Jazz Pharmaceuticals Receives FDA Approval For Intravenous Administration Of Erwinaze® (asparaginase Erwinia chrysanthemi)

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Expanded U.S. Labeling Offers an Alternative Method to Administer Erwinaze to Patients with ALL

DUBLIN, Dec. 19, 2014 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the U.S. Food and Drug Administration (FDA) approved the intravenous administration of Erwinaze® (asparaginase *Erwinia chrysanthemi*). 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[1].

"Administration of Erwinaze through an intravenous infusion provides physicians another option for patients, including those who cannot tolerate intramuscular injections," said Jeffrey Tobias, M.D., executive vice president, research and development and chief medical officer of Jazz Pharmaceuticals plc. "Gaining FDA approval of this expanded label for Erwinaze reflects our continued commitment to improving patients' lives."

Prior to this approval, the only approved route of administration for Erwinaze was through intramuscular injection. With the expanded label, the formulation of Erwinaze currently on the market may now be administered to patients by either intravenous infusion or intramuscular injection. The updated product label provides data and information to help physicians understand the different administration options and determine which route of administration is most appropriate for their patients.

The FDA approval was based on a pharmacokinetic study of intravenous asparaginase *Erwinia chrysanthemi* following hypersensitivity to *E coli*-derived asparaginase. The intravenous administration trial was conducted at 10 centers in the U.S. and recruited a total of 30 patients, of which 24 patients were evaluable for the primary endpoint, which was the proportion of patients having an asparaginase activity level of greater than 0.1 IU/mL 48 hours after dosing[1, 2].

About Erwinaze

Erwinaze® (asparaginase *Erwinia chrysanthemi*) is currently approved in the U.S. for administration via intramuscular injection or via intravenous infusion in conjunction with chemotherapy. It 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[1]. Erwinaze is derived from the bacterium *Erwinia chrysanthemi* and is therefore immunologically distinct from *E. coli*-derived asparaginase and suitable for patients with hypersensitivity to *E. coli*-derived treatments[3]. Outside of the U.S., Erwinaze is sold under the name Erwinase®. Please consult local labeling for product information specific to your country.

Erwinaze is contraindicated in patients with a history of serious hypersensitivity reactions to Erwinaze, including anaphylaxis; or where serious pancreatitis, serious thrombosis or serious hemorrhagic events occurred with prior L-asparaginase therapy. Discontinue Erwinaze if serious hypersensitivity, including anaphylaxis, or severe or hemorrhagic pancreatitis occurs and initiate appropriate therapy. Administer in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis. Glucose intolerance has been reported which, in some cases may be irreversible. Discontinue Erwinaze if a serious thrombotic or hemorrhagic event occurs until symptoms resolve.

The most common adverse reactions (incidence 1% or greater) with Erwinaze treatment are systemic hypersensitivity, hyperglycemia, abnormal transaminases, fever, pancreatitis, local reactions, vomiting, nausea, thrombosis, hyperbilirubinemia, abdominal pain/discomfort and diarrhea. To see full prescribing information, visit www.erwinaze.com

About ALL

Acute lymphoblastic leukemia (ALL) is a cancer that affects the white blood cells. Approximately 5,000-6,000 new patients are diagnosed in the U.S. per year[4]. ALL is the most common cancer in children[5]. While treatment outcomes in adult ALL have remained largely unchanged, treatment outcomes have significantly improved in children, with 5-year survival rates over 80%[4]. Asparaginase treatment is recommended as an important component of a multi-agent chemotherapy regimen in ALL[6].

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing differentiated products that address unmet medical needs. The company has a diverse portfolio of products and/or product candidates in the areas of sleep, hematology/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, Versacloz® (clozapine) oral suspension, FazaClo® (clozapine, USP) HD and FazaClo LD. Jazz Pharmaceuticals also has a number of products marketed outside the U.S., including Erwinase® and Defitelio® (defibrotide). For more information, please visit www.jazzpharmaceuticals.com

References

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5. Leukemia & Lymphoma Society, www.lls.org
6. Shinnick SE, et al. *J Pediatr Oncol Nurs*. 2013;30(2):63-77

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Investors: Kathee Littrell, Vice President, Investor Relations, Ireland, +353 1 634 7887, U.S., +1 650 496 2717, or Media: Laurie Hurley, Vice President, Corporate Affairs, Ireland, +353 1 634 7894, U.S., +1 650 496 2796