Sunosi® Public Testimony for Nevada P&T Committee Meeting Sept 28, 2023

Thank you for the opportunity to provide information about Sunosi® (solriamfetol). My name is Charlotte Wincott, and I am Associate Director of Medical Affairs at Axsome Therapeutics.

I am here today to request that Sunosi be placed in the preferred position, removing the step edits in place to allow physicians the ability to exercise their clinical judgment for appropriate patients.

Sunosi is indicated for the treatment of excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi is not indicated to treat the underlying airway obstruction in OSA, and primary airway therapy should be continued with Sunosi.[1]

Sunosi's effects are thought to be mediated through its function as a selective dopamine and norepinephrine reuptake inhibitor.[1,2] 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.[1,3]

Sunosi was approved based on 4 placebo-controlled phase 3 clinical studies of patients with EDS due to narcolepsy or OSA.[4-7]

- In all studies, Sunosi resulted in robust improvements in objective measures of wakefulness as early as week 1 and maintained through week 12, with improved wakefulness lasting through 9 hours post-dose at week 12.[4,5]
- Sunosi improved patient-reported sleepiness within 1 week of initiating treatment, and these improvements were maintained through 1 year in an open label safety and maintenance of efficacy study. Over 70% of OSA patients achieved normative levels of sleepiness at week 12.[4,5,7]
- 78% to 90% of participants with narcolepsy or OSA reported improvement in their overall condition at week 12, and these improvements were maintained at 1 year. Similar results were found for clinician's assessment of overall condition.[4,5,7]

Additionally, in a phase 4 study, Sunosi demonstrated significant improvements in cognitive function in patients with EDS due to OSA.[8]

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. Sunosi is associated with small, dose dependent increases in blood pressure and heart rate. The use of MAOIs is contraindicated.[1]

While no head-to-head studies have been conducted, an independent meta-analysis of 14 clinical trials concluded that Sunosi, armodafinil–modafinil, and pitolisant reduced daytime sleepiness for patients with OSA with Sunosi having superior effectiveness.[9]

In summary, Sunosi exhibits robust, long-lasting improvements in wakefulness and has a well-established safety profile. We request respectfully that Sunosi be placed in the preferred position and that step therapy be removed to allow physicians the ability to exercise their clinical judgement for appropriate patients. Thank you very much for your consideration.

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