ProSomnus to Design Head-to-Head Clinical Trial vs. Hypoglossal Nerve Stimulation

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Preliminary severe Obstructive Sleep Apnea data from FLOSAT study indicates opportunity for head-to-head trial between precision oral appliance therapy and hypoglossal nerve stimulation

PLEASANTON, Calif., July 13, 2023 (GLOBE NEWSWIRE) -- ProSomnus, Inc. (NASDAQ: OSA), a leading CPAP alternative for the treatment of Obstructive Sleep Apnea (OSA), announced plans to design a head-to-head clinical trial comparing its precision oral appliance therapy (OAT) and hypoglossal nerve stimulation (HNS) in treating patients with severe OSA.

The clinical trial plans follow updated results from the First Line Obstructive Sleep Apnea Treatment Study (FLOSAT), a prospective, independent, head-to-head, crossover study comparing the effectiveness of precision OAT and CPAP among patients with moderate to severe OSA. The updated, preliminary data demonstrated that precision OAT was highly effective and non-inferior to CPAP as a first-line therapy for patients with moderate and severe OSA, even without the benefit of additional future titrations. The data were recently presented at the Royal Society of Medicine's Sleep Symposium in London.

An additional and potentially important observation from the preliminary FLOSAT data is the performance of precision OAT devices for severe OSA patients relative to the results published for HNS. Using the same criteria for efficacy – an AHI < 20 and a 50% improvement – 79% of exclusively severe OSA patients were successfully treated with non-invasive precision OAT devices, while the STAR trial reported 66% of patients with moderate to severe OSA were successfully treated using a surgically implanted HNS device, even with the exclusion of concentric collapse patients. Further, secondary analysis indicates that precision oral devices are associated with lower rates of adverse events and lower total treatment costs than HNS. Based on these findings, ProSomnus intends to design a head-to-head clinical trial comparing precision OAT and HNS. More information will be available on ProSomnus's previously announced second quarter 2023 investor call, scheduled for Thursday, August 3 at 5:30 am PT / 8:30 am ET.

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.

Forward-looking statements
This press release contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the U.S. Private Securities Litigation Reform Act of 1995. Forward looking statements include all statements that are not purely historical regarding ProSomnus's or its management's intentions, beliefs, expectations and strategies for the future, including those related to the timing, design, parameters and potential results of ProSomnus's clinical trial plans. All forward-looking statements included in this press release, including indications regarding ProSomnus's expected clinical trial plans, are made as of the date of this release, based on information currently available to ProSomnus, deal with future events, are subject to various risks and uncertainties, and actual results could differ materially from those anticipated in those forward-looking statements. The risks and uncertainties that may cause actual results to differ materially from ProSomnus's current expectations are more fully described in ProSomnus's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 14, 2023, any subsequently filed Quarterly Reports on Form 10-Q, and its other reports, each as filed with the Securities and Exchange Commission. Except as required by law, ProSomnus assumes no obligation to update any such forward-looking statement after the date of this report or to conform these forward-looking statements to actual results.

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