



Jazz Pharmaceuticals, Inc. Announces Submission of Complete Response to FDA Approvable Letter for LUVOX(R) CR

January 31, 2008

PDUFA Date Set for February 29, 2008

PALO ALTO, Calif., Jan. 31 /PRNewswire-FirstCall/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the submission of the response by Solvay Pharmaceuticals, Inc. to the FDA approvable letter for Once-A-Day LUVOX(R) CR (fluvoxamine maleate) Extended-Release Capsules. The FDA has notified Solvay Pharmaceuticals that the Agency considers this a complete, class 1 response and the PDUFA action date is February 29, 2008. Jazz Pharmaceuticals continues to expect to launch LUVOX CR in the United States during the first quarter of 2008, subject to FDA approval.

In an approvable letter received on December 21, 2007, the FDA requested additional information concerning a CMC issue. Jazz Pharmaceuticals and Solvay Pharmaceuticals believe that the response submitted to the FDA on December 28, 2007 fully addressed that CMC issue. The approvable letter did not raise any questions related to safety or efficacy of LUVOX CR and included the FDA's proposed labeling.

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.

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>.

LUVOX is a registered trademark of Solvay Pharmaceuticals, Inc.

"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 implications of the approvable letter for LUVOX CR. These forward-looking statements inherently 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, whether or when LUVOX CR will be approved or launched. 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.

SOURCE Jazz Pharmaceuticals, Inc.

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