharmaceuticals expects to launch Luvox CR in the United States during the first quarter of 2008.

### About Obsessive Compulsive Disorder

Obsessive compulsive disorder (OCD) is a chronic anxiety disorder characterized by persistent, unwanted thoughts, or obsessions, and repetitive behaviors or rituals, or compulsions. According to the National Institute of Mental Health (NIMH), OCD affects approximately 2.2 million adults in the United States. It is estimated that 60% of patients with OCD worldwide receive no treatment for their disorder. Patients with OCD use rituals to help control anxiety related to their obsessive thoughts, and these rituals become disruptive to their daily life. While these patients often realize that their obsessions and compulsions are irrational or excessive, they frequently have little or no control over them. Rituals adopted by OCD patients may provide them with transient relief from anxiety, but the rituals do not provide sustained comfort. Frequently, the rituals become so overwhelming that patients are unable to function normally in their daily lives.

### About Social Anxiety Disorder

Social anxiety disorder (SAD) 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. According to the NIMH, SAD affects approximately 15 million adults in the United States. Despite the prevalence of the disorder, SAD remains underdiagnosed and undertreated by clinicians. SAD patients have anticipatory anxiety about these situations, and this anxiety can become so pronounced that patients cannot function normally in their daily lives. Social anxieties can be limited to a particular situation or apply to a variety of situations. In addition to anxiety, patients experience physical symptoms including blushing, sweating, trembling, and nausea.

### About Jazz Pharmaceuticals, Inc.

Jazz Pharmaceuticals 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>.

### "Safe Harbor" Statement Under the Private Securities Litigation Reform Act of 1995

Certain statements set forth above may constitute forward-looking statements about the business of Jazz Pharmaceuticals, including, but not limited to, whether the FDA will take action on, or approve for marketing, Luvox CR or Luvox on their respective PDUFA action dates or at all. Pharmaceutical product development inherently involves significant risks and uncertainties. For further information with respect to factors that could cause the results of Jazz Pharmaceuticals to differ materially from expectations, reference is made to the risks outlined under "Risk Factors" and elsewhere in the Form S-1 Registration Statement dated May 31, 2007 filed by Jazz Pharmaceuticals with the Securities and Exchange Commission. Actual results may differ materially from the expectations of Jazz Pharmaceuticals due to these risks and uncertainties. Jazz Pharmaceuticals, Inc. 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 Jazz Pharmaceuticals' expectations.

### SOURCE Jazz Pharmaceuticals, Inc.

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