Updated Clinical Trial Data Indicates Precision Oral Appliance Therapy with ProSomnus Devices is Non-Inferior to CPAP Therapy for the Treatment of Moderate to Severe Obstructive Sleep Apnea

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Precision oral appliance therapy effective among 90% of moderate and 85% of severe OSA patients

In an Intent-to-Treat analysis, precision OAT demonstrated twice the mean disease alleviation as CPAP

Results for treating Severe OSA patients with precision oral appliance therapy establish rationale for head-to-head clinical trial with hypoglossal nerve stimulation

PLEASANTON, Calif., Aug. 23, 2023 (GLOBE NEWSWIRE) -- ProSomnus, Inc. (NASDAQ: OSA), a leading CPAP alternative for the treatment of Obstructive Sleep Apnea ("OSA"), announced updated clinical trial data, presented at the ProSleep 2023 Users Conference earlier this month. The updated data indicate that the First Line Obstructive Sleep Apnea Treatment study (FLOSAT) is on track to achieve all endpoints.

FLOSAT is an ongoing, prospective, independent, head-to-head study comparing the effectiveness of precision OAT as first-line treatment versus CPAP therapy. ProSomnus EVO® devices are being used exclusively for the precision OAT arm of the study. A total of 136 patients with moderate and severe OSA were included in the study.

Key findings to date include:

- Precision oral appliance therapy is effective, and non-inferior to CPAP, as a first-line treatment for moderate to severe OSA
- Precision OAT was effective among 90% of moderate and 85% of severe OSA patients
- Precision oral appliance therapy was preferred by patients, with 98% continuing therapy at three months versus 22% discontinuing CPAP therapy over the same period of time
- In an intention to treat analysis factoring efficacy and adherence, precision OAT (ProSomnus) demonstrated twice the mean disease alleviation as CPAP

"The FLOSAT study was designed to evaluate whether precision Oral Appliance Therapy could be utilized for the very practical and emergent issue of patients with OSA who could not access CPAP due to the recall," commented Prof. Dr. Olivier Vanderveken, Antwerp University Hospital. "The preliminary results of this study indicate that precision oral appliances are an effective and patient preferred treatment option, which is particularly relevant for the growing number of sleep clinicians practicing the P4 approach to making medicine more predictive, preventive, personalized and participatory."

An additional observation from FLOSAT is the performance of precision OAT among severe OSA patients, in the context of data reported for hypoglossal nerve stimulation (HNS). Using the same criteria for efficacy – an AHI < 20 and a 50% improvement – 85% of severe OSA patients were successfully treated with non-invasive precision OAT. Clinical studies for the surgically implanted HNS devices, such as the STAR trial, report success in the range of 66% even with patient selection and the exclusion of concentric collapse patients. In July, ProSomnus announced plans to design a head-to-head clinical trial comparing precision OAT and HNS in treating patients with severe OSA.

Patients are actively being enrolled in the Severe OSA Study, a multi-center, prospective, clinical trial designed to demonstrate the safety and effectiveness of ProSomnus devices for the treatment of severe OSA and apply for FDA label expansion.

"The updated data and analysis from FLOSAT is validation that precision oral appliance therapy with ProSomnus devices is an effective front-line treatment for moderate to severe OSA," said Len Liptak, Co-Founder and Chief Executive Officer of ProSomnus. "This is an important finding. Each year millions of people worldwide are diagnosed with moderate to severe OSA. An estimated 40% of them refuse CPAP. Over two and a half million people have been impacted by the recent CPAP recall and seek alternatives. The results of this study indicate that precision OAT with ProSomnus devices is an effective, and preferred, option for these patients."

Data from FLOSAT will also be presented at the iBEDSSMA Symposium, taking place in Knokke-Heist, Belgium, from September 22-23, and the World Sleep Congress, taking place in Rio de Janeiro, Brazil, from October 20-25.

About FLOSAT
Designed and conducted by The Antwerp University Hospital (UZA), the primary endpoints of FLOSAT are to evaluate the overall effectiveness of OAT as a first-line treatment for OSA, compare the overall effectiveness of OAT with that of CPAP and evaluate patients' preference. ProSomnus devices are being used exclusively for the precision OAT arm of the study. A total of 136 patients enrolled in FLOSAT, all with moderate to severe OSA, body mass index less than 35 kg/m2, and central AHI less than 30% of total AHI, and all of whom had not received any previous OSA therapy and were eligible for OAT. After completing three months of first-line treatment with OAT followed by three months of CPAP, participants are asked which therapy they prefer. More information can be found at www.ClinicalTrials.gov using the identifier NCT05393531.

About ProSomnus
ProSomnus (NASDAQ: OSA) is a leading CPAP alternative for the treatment of Obstructive Sleep Apnea, a serious medical disease affecting over 1 billion people worldwide, that is associated with comorbidities including heart failure, stroke, hypertension, morbid obesity, and type 2 diabetes. ProSomnus intraoral medical devices are engineered to precisely track the treatment plan and anatomy for each patient. Non-invasive, patient preferred and easy to use, ProSomnus devices have demonstrated excellent efficacy, safety, adherence, and overall outcomes in a growing body of clinical investigations. ProSomnus precision intraoral devices are FDA-cleared, patented, and covered by commercial medical insurance, Medicare, TRICARE and many Government sponsored healthcare plans around the world, representing over 200 million covered lives. To learn more, visit

www.ProSomnus.com.

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This press release contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E the Securities Exchange Act of 1934, both as amended. Statements that are not historical facts, including statements regarding ProSomnus's or its management's intentions, beliefs, expectations and strategies for the future, including those related to ProSomnus's clinical trial plans and the stated or implied preliminary results, results and data of future and ongoing studies involving the use of ProSomnus's products and therapies, ProSomnus's labeling expansion, the outcome and timing for ProSomnus's trials, ProSomnus's future growth, expenses and margins, and the growing markets for its devices, are forward-looking statements. These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "plans," "may," "will," "potential," "projects," "predicts," "continue," or "should," or, in each case, their negative or other variations or comparable terminology. The forward-looking statements contained in this press release are based on our current expectations and beliefs concerning future developments and their potential effects on us. These forward-looking statements are not guarantees of future performance and are subject to various risks and uncertainties, assumptions (including assumptions about general economic, market, industry and operational factors), known or unknown, which could cause the actual results to vary materially from those indicated or anticipated. A further list and description of risks and uncertainties can be found in ProSomnus's most recent annual report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") any subsequently filed quarterly reports on Form 10-Q, and other documents that the parties may file or furnish with the SEC, which you are encouraged to read. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by such forward-looking statements. Forward-looking statements do not represent our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements.

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