



Jazz Pharmaceuticals Announces That Patient Enrollment is Complete for the Phase 3 Study of JZP-110 Evaluating Excessive Sleepiness in Narcolepsy

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DUBLIN, Nov. 28, 2016 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that patient enrollment has been completed in its Phase 3 study evaluating JZP-110 in excessive sleepiness (ES) associated with narcolepsy.

"This is an important milestone in our JZP-110 Phase 3 program," said Karen Smith, M.D., Ph.D., global head of research and development and chief medical officer of Jazz Pharmaceuticals. "We expect to report the top-line results from our two Phase 3 studies evaluating ES in obstructive sleep apnea in the first quarter of 2017 and the top-line results from this Phase 3 narcolepsy study in the second quarter of 2017."

The Phase 3 narcolepsy study was a double-blind, placebo-controlled, multiple-center study evaluating the safety and efficacy of JZP-110 in the treatment of ES in adult patients with narcolepsy. The study enrolled 240 patients. The co-primary endpoints were the Maintenance of Wakefulness Test and the Epworth Sleepiness Scale. These are validated endpoints, commonly used in clinical trials, that measure the ability to stay awake and the severity of excessive sleepiness, respectively, in patients.

About JZP-110

JZP-110 is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) in late-stage development for treatment of ES in adult patients with narcolepsy or obstructive sleep apnea (OSA). Jazz Pharmaceuticals has worldwide development, manufacturing, and commercialization rights to JZP-110, excluding certain jurisdictions in Asia. JZP-110 has orphan drug designation in the United States for narcolepsy. The JZP-110 clinical program includes two Phase 3 studies evaluating ES in adult patients with OSA, one Phase 3 study evaluating ES in adult patients with narcolepsy and an open label long-term safety study. Patient enrollment in the OSA and narcolepsy studies is complete and enrollment in the open-label study is ongoing.

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Defitelio® (defibrotide sodium) in the U.S. and markets Erwinaze® and Defitelio® (defibrotide) in countries outside the U.S. 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 expected timing of reporting top-line results from the company's Phase 3 OSA and narcolepsy studies, and other statements that are not historical facts. These forward-looking statements are based on the company's current plans, objectives, estimates, expectations and intentions, 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 difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and other risks and uncertainties affecting the company and its development programs, including those described 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 company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 and future filings and reports by the company. Other risks and uncertainties of which the company is not currently aware may also affect the company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by the company on its website or otherwise. The company undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.



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SOURCE Jazz Pharmaceuticals plc

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