SLEEP

Does the Efficacy and Safety of Pitolisant Persist in Patients With OSA When Taken Long-Term?



STUDY DESIGN

- Included all adults (both pitolisant and placebo arms) from short-term HAROSA randomized controlled trials (RCTs)
- Participants offered pitolisant up to week 52
- <u>Primary efficacy outcome</u> Epworth Sleepiness Scale (ESS) score between baseline and week 52
- <u>Safety outcomes</u> Treatment-emergent adverse event(s) (TEAE[s]), serious TEAEs, and special interest TEAEs

376 of 512

Adults included in HAROSA RCTs completed 1-year follow-up

RESULTS

-8.0 [-8.3, -7.5] EFFICACY

The pooled mean difference in ESS score from baseline to 1 year for the intention-to-treat sample

35.1%, 2.0%, AND 11.1% SAFETY

The overall proportions of TEAE, serious TEAE, and TEAE of special interest

No cardiovascular safety issues were reported



Pitolisant is safe and effective when used to reduce daytime sleepiness over 1 year in adults with OSA, with or without CPAP treatment.

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