Jazz Pharmaceuticals Announces First Patient Enrolled in Phase 2 Clinical Study Evaluating JZP-110 for Excessive Sleepiness in Parkinson's Disease

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DUBLIN, Feb. 8, 2017 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the first patient has been enrolled in a Phase 2 clinical study evaluating JZP-110, a selective dopamine and norepinephrine reuptake inhibitor, as a potential treatment for excessive sleepiness (ES) in adult patients with Parkinson's disease. The clinical study will be conducted across approximately 15 centers in the United States.

"Excessive sleepiness is a debilitating symptom of Parkinson's disease, and we are interested in determining whether the wake-promoting effects of JZP-110 could be beneficial in this patient population," said Karen Smith, M.D., Ph.D., global head of research and development and chief medical officer of Jazz Pharmaceuticals. "The initiation of this study is another step forward in our development program for JZP-110 and our efforts to develop new treatment options for people with sleep disorders."

The Phase 2 study is a double-blind, placebo-controlled, randomized, multicenter, crossover study evaluating the safety, efficacy and pharmacokinetics of JZP-110 in adult patients with Parkinson's disease and ES. The study is expected to enroll approximately 50 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 Phase 3 clinical program includes two studies evaluating ES in adult patients with OSA, one 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 ES in Parkinson's Disease Parkinson's disease (PD) is a chronic neurodegenerative brain disorder with motor and non-motor symptoms affecting as many as one million people in the United States.[1] Excessive sleepiness (ES) is a common non-motor symptom of PD, affecting 20-50% of patients.[2-4] ES contributes significantly to the disease burden of PD, and is a major cause of decreased quality of life in patients.[5,6] ES also poses significant safety risks for patients with PD and may lead to an increased risk for falls and motor vehicle accidents.[7,8] There are currently no FDA-approved drugs for the treatment of ES in PD.

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 Erwinase® 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 JZP-110 as a potential treatment for excessive sleepiness (ES) in adult patients with Parkinson's disease 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 of pharmaceutical product development and clinical success thereof, the uncertainty of regulatory approval, 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.

References:

1 Parkinson's Disease Foundation, http://www.pdf.org/en/parkinson_statistics 2 Arnulf I. Excessive daytime sleepiness in parkinsonism. Sleep Medicine Revews (2005) 9, 185-200. 3 Knie B. Excessive daytime sleepiness in patients with Parkinson's Disease. CNS Drugs 2011; 25 (3): 203-212 4 Salawu F and Olokoba A. Excessive daytime sleepiness and unintended sleep episodes associated with Parkinson's Disease. Oman Medical Journal 2015; 30 (1): 3-10. 5 Ondo W. Daytime sleepiness and other sleep disorders in Parkinson's Disease. Neurology 2001; 57: 1392-1396. 6 Weerkamp N. Nonmotor symptoms in nursing home residents with Parkinson's Disease: prevalence and effect on quality of life. J Am Geriatr Soc 2013; 61: 1714-1721. 7 Meindorfner C. Driving in Parkinson's Disease: mobility, accidents, and sudden onset of sleep at the wheel. Movement Disorders 2005; 20 (7): 832-842. 8 Spindler M. Daytime sleepiness is associated with falls in Parkinson's disease. J. Parkinson's Dis. 2013; 3(3): 387-391.

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