Jazz Pharmaceuticals Announces First Patients Enrolled in Phase 3 Clinical Development Program Evaluating JZP-110 as a Potential Treatment of Excessive Daytime Sleepiness (EDS) Associated with Narcolepsy or with Obstructive Sleep Apnea (OSA)

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Jazz Advances its Clinical Development Program in Sleep and Narcolepsy

DUBLIN, June 8, 2015 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) announced today that the first patients have been enrolled in a Phase 3 clinical development program evaluating the safety and efficacy of its investigational drug candidate, JZP-110, as a wake-promoting agent in the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy or with obstructive sleep apnea (OSA). The JZP-110 clinical development program includes three Phase 3 studies being conducted in the United States (U.S.), Canada and the European Union (EU). The program also includes an open-label extension study to evaluate the long-term safety of JZP-110.

"This R&D milestone represents another step forward in Jazz's development program for JZP-110 and in our efforts to develop new treatment options for people with narcolepsy and with other sleep disorders," said Karen Smith, M.D., Ph.D., Global Head of Research and Development and Chief Medical Officer of Jazz Pharmaceuticals. "We are excited to advance JZP-110 into Phase 3 clinical development to further evaluate it as a wake-promoting agent, and we look forward to continued collaboration with the FDA and key thought leaders as we advance development of JZP-110."

Clinical Program Study Design

Approximately 880 patients in the aggregate are expected to be enrolled in the three Phase 3 studies to be conducted across 67 medical centers in the U.S., Canada and EU. The co-primary endpoints for all three Phase 3 clinical studies -- the Maintenance of Wakefulness Test (MWT) and the Epworth Sleepiness Scale (ESS) -- will measure patients' improvement in ability to stay awake and in sleepiness. Up to 450 patients are expected to be enrolled in the open-label, long-term safety extension study. For more information on the clinical trials, go to www.clinicaltrials.gov

- Study 14-002: A 12-week, double-blind, randomized, placebo-controlled, multi-center, four-treatment parallel group study of the safety and efficacy of JZP-110 in the treatment of EDS in adult patients with narcolepsy.
- Study 14-003: A 12-week double-blind, placebo-controlled, randomized, multi-center study of the safety and efficacy of JZP-110 in the treatment of EDS in adult patients with OSA.
- Study 14-004: A six-week, double-blind, placebo-controlled, randomized-withdrawal, multi-center study of the safety and efficacy of JZP-110 in the treatment of EDS in adult patients with OSA.
- Study 14-005: A long-term (52 week) open-label safety and maintenance of efficacy study of JZP-110 in the treatment of EDS in adult patients with narcolepsy or with OSA to assess the long-term safety and maintenance of efficacy in patients.

"People living with EDS associated with narcolepsy and patients with unresolved EDS in OSA often experience an inadequate response to, or have difficulty tolerating, their currently prescribed wake-promoting treatment, underscoring the need for new treatment options. The Phase 3 clinical development program will further define the clinical profile of JZP-110 as a potential alternative for these patients," said Richard Bogan, M.D., Associate Clinical Professor at the University of South Carolina School of Medicine and Chief Medical Officer of SleepMed Inc.

About JZP-110

JZP-110 is a late-stage investigational wake-promoting agent being developed as a treatment for EDS in adult patients with narcolepsy or with OSA. Jazz has worldwide development, manufacturing, and commercialization rights to JZP-110, excluding certain jurisdictions in Asia. The proof of concept for moving into the Phase 3 clinical development program was based on consistent results from two Phase 2 clinical studies evaluating JZP-110 as a potential new treatment of EDS in adult patients with narcolepsy. The data from the Phase 2b study was previously presented at a late breaker session during the 28th Annual Meeting of the Associated Professional Sleep Societies (APSS) on June 2, 2014.

About EDS

EDS is a primary symptom for patients with narcolepsy and is common in patients with OSA. Despite current therapies, many patients with narcolepsy or with OSA continue to experience EDS.[1, 2] Narcolepsy is a chronic, debilitating, condition that impacts approximately 160,000 people in the United States.[3] Less than half of the estimated 160,000 people living with narcolepsy in the U.S. have been properly diagnosed and approximately 50,000 of those who are diagnosed receive wake-promoting therapies. OSA is a serious chronic sleep disorder in which breathing repeatedly stops and starts during sleep. In the U.S., approximately 500,000 patients receive wake-promoting therapies for EDS associated with OSA.[4]

About Jazz Pharmaceuticals plc

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/or product candidates with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase *Erwinia chrysanthemi*) in the U.S., and markets Erwinase® and Defitelio® (defibrotide) in Europe and other 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 Jazz Pharmaceuticals' clinical development program involving JZP-110, the potential of JZP-110 as a wake-promoting agent and to treat EDS associated with narcolepsy or with OSA, Jazz Pharmaceuticals' ability to deliver new treatment options to patients, 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 difficulty and uncertainty of pharmaceutical product development, the uncertainty of clinical success, such as the risk that results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, the uncertainty of regulatory approval, 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, 2015 and future filings and reports by the company. 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.

References:

1. *NA Antic et al. The effect of CPAP in normalizing daytime sleepiness, quality of life, and neurocognitive function in patients with moderate to severe OSA. Sleep. 2011: Jan 1; 34(1):111-9.*
2. *C Guilleminault et al. Problems associated with switch to modafinil – a novel alerting agent in narcolepsy. Eur J Neurol. 2000 Jul; 7(4):381-4.*
3. *CR Baumann et al. Narcolepsy: Pathophysiology, Diagnosis, and Treatment. Springer: NY 2011.*
4. *SH Launois et al. Current Opinion in Pulmonary Medicine. 19(6):601-608, November 2013.*

SOURCE Jazz Pharmaceuticals plc

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