Jazz Pharmaceuticals Submits Marketing Authorization Application to European Medicines Agency for Solriamfetol as a Treatment to Improve Wakefulness and Reduce Excessive Daytime Sleepiness in Adult Patients with Narcolepsy or Obstructive Sleep Apnea

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DUBLIN, Nov. 9, 2018 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency for solriamfetol, a selective dopamine and norepinephrine reuptake inhibitor, as a treatment to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with narcolepsy (with or without cataplexy) or obstructive sleep apnea (OSA).

"Excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea can be debilitating for patients and challenging for the medical community to diagnose and treat," 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. "Jazz is committed to addressing unmet needs in sleep medicine by delivering meaningful treatment options."

"In the European Union, there is no approved treatment for people with excessive daytime sleepiness associated with obstructive sleep apnea, and people with excessive daytime sleepiness due to narcolepsy may benefit from the availability of new treatment options," said Professor Yves Dauvilliers, M.D., Ph.D. Head of Sleep and Wake Disorders at the University Hospital of Montpellier, France. "As the sleep medical community improves its understanding and diagnosis of these conditions, it is increasingly important that patients have multiple treatment options available to help them manage their condition more effectively."

Jazz has studied solriamfetol extensively via the Treatment of OSA and Narcolepsy Excessive Sleepiness (TONES) Phase 3 program, which was comprised of four studies that evaluated:

- solriamfetol in EDS in adult patients with narcolepsy (TONES 2) or OSA (TONES 3 and TONES 4), and
- the long-term safety and maintenance of efficacy for solriamfetol as a treatment for EDS in patients with narcolepsy or OSA (TONES 5).

Jazz presented long-term safety and maintenance of efficacy results from the TONES 5 Phase 3 study of solriamfetol in adult patients with EDS associated with OSA or with narcolepsy at the annual meeting of the Associated Professional Sleep Societies (APSS) in June 2018. TONES 2, 3 and 4 data were presented at APSS in 2017.

Notes to Editors

About Obstructive Sleep Apnea and Excessive Daytime Sleepiness
In the EU, obstructive sleep apnea (OSA) is a prevalent disease (as high as 14% in men and 7% in women) in which excessive daytime sleepiness is a major presenting complaint in many cases.[1] Excessive daytime 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 daytime sleepiness in many patients; however, pathological sleepiness often continues despite primary treatment of the airway obstruction with PAP or other therapies.[2-5] It is estimated that excessive daytime sleepiness persists in one in three people utilizing CPAP for OSA.[6]

About Narcolepsy and Excessive Daytime Sleepiness
Narcolepsy is a debilitating neurological disorder characterized by excessive daytime sleepiness, and the inability to regulate sleep-wake cycles normally.[7] It affects an estimated one in 2,000 people in the EU,[8] with symptoms typically appearing in early adulthood. Globally, it is estimated that more than 50% of patients with narcolepsy have not been diagnosed.[9] Studies have shown it may take 10 years or more for people with narcolepsy to receive a correct diagnosis.[10] Excessive daytime sleepiness is the primary symptom of narcolepsy and is present in all people with the disorder.[11] Excessive daytime sleepiness is characterized by the inability to stay awake and alert during the day, resulting in unplanned drowsiness or lapses into sleep.[7, 11,12]

About Solriamfetol
Solriamfetol is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) in development for treatment of EDS 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, maintains rights in 12 Asian markets, including Korea, China and Japan. Solriamfetol has orphan drug designation in the United States for narcolepsy. In March 2018, Jazz announced that the U.S. Food and Drug Administration (FDA) accepted for filing with standard review the company's New Drug Application (NDA) seeking marketing approval for solriamfetol for the treatment of ES in adult patients with narcolepsy or OSA. The Prescription Drug User Fee Act (PDUFA) goal date for an FDA decision is December 20, 2018.

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.

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