



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

December 21, 2007

PALO ALTO, Calif., Dec. 21 /PRNewswire-FirstCall/ -- Today, Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced that the U.S. Food and Drug Administration (FDA) has issued an approvable letter for Once-A-Day LUVOX(R) CR (fluvoxamine maleate) Extended-Release Capsules, for which Jazz Pharmaceuticals and Solvay Pharmaceuticals, Inc. are seeking marketing approval for the treatment of two anxiety disorders, social anxiety disorder (SAD) and obsessive compulsive disorder (OCD).

The FDA requested information related to the companies' response concerning the previously disclosed CMC issue. The companies are seeking clarification from FDA and look forward to working with FDA to resolve this as quickly as possible. The approvable letter did not raise any questions related to safety or efficacy of LUVOX(R) CR. The approvable letter included the FDA's proposed labeling.

Separately, the FDA approved LUVOX(R) (fluvoxamine maleate) for the treatment of OCD on December 20, 2007.

Jazz Pharmaceuticals will host an investor conference call and live audio webcast to discuss this corporate update on December 24, 2007 at 8:30 a.m. Eastern Time/5:30 a.m. Pacific Time. The live webcast and press release may be accessed on Jazz Pharmaceuticals' website at <http://www.JazzPharmaceuticals.com>. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. An archived version of the webcast will be available through January 7, 2008. Investors may participate in the conference call by dialing 1-866-383-8009 in the U.S., or 1-617-597-5342 outside the U.S., and entering passcode 31811188. A replay of this call will be available until January 7, 2008 at 1-888-286-8010 (U.S.), or 1-617-801-6888 (international), using the passcode 32600407.

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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