National Institute for Health and Care Excellence (NICE) Issues Positive Guidance for Jazz Pharmaceuticals' Sunosi® (solriamfetol) for the Treatment of Adults with Excessive Daytime Sleepiness (EDS) Caused by Narcolepsy

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Sunosi® (solriamfetol) is the first treatment for adults with excessive daytime sleepiness (EDS) caused by narcolepsy to receive a positive recommendation from NICE

Pivotal Phase 3 Treatment of Obstructive sleep apnoea and Narcolepsy Excessive Sleepiness (TONES) studies demonstrated the clinical effectiveness and safety profile of solriamfetol in people with narcolepsy. TONES 5 demonstrated that the clinical effects of solriamfetol were maintained long term

Positive NICE recommendation means solriamfetol will be available in England and Wales to adults with EDS caused by narcolepsy for whom modafinil and either dexamfetamine or methylphenidate have not worked well enough or are not suitable

OXFORD, England, Nov. 18, 2021 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the National Institute for Health and Care Excellence (NICE) has issued a positive Final Appraisal Document (FAD) recommending Sunosi® (solriamfetol) for adults with excessive daytime sleepiness (EDS) caused by narcolepsy.1 Solriamfetol is recommended as an option for treating EDS in adults with narcolepsy with or without cataplexy. This is only if modafinil and either dexamfetamine or methylphenidate* have not worked well enough or are not suitable.[1]

EDS is a defining clinical symptom of narcolepsy and is usually the first symptom to appear.[2,3] EDS can interfere with every aspect of a person's life including their physical and mental health, relationships, employment, career, daily activities, social interactions and family life.[4]

"This decision increases treatment options for people with narcolepsy, creating more opportunity for them to access effective treatment sooner. This is a key aim of Narcolepsy UK's Charter as access to effective treatment can dramatically improve multiple aspects of people's lives including their education, working, family and social life," said Matt O'Neill, chair of trustees at Narcolepsy UK. "We welcome NICE's decision and the committee's recognition of the need for pragmatism when faced with limited evidence with which to compare the cost-effectiveness of treatments for rare diseases such as narcolepsy."

Dr Paul Reading, consultant neurologist at South Tees National Health Service (NHS) Foundation Trust, said: "NICE's recommendation to offer routine NHS access to solriamfetol gives clinicians a much-needed additional treatment option in the management of EDS in narcolepsy for adult patients. Solriamfetol is a once-daily, effective therapy with an interesting mechanism of action as a dual-acting dopamine and noradrenaline reuptake inhibitor."

Commenting on the recommendation, Simon Newton, general manager, UK and Ireland, at Jazz Pharmaceuticals, said: "We are delighted that by recommending Sunosi®, NICE has given a green light to the NHS to fund a treatment for EDS in adults with narcolepsy. NICE's recommendation marks an important milestone in our commitment to offer life-changing medicines that address unmet needs for people living with chronic, and often highly-debilitating, sleep disorders."

About Narcolepsy

Narcolepsy is a chronic, debilitating neurological disorder characterised by excessive daytime sleepiness (EDS) and an inability to regulate sleep-wake cycles normally.[5] An estimated 30,000 people in the UK have narcolepsy.[6,7] Patients with EDS due to narcolepsy experience sleep attacks and, despite fighting the urge to sleep, may unintentionally fall asleep for short periods.[8,9] These sleep attacks may happen at inappropriate or potentially dangerous times such as during driving, cycling, eating, or mid-conversation.[10]

There is no cure for narcolepsy, therefore this EDS is lifelong and has a substantial negative impact on a person's ability to function psychologically, socially and professionally.[6] Early access to effective treatment can transform lives and reduce the impact of narcolepsy on a person's physical and mental health.[6]

About Sunosi® (solriamfetol)

Once-daily Sunosi® (solriamfetol) is indicated to improve wakefulness and reduce EDS in adult patients with narcolepsy with the approved doses of 75 mg or 150 mg daily. The NICE recommendation for solriamfetol is based on data from three studies in the Treatment of Obstructive sleep apnoea and Narcolepsy Excessive Sleepiness (TONES) clinical trial programme.[1,11,12,13] The clinical trial programme for solriamfetol evaluated over 900 adults with EDS associated with narcolepsy or obstructive sleep apnoea (OSA). Solriamfetol demonstrated its superiority relative to placebo and was shown to maintain its effect after six months of use.[11,12,13,14]

For a full list of side effects and information on dosage and administration, contraindications and other precautions when using solriamfetol, please refer to the Summary of Product Characteristics, included with this press release, for further information: https://www.medicines.org.uk/emc/product/11016/smpc
https://www.medicines.org.uk/emc/product/11017/smpc

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (NASDAQ: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases—often with limited or no therapeutic options.

We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries.

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* Methylphenidate is not licensed for the treatment of EDS due to narcolepsy in the UK

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