Jazz Pharmaceuticals Announces Presentation Of Largest Safety Trial To Date Of Patients Treated With Erwinaze®

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-- Data from Compassionate Use Protocol Presented at the 2012 American Society of Hematology Annual Meeting --

DUBLIN, Dec. 10, 2012 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that data from the largest safety trial to date of patients treated with Erwinaze® (asparaginase *Erwinia chrysanthemi*) have been presented at the American Society of Hematology Annual Meeting and Exposition taking place in Atlanta, Georgia. The poster, titled "L-Asparaginase (L-ASP) Related Toxicities with Asparaginase *Erwinia Chrysanthemi* in a Large Compassionate Use Protocol," was presented by Paul V. Plourde, M.D., senior vice president of clinical oncology at Jazz Pharmaceuticals.

The poster presentation is based on results of a compassionate use protocol in patients who received Erwinaze as part of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia who developed a hypersensitivity to *E.coli*-derived asparaginase. The poster summarizes the safety results in 940 patients at participating U.S. oncology treatment centers between February 2006 and November 2011, when Erwinaze was available under a compassionate use protocol prior to its approval by the U.S. Food and Drug Administration in November 2011. The trial includes additional follow up data that further describe the incidence of adverse events associated with Erwinaze treatment, which are consistent with the known safety profile of Erwinaze.

"The extensive information collected in this study provides important information that further evaluates the safety profile of Erwinaze," stated Jeffrey Tobias, MD, executive vice president of research and development and chief medical officer of Jazz Pharmaceuticals. "This additional information may help physicians as they make important treatment decisions related to Erwinaze."

About Erwinaze: Indication and Important Safety Information

Erwinaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to *E.coli*-derived asparaginase. Erwinaze was originally discovered by the UK Health Protection Agency. Erwinaze was approved by the U.S. Food and Drug Administration in November 2011.

Erwinaze is contraindicated in patients with a history of serious hypersensitivity to Erwinaze, including anaphylaxis; history of serious pancreatitis, thrombosis or hemorrhage with prior L-asparaginase therapy. Discontinue if serious hypersensitivity, including anaphylaxis, or severe or hemorrhagic pancreatitis occur. Monitor glucose at baseline and periodically during treatment since intolerance may not be reversible. With thrombosis and hemorrhage, discontinue until resolved. Use in pregnant women only if clearly needed. Do not use in lactating women. The most common adverse reactions (≥ 1%) are serious hypersensitivity, including anaphylaxis, pancreatitis, abnormal transaminases, coagulation abnormalities, nausea, vomiting, and hyperglycemia.

Please see full Prescribing Information at www.erwinaze.com.

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 can be life-threatening and 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.

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 future treatment decisions involving the potential use of Erwinaze 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 and uncertainties associated with effectively commercializing Erwinaze, risks related to market acceptance of Erwinaze by physicians and the medical community, 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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