Jazz Pharmaceuticals Announces FDA Acceptance of NDA for Solriamfetol (JZP-110) for Excessive Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea

March 2, 2018

DUBLIN, March 2, 2018 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing with standard review the company's New Drug Application (NDA) seeking marketing approval for solriamfetol, an investigational medicine for the treatment of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA). The Prescription Drug User Fee Act (PDUFA) goal date for an FDA decision is December 20, 2018.

"We believe this medicine will provide a meaningful option for patients living with excessive sleepiness due to narcolepsy or OSA, and we look forward to working with the FDA during the review process for solriamfetol," said Karen Smith, M.D., Ph.D., executive vice president, research and development and chief medical officer at Jazz Pharmaceuticals. "Jazz continues to invest in ongoing research, education and advocacy on behalf of the sleep community, including studying solriamfetol for the treatment of excessive sleepiness in other areas of unmet need, such as Parkinson's disease."

The solriamfetol Phase 3 clinical program includes one study evaluating excessive sleepiness in adult patients with narcolepsy (TONES 2), two studies evaluating excessive sleepiness in adult patients with OSA (TONES 3 and TONES 4), and an open-label, long-term safety and maintenance of efficacy study (TONES 5) in the treatment of excessive sleepiness in patients with narcolepsy or OSA.

About OSA and Excessive Sleepiness
OSA is a prevalent disease (as high as 14% in men and 5% in women) with excessive sleepiness being a major presenting complaint in many cases.[1-2] Excessive sleepiness in OSA is associated with impairments in cognitive function, safety, productivity, interpersonal relationships, and overall quality of life. Positive Airway Pressure (PAP) therapy, with its most common form being Continuous Positive Airway Pressure (CPAP), has been shown to be an effective therapy for sleep-related airway obstruction, with frequent improvement in excessive sleepiness in many patients; however, not all patients tolerate CPAP therapy and among those who tolerate CPAP, usage is highly variable. It is estimated that excessive sleepiness persists in 13%–65% of people utilizing CPAP for OSA.[3-5]

About Narcolepsy
Narcolepsy is a debilitating neurological disorder characterized by excessive sleepiness, and the inability to regulate sleep-wake cycles normally.[6] It affects an estimated one in 2,000 people in the United States, with symptoms typically appearing in early adulthood. It is estimated that more than 50% of patients with narcolepsy have not been diagnosed.[7] Studies have shown it may take 10 years or more for people with narcolepsy to receive a correct diagnosis.[8] Excessive sleepiness is the primary symptom of narcolepsy and is present in all people with the disorder.[2] Excessive sleepiness is characterized by the inability to stay awake and alert during the day resulting in unplanned lapses into sleep or drowsiness.[2,7,9]

About Solriamfetol (JZP-110)
Solriamfetol (JZP-110) 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 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® and Defitelio® (defibrotide) in countries outside the U.S. For country-specific product information, please visit www.jazzpharmaceuticals.com/products. For more information, please visit 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 solriamfetol (JZP-110) as a potential treatment for excessive sleepiness in adult patients with narcolepsy or OSA, including the company's belief that solriamfetol will provide a meaningful option for patients with excessive sleepiness due to 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: pharmaceutical product development; the regulatory approval process, including the risk that the company is unable to obtain FDA approval for solriamfetol in a timely manner or at all; and the manufacture and effective commercialization of solriamfetol, 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 Annual Report on Form 10-K for the year ended December 31, 2017 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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