Effects of Solriamfetol on Cognitive Function in Participants With Cognitive Impairment Associated With Excessive Daytime Sleepiness in Obstructive Sleep Apnea: Results of the SHARP Study

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Introduction

• Excessive daytime sleepiness (EDS) is a common symptom of obstructive sleep apnea (OSA) and has been reported to persist in 10%–28% of patients despite treatment with continuous positive airway pressure (CPAP).
• Cognitive impairment is a burdensome symptom in many patients with EDS associated with OSA and may involve performance deficits in several cognitive domains.
  – Impaired cognitive function can persist in patients despite CPAP therapy.
  – Pecilricular evidence has demonstrated that solriamfetol activates trace amine-associated receptor 1 (TAAR1P).
  – TAAR1 agonism has emerged as a potential pharmacological target to improve cognitive function.

Methods

• SHARP was a phase 4, multicenter, randomized, double-blind, placebo-controlled, 2-period crossover trial (NCT04789174) conducted from May 17, 2021, to September 19, 2022, across 28 sites in North America and Europe.

Objective

• Safety and tolerability; treatment-emergent adverse events (TEAEs)
• Effect sizes (Cohen’s d) were determined for primary and secondary endpoints.

Results

• Of 173 participants screened, 59 were enrolled and randomly assigned to 1 of the 2 treatment sequences; 57 participants completed the study.

Figure 1. SHARP Study Design

Figure 2. Overall DSST RBANS Scores Improved After Solriamfetol Treatment Compared With Placebo

Figure 3. BC-CI Scores Improved After Solriamfetol Treatment Compared With Placebo

Table 1. Baseline Demographic and Clinical Characteristics

Table 2. Treatment-Emergent Adverse Events

Conclusions

• Solriamfetol (150 mg/day) demonstrated improvement on objective and subjective measures of cognitive function and reduced subjective sleepiness in patients with cognitive impairment associated with OSA and EDS.
• The safety profile of solriamfetol was consistent with prior studies.

The results confirm and expand on findings from previous studies that solriamfetol improves EDS in patients with OSA.