



ProSomnus® Presents Data Validating Proprietary FDA-cleared Oral Appliance Therapy Devices at 2022 American Academy of Dental Sleep Medicine Annual Meeting

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Data suggest ProSomnus's patient-preferred devices can be suitable alternative to CPAP

SAN FRANCISCO, May 13, 2022 (GLOBE NEWSWIRE) -- ProSomnus, the leader in patient-preferred medical devices for the treatment of obstructive sleep apnea, today announced the results of three studies evaluating its oral appliance therapy devices in the treatment of obstructive sleep apnea. ProSomnus presented the data in three poster presentations at the 2022 American Academy of Dental Sleep Medicine (AADSM) Annual Meeting, held from May 13-15 in Dallas, Texas.

Emerging data continue to show the potential of oral appliance therapy in treating obstructive sleep apnea, the recurring collapse of the airway during sleep which results in oxygen shortages and abrupt awakenings accompanied by gasping or choking. In addition to daytime sleepiness, obstructive sleep apnea is associated with comorbidities such as heart failure, stroke, hypertension, morbid obesity and type 2 diabetes. Patients with untreated obstructive sleep apnea are 23 times more likely to suffer a heart attack and four times more likely to have a stroke. It is estimated that approximately one billion people worldwide and over 74 million people in North America suffer from obstructive sleep apnea, with approximately 56 million of those 74 million people in North America undiagnosed.

The ProSomnus EVO™ Sleep and Snore Device – shaped like a mouthguard for a patient's upper and lower jaw – is an alternative to legacy obstructive sleep apnea treatment and can result in better efficacy and better patient compliance with fewer side effects. It enables easier breathing by holding the jaw gently forward and opening the airway in the back of the throat, making it less likely for the air passing through a partially closed airway to cause snoring or more severe sleep interruptions.

"These data presented at AADSM validate ProSomnus's oral appliance therapy devices in mild and moderate obstructive sleep apnea and, in particular, show great promise among patients with severe obstructive sleep apnea," said John E. Remmers, MD, Chief Scientist of ProSomnus. "Obstructive sleep apnea is a global medical issue and improving how we treat it requires collaboration from around the world. We see the AADSM Annual Meeting as a great platform for presenting this pioneering research."

The presented abstracts validating ProSomnus's oral appliance therapy devices include:

- **The use of a Digitally Milled Oral Appliance in the Treatment of Severe Obstructive Sleep Apnea**
 - An evaluation of data from two studies found ProSomnus's oral appliance therapy effective with most severe obstructive sleep apnea patients, suggesting that oral appliance therapy could be a suitable alternative to CPAP, especially when generated from digital intraoral scans using computer-aided design and manufacturing. Of 41 patients with severe obstructive sleep apnea, 73.2 percent achieved a respiratory event index (REI) decrease from a baseline of at least 50 percent after being treated with ProSomnus's oral appliance therapy, while 68.2 percent achieved an REI of less than 15 h⁻¹.
- **Recapturing a Posterior Open Bite Using a Precision Milled Morning Occlusal Guide**
 - An analysis suggested that digital archives and remaking a re-alignment device – called a Morning Occlusal Guide (MOG) – in the same morning maximum intercuspal position (MIP) can be important in recapturing bite changes in oral appliance therapy. The poster examines one patient who demonstrated a unilateral posterior open bite, often seen as a common and unavoidable side effect of oral appliance therapy. 10 days after the patient was presented with a MOG ordered from ProSomnus's digital case archives, posterior occlusion had been reestablished. ProSomnus is the only manufacturer that has demonstrated the ability to make a MOG and recapture original bite relationship from a patient's digital records.
- **Efficacy of a Novel Iterative Device and Material**
 - Data from 55 patients treated at four dental sleep medicine centers showed significantly improved results to previous data reported on the effectiveness of the ProSomnus EVO. Of the 55 patients, 15 had mild obstructive sleep apnea, 23 had moderate and 17 had severe, with an average pretreatment apnea hypopnea index (AHI) of 26.4. After being treated with the ProSomnus EVO:
 - The patients achieved an average AHI reduction of 75 percent, from 26.4 to 6.6.
 - 62 percent of all patients exhibited an AHI of less than five.
 - 85 percent of all patients demonstrated an AHI of less than 10.
 - 59 percent of patients with severe obstructive sleep apnea attained an AHI below 10.

"Innovations have improved outcomes for a wide range of medical conditions," said Len Liptak, Co-Founder and Chief Executive Officer of ProSomnus. "In this spirit, these three scientific abstracts investigate the impact of precision intraoral device innovations for the treatment of obstructive sleep apnea. We are pleased that these investigations associate ProSomnus precision intraoral devices with improved outcomes."

About ProSomnus

ProSomnus is the first manufacturer of precision, mass-customized oral appliance therapy devices to treat obstructive sleep apnea, which affects over 74 million Americans and is associated with serious comorbidities, including heart failure, stroke, hypertension, morbid obesity and type 2 diabetes.

ProSomnus's patented devices are a more comfortable and less invasive alternative to Continuous Positive Airway Pressure (CPAP) therapy, and lead to more effective and patient-preferred outcomes. With more than 150,000 patients treated, ProSomnus's devices are the most prescribed oral appliance therapy in the U.S. To learn more, visit www.ProSomnus.com.

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