Jazz Pharmaceuticals Announces That Patient Enrollment is Complete for the Phase 3 Studies of JZP-110 Evaluating Excessive Sleepiness in Obstructive Sleep Apnea

September 26, 2016

DUBLIN, Sept. 26, 2016 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that patient enrollment has been completed for its two Phase 3 studies evaluating JZP-110 in excessive sleepiness (ES) associated with obstructive sleep apnea (OSA).

"We are pleased to have reached this important milestone in our Phase 3 program," said Karen Smith, M.D., Ph.D., global head of research and development and chief medical officer of Jazz Pharmaceuticals. "We look forward to reporting the top-line results from the two OSA studies in the first quarter of 2017."

The two Phase 3 OSA studies enrolled approximately 654 patients. Both studies were double-blind, placebo-controlled, multiple-center studies evaluating the safety and efficacy of JZP-110 in the treatment of ES in adult patients with OSA. Study 14-003 evaluated four doses of JZP-110 or placebo for a 12-week period and study 14-004 was a six-week, flexible-dose, randomized withdrawal study. The studies have co-primary endpoints of the Epworth Sleepiness Scale (ESS) and the Maintenance of Wakefulness Test (MWT). These are validated endpoints, used in clinical practice, to measure the severity of excessive sleepiness and ability to stay awake 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 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 additional studies: the Phase 3 safety and efficacy study evaluating JZP-110 for the treatment of ES in narcolepsy and the open label long-term safety study. Enrollment in these studies 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 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 the expected timing of reporting top-line results from the company's Phase 3 OSA 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 June 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

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