Jazz Pharmaceuticals Receives New PDUFA Goal Date for Solriamfetol for Excessive Daytime Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea

December 21, 2018

DUBLIN, Dec. 21, 2018 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the U.S. Food and Drug Administration (FDA) has extended the review period for its new drug application (NDA) for solriamfetol as a treatment to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA). The updated Prescription Drug User Fee Act (PDUFA) goal date is now March 20, 2019.

The FDA determined that an NDA submission made by Jazz during the course of discussions regarding draft labeling for solriamfetol constitutes a major amendment to the NDA, resulting in a three-month extension of the PDUFA goal date to provide time for a full review of the submission.

"We appreciate the opportunity to work with the FDA to complete the review process as soon as possible," said Jed Black, M.D., senior vice president, Sleep and CNS Medicine at Jazz Pharmaceuticals and adjunct professor, Stanford University Medical Center, Stanford Center for Sleep Sciences and Medicine. "We are committed to addressing unmet needs in sleep medicine and look forward to offering solriamfetol as a meaningful treatment option for patients living with excessive daytime sleepiness associated with narcolepsy or OSA."

Jazz Pharmaceuticals will host a brief investor conference call and live audio webcast on Friday, December 21, 2018 at 8:30 a.m. EST (1:30 p.m. GMT) to discuss the PDUFA goal date extension and a business update. The live webcast may be accessed from the Investors section of the company's website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. Investors may participate in the conference call by dialing +1 855 353 7924 in the U.S., or +1 503 343 6056 outside the U.S., and entering passcode 6766127.

A replay of the conference call will be available through December 28, 2018 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 6766127. An archived version of the webcast will be available for at least one week in the Investors section of the company's website at www.jazzpharmaceuticals.com.

About Solriamfetol
Solriamfetol is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) in development for treatment of excessive sleepiness in adult patients with narcolepsy, OSA, and Parkinson's disease. In 2014, Jazz Pharmaceuticals acquired a license to develop and commercialize solriamfetol from Aerial Biopharma. Jazz Pharmaceuticals has worldwide development, manufacturing, and commercialization rights to solriamfetol, excluding certain jurisdictions in Asia. SK Biopharmaceuticals, the discoverer of the compound (also known as SKL-N05), maintains rights in 12 Asian markets, including Korea, China and Japan. Solriamfetol has orphan drug designation in the United States for narcolepsy.

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 product candidates with a focus in the areas of sleep and hematology/oncology. In these therapeutic areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Defitelio® (defibrotide sodium) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinase®, Defitelio® (defibrotide) and Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion in countries outside the U.S. For country-specific product information, please visit http://www.jazzpharmaceuticals.com/products. For more information, please visit http://www.jazzpharmaceuticals.com/ and follow us on Twitter at @JazzPharma.

"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 company offering solriamfetol as a meaningful treatment option for patients with excessive daytime sleepiness associated with narcolepsy or OSA, 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 time-consuming and uncertain regulatory approval process, including the risk that the solriamfetol NDA may not be approved by the FDA on the anticipated timeline or at all, and that the label for solriamfetol may be more restrictive than anticipated; and the manufacture and effective commercialization of solriamfetol; and other risks and uncertainties affecting the company, 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, 2018 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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