



Jazz Pharmaceuticals Completes Acquisition Of Rights To Defibrotide In The Americas From Sigma-Tau Pharmaceuticals, Inc.

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Jazz Pharmaceuticals owns worldwide rights to defibrotide

DUBLIN, Aug. 5, 2014 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced the closing of its acquisition of rights to defibrotide in the United States (U.S.) and all other countries in the Americas from Sigma-Tau Pharmaceuticals, Inc. (Sigma-Tau). Jazz Pharmaceuticals now owns worldwide rights to defibrotide.

Defibrotide is a novel product that is marketed by Jazz Pharmaceuticals in the European Union (EU) under the name Defitelio® for the treatment of severe hepatic veno-occlusive disease (VOD) in patients over one month of age undergoing hematopoietic stem cell transplantation (HSCT) therapy. In the U.S., Jazz Pharmaceuticals is working with the Food and Drug Administration (FDA) on the regulatory pathway for submission of a New Drug Application (NDA) for the potential approval of defibrotide to treat patients with severe VOD.

Under the previously-announced definitive agreement with Sigma-Tau, a wholly-owned subsidiary of Jazz Pharmaceuticals acquired the rights to defibrotide in the Americas for an upfront payment of \$75 million plus potential milestone payments of \$25 million upon the acceptance for filing by the FDA of the first NDA for defibrotide for VOD and up to an additional \$150 million based on the timing of potential FDA approval of defibrotide for VOD.

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.

"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 potential submission, acceptance for filing and potential approval of an NDA for defibrotide 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 the company's ability to successfully manage the risks associated with integrating defibrotide into the company's product portfolio; the possibility that Jazz Pharmaceuticals may fail to realize the anticipated benefits (commercial or otherwise) from the acquisition of the rights to defibrotide in the Americas from Sigma-Tau; the inherent uncertainty associated with the regulatory approval process, including the risks that Jazz Pharmaceuticals may be required to conduct additional time-consuming and costly clinical trials in order to obtain any regulatory approval of defibrotide in the U.S. and that Jazz Pharmaceuticals may otherwise be unable to obtain or maintain any regulatory approvals for defibrotide in the U.S.; the difficulty and uncertainty of pharmaceutical product development, including the timing and cost thereof; other risks related to future opportunities and plans; and those other risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 and future filings and reports by the company, including the Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. 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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