



Jazz Pharmaceuticals, Inc. Announces Receipt of FDA Orphan Drug Designation for Recurrent Acute Repetitive Seizures Product Candidate

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PALO ALTO, Calif., Jan 07, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Jazz Pharmaceuticals, Inc. (Nasdaq: JAZZ) announced today that it has received orphan drug designation from the U.S. Food and Drug Administration (FDA) for its JZP-8 product candidate for the treatment of recurrent acute repetitive seizures. In December 2007, Jazz Pharmaceuticals dosed the first patient in a Phase II clinical trial of JZP-8.

JZP-8 is a novel drug delivery formulation incorporating clonazepam, a widely prescribed benzodiazepine. The product candidate is designed to be a fast-acting intranasal spray for the treatment of recurrent acute repetitive seizures in patients with epilepsy. Jazz Pharmaceuticals previously completed development activities to select the active pharmaceutical ingredient for the product, to determine its formulation, and to assess its safety and tolerability in early stage studies.

"JZP-8 is one of the first development product candidates from our internal product identification and development program to enter Phase II," said Samuel R. Saks, M.D., Chief Executive Officer of Jazz Pharmaceuticals. "Dosing of the first patient in our Phase II clinical trial and receipt of orphan drug designation are important milestones for this program."

About Recurrent Acute Repetitive Seizures

Recurrent acute recurrent repetitive seizures (ARS) are bouts of acute seizure activity occurring within a 24-hour period in adults and a 12-hour period in children. ARS, also called seizure clusters, occurs in a small subset of patients with epilepsy who regularly experience breakthrough seizures in flurries or clusters despite treatment with a regimen of anti-epileptic drugs. ARS is a rare disorder, with an estimated prevalence in the United States of approximately 90,000 to 180,000 people.

About Orphan Drug Designation

Orphan drug designation is granted by the FDA to encourage the development of treatments for diseases or conditions that affect fewer than 200,000 patients in the United States. Drug products that receive orphan drug designation obtain seven years of marketing exclusivity from the date of FDA marketing approval, as well as tax credits for clinical trial costs and waivers of marketing application filing fees.

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>.

"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 development program for the JZP-8 product candidate and the company's internal product concept generation program. 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 clinical studies of JZP-8 will be completed or will be successful, and whether or when the product candidate 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.

<http://www.jazzpharmaceuticals.com>