Public Comments for Sunosi® for West Virginia DUR Board Meeting November 15th, 2023

Thank you for the opportunity to provide information about Sunosi® (solriamfetol). My name is Samantha Floam, DMD, and I am Director, Medical Affairs, at Axsome Therapeutics. I am here today to request that patient access to Sunosi be maintained and step therapy requirements reduced.

Sunosi is indicated to improve wakefulness in adults with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi is not indicated to treat the underlying airway obstruction in OSA. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. The approved dose range for Sunosi is 75 mg to 150 mg once daily in patients with narcolepsy and 37.5 mg to 150 mg in patients with OSA.[1]

While the exact mechanism of action in humans is unknown, the effects of Sunosi are thought to be mediated through its function as a selective dopamine and norepinephrine reuptake inhibitor (DNRI).[1] Sunosi is a schedule IV medication, defined by the DEA as having a low potential for abuse and dependence, and is a wake-promoting agent, not a stimulant.[1]

Sunosi was approved based on 4 placebo-controlled phase 3 clinical studies of patients with EDS associated with narcolepsy or OSA.[1] In these studies, participants treated with Sunosi exhibited robust improvements in objective wakefulness, subjective sleepiness, and patient-reported changes in their condition compared to placebo.[1-5]

- In TONES 2, a 12-week study of 239 participants with EDS associated with narcolepsy, participants treated with 150 mg Sunosi exhibited improvements in objective wakefulness and patient-reported sleepiness as early as week 1 that was maintained through week 12. At week 12, wakefulness was improved through 9 hours post dose.[1,2]

- In TONES 3, a 12-week study of 476 patients with EDS associated with OSA, participants treated with Sunosi exhibited substantial improvements in objective wakefulness and patient-reported sleepiness as early as week 1 that was maintained through week 12. Over 70% of participants achieved normative levels of sleepiness. Improvements in wakefulness lasted through 9 hours and up to 90% of patients reported improvements in their condition with the 150 mg dose at week 12.[1,3]

- In TONES 4, a 6-week randomized withdrawal study of 174 participants with EDS associated with OSA, participants who switched to placebo worsened on measures of wakefulness and sleepiness compared to participants who continued on Sunosi.[1,4]

- In TONES 5, a 1-year open label safety and maintenance of efficacy study of 638 participants with narcolepsy or OSA, patients exhibited improvements in sleepiness which were maintained through 52 weeks.[1,5]

- The most common adverse events reported with Sunosi in 12-week clinical studies in OSA and narcolepsy were headache, nausea, decreased appetite, anxiety, and insomnia.[1] No new safety concerns emerged in the one-year open label study.[5] Sunosi is associated with small, dose dependent increases in blood pressure and heart rate.[1] Please consult the Sunosi prescribing information <https://www.sunosihcp.com/assets/files/sunosi.en.uspi.pdf> for additional important safety information.

Axsome Therapeutics, Inc.
One World Trade Center, 22nd Floor, New York, NY 10007

A recently published, real-world analysis of Sunosi use in patients with narcolepsy in Germany found efficacy similar to that reported in the phase 3 clinical trials. Improvements were seen regardless of whether patients switched to Sunosi from another narcolepsy medication, added to an existing treatment regimen, or were new to therapy. Similarly, 90% of patients in this study reported improvement in their condition and the safety profile was similar to that observed in clinical studies.[6]

While no head-to-head studies have been conducted comparing Sunosi to other wake-promoting agents, an indirect treatment comparison of clinical trial data for Sunosi, modafinil, and armodafinil in patients with EDS in OSA has been published suggesting favorable performance and a comparable safety profile for 150 mg Sunosi compared to other WPAs.[7] A second, recently published, independent, network meta-analysis of 14 clinical trials concluded that solriamfetol, armodafinil–modafinil, and pitolisant reduced daytime sleepiness for patients with OSA with solriamfetol having superior effectiveness.[8]

In clinical studies of patients with OSA, Sunosi use was not associated with reductions in CPAP use.[9,10] Pharmacokinetic drug interactions with concomitant medications are not expected to occur with Sunosi.[1]

There may be potential for pharmacodynamic drug interactions with medications that raise blood pressure or drugs that interact with the dopamine system. It is advised that patients' blood pressure is periodically monitored throughout treatment and that caution is used in those with a history of psychotic or bipolar disorders. The use of monoamine oxidase inhibitors within 14 days of Sunosi administration is contraindicated.[1]

The American Academy of Sleep Medicine's clinical practice guideline on the treatment of central disorders of hypersomnolence provides a strong recommendation for use of Sunosi in the treatment of narcolepsy in adults based on improvements in clinical outcomes of EDS, disease severity, and quality of life.[11]

In summary, Sunosi is the first and only DNRI for the treatment of EDS associated with OSA or narcolepsy. It exhibits robust, long-lasting improvements in wakefulness, has a well-established safety profile, and is supported by emerging evidence of real-world effectiveness and safety. We request that patient access to Sunosi be maintained and step therapy requirements limited.

References:

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