Jazz Pharmaceuticals Begins Clinical Trial of Intravenously Administered Erwinaze® In Patients with Acute Lymphoblastic Leukemia

December 3, 2012

DUBLIN, Dec. 3, 2012 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the first patient has been enrolled and dosed in a clinical trial of Erwinaze® (asparaginase *Erwinia chrysanthemi*) administered intravenously (IV) as an alternative method of administration to treat patients with acute lymphoblastic leukemia (ALL) with hypersensitivity to *E. coli*-derived asparaginase therapy.

"Intravenous administration of Erwinaze may provide meaningful benefit to patients, their caregivers and families by avoiding the need for multiple intramuscular injections," stated Lynda Vrooman, MD, MSc, a pediatric oncologist at Dana-Farber/Children's Hospital Cancer Center and principal investigator of the trial. "Intramuscular injections can be painful and difficult for patients, and this alternative route of administration, if it is shown to be feasible, would be an important advancement in the care of certain ALL patients, many of whom are young children."

The trial is designed to enroll up to 25 ALL patients in the U.S. and Canada who have a documented Grade 2 or higher hypersensitivity reaction to native or pegylated *E. coli* asparaginase and have not completed their full courses of prescribed asparaginase therapy. Preliminary pharmacokinetic data from the trial are expected in the second half of 2013.

"This important clinical trial underscores our commitment to those patients with ALL who require treatment with Erwinaze," noted Jeffrey Tobias, MD, executive vice president of research and development, and chief medical officer of Jazz Pharmaceuticals. "It also reflects our strategy of supporting our core growth products by investment in patient-centric initiatives."

About Acute Lymphoblastic Leukemia (ALL)
Acute lymphoblastic leukemia affects approximately 6,000 Americans, 60 percent of whom are children. ALL is the most common form of childhood cancer, with the peak incidence between two and five years of age. ALL has a 90 percent survival rate with treatment including asparaginase-based regimens, but progresses quickly if left untreated. A majority of asparaginase treatments derive from *E. coli;* however, approximately 15 to 20 percent of ALL patients develop hypersensitivity to *E. coli*-derived asparaginase regimens. Erwinaze asparaginase-based therapy plays a critical role for patients with no other treatment options.

About Jazz Pharmaceuticals
Jazz Pharmaceuticals plc is a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing innovative products that address unmet medical needs. The company has a diverse portfolio of products in the areas of narcolepsy, oncology, pain and psychiatry. The company's U.S. marketed products in these areas include: Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Prialt® (ziconotide) intrathecal infusion, Luvox CR® (fluvoxamine maleate), FazaClo® (clozapine, USP) HD and FazaClo LD. Outside of the U.S., Jazz Pharmaceuticals also has a number of products marketed by its international division, EUSA Pharma.

"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 enrollment and data collection in the Erwinaze IV administration trial and the timing thereof, the potential for future patient benefit from IV administration of Erwinaze, future product growth and investment and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. 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, risks related to the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval, including the risks that the results from the clinical trial may be negative or inconclusive, which could preclude FDA approval of IV administration of Erwinaze and could result in adverse regulatory action related to the company's current Erwinaze commercial product, other risks related Jazz Pharmaceuticals' business, including dependence on sales of Xyrem® and the company's ability to maintain and increase sales of Xyrem and other products, including Erwinaze, and those other risks detailed from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals' filings and reports with the Securities and Exchange Commission (Commission File No. 001-33500), including in Jazz Pharmaceuticals' Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 and future filings and reports by the company. Jazz Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events or changes in its expectations.

SOURCE Jazz Pharmaceuticals plc

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