ProSomnus® Announces Completion of Enrollment in Antwerp University Hospital's First Line Obstructive Sleep Apnea Treatment Study (FLOSAT)

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First prospective crossover study comparing the effectiveness of precision oral appliance therapy as front-line therapy relative to CPAP for the treatment of obstructive sleep apnea

ProSomnus precision intraoral medical devices exclusively utilized for the precision oral appliance therapy arm of the study

SAN FRANCISCO, Dec. 21, 2022 (GLOBE NEWSWIRE) -- ProSomnus, Inc. ("the Company") (NASDAQ: OSA), a pioneer in precision medical devices for the treatment of Obstructive Sleep Apnea (OSA), today announced full enrollment in the First Line Obstructive Sleep Apnea Treatment study (FLOSAT). FLOSAT is a prospective, independent, head-to-head, crossover study comparing the effectiveness of precision oral appliance therapy (OAT) as first-line treatment versus continuous positive airway pressure (CPAP) therapy. ProSomnus precision intraoral medical devices are being used exclusively for the precision OAT arm of the study.

Designed and conducted by The Antwerp University Hospital (UZA), Belgium, the primary endpoint of FLOSAT is to evaluate the overall effectiveness of precision OAT therapy as first line treatment in comparison with CPAP devices. Treatment effectiveness is calculated as the product of therapeutic efficacy and nightly compliance. Efficacy is the reduction in OSA severity as measured by polysomnography. Nightly compliance, or hours of usage per night, is objectively recorded by micro-sensors embedded in the devices. Secondary endpoints include patient preference.

The enrollment target is 121 patients with moderate and severe OSA. All 121 patients have already completed the OAT arm of the study. The researchers expect to have the full results of the study in early 2023.

"Antwerp University Hospital continuously looks for ways to enhance the global medical community's understanding of key health issues, including OSA," said Prof. Dr. Olivier M. Vanderveken, M.D., Ph.D., Chair of the Department of Head and Neck Surgery at Antwerp University Hospital. "FLOSAT has the potential to reveal a great deal about the differences in efficacy between precision OAT and CPAP, and we believe that measuring and comparing patient adherence to these two types of therapies will help us better understand their viability for patients with OSA."

"At a time when medicine is moving toward patient-centric care models to optimize outcomes, a lack of validated therapeutic options has limited sleep clinicians to chiefly prescribing CPAP, particularly as first-line treatment," said Len Liptak, Co-Founder and Chief Executive Officer of ProSomnus. "One of the strategic objectives of FLOSAT is to evaluate whether precision OAT is viable as a first-line treatment option for patients with moderate and severe OSA. If validated, FLOSAT should represent an important contribution toward a more patient-centric approach to treating OSA and away from the current one-size-fits-all modality."

More information about the FLOSAT study can be found at www.clinicaltrials.gov using the identifier NCT05393531.

About OSA
OSA is the recurring collapse of the airway during sleep, resulting in oxygen shortages and abrupt awakenings accompanied by gasping or choking. In addition to daytime sleepiness, OSA is associated with serious comorbidities, including heart failure, stroke, hypertension, morbid obesity and type 2 diabetes. Patients with untreated OSA are 23 times more likely to suffer a heart attack and four times more likely to have a stroke. It is estimated that more than one billion people worldwide and over 74 million people in North America suffer from OSA. Approximately 56 million of those 74 million people in North America are undiagnosed.

About ProSomnus
ProSomnus (NASDAQ: OSA) is the first manufacturer of precision, mass-customized Precision Oral Appliance Therapy devices to treat OSA, which affects over 74 million Americans and is associated with serious comorbidities, including heart failure, stroke, hypertension, morbid obesity and type 2 diabetes. ProSomnus' 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' devices are the most prescribed Precision Oral Appliance Therapy in the U.S. To learn more, visit www.ProSomnus.com.

Important Notice Regarding Forward-Looking Statements
This Press Release contains certain "forward-looking statements" within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, both as amended. Statements that are not historical facts, including statements about the parties' perspectives and expectations, are forward-looking statements. The words "expect," "believe," "estimate," "intend," "plan" and similar expressions indicate forward-looking statements. 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.

Such risks and uncertainties include, but are not limited to: (i) the effect of the announcement or the business combination on ProSomnus's business relationships, operating results and business generally; (ii) risks that the business combination disrupts current plans and operations of ProSomnus; (iii) the outcome of any legal proceedings that may be instituted against ProSomnus or Purchaser related to the business combination; (iv) changes in the competitive industries in which ProSomnus operates, variations in operating performance across competitors, changes in laws and regulations affecting ProSomnus's business and changes in the combined capital structure; (v) the ability to implement business plans, forecasts and other expectations after the completion of the business combination, and identify and realize additional opportunities; (vi) the risk of downturns in the market and ProSomnus's industry including, but not limited to, as a result of the COVID-19 pandemic; (vii) costs related to the transaction and the failure to realize anticipated benefits of the transaction or to realize estimated pro forma results and underlying assumptions, including with respect to estimated stockholder redemptions; (viii) the risk of potential future significant dilution to stockholders resulting from lender conversions under the convertible debt financing; and (ix) risks and uncertainties related to ProSomnus's business, including, but not limited to, risks relating to the uncertainty of the

projected financial information with respect to ProSomnus; risks related to ProSomnus's limited operating history, the roll-out of ProSomnus's business and the timing of expected business milestones; ProSomnus's ability to implement its business plan and scale its business, which includes the recruitment of healthcare professionals to prescribe and dentists to deliver ProSomnus oral devices; the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for mild-to-moderate OSA; expectations concerning the effectiveness of OSA treatment using ProSomnus oral devices and the potential for patient relapse after completion of treatment; the potential financial benefits to dentists and other healthcare professionals from treating patients with ProSomnus oral devices and using ProSomnus's monitoring tools; ProSomnus's potential profit margin from sales of ProSomnus oral devices; ProSomnus's ability to properly train dentists in the use of the ProSomnus oral devices and other services it offers in their dental practices; ProSomnus's ability to formulate, implement and modify as necessary effective sales, marketing, and strategic initiatives to drive revenue growth; ProSomnus's ability to expand internationally; the viability of ProSomnus's intellectual property and intellectual property created in the future; acceptance by the marketplace of the products and services that ProSomnus markets; government regulations and ProSomnus's ability to obtain applicable regulatory approvals and comply with government regulations, including under healthcare laws and the rules and regulations of the U.S. Food and Drug Administration; and the extent of patient reimbursement by medical insurance in the United States and internationally. A further list and description of risks and uncertainties can be found in Lakeshore's initial public offering prospectus dated June 10, 2021 and in the Company's quarterly reports on Form 10-Q and annual reports on Form 10-K filed with the Securities and Exchange Commission (the "SEC") subsequent thereto and in the Registration Statement on Form S-4 and proxy statement that has been filed with the SEC by Lakeshore in connection with the business combination, 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. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements relate only to the date they were made, and the Company and its subsidiaries undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made except as required by law or applicable regulation.

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