ProSomnus Reports Successful Pilot Study Validation of Next Generation Remote Patient Monitoring Device for Obstructive Sleep Apnea

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PLEASANTON, Calif., Feb. 22, 2024 (GLOBE NEWSWIRE) -- ProSomnus, Inc. (NASDAQ: OSA) (the "Company"), the leading non-CPAP Obstructive Sleep Apnea (OSA) therapy™, announced results of its pilot study for the Company's Next Generation Remote Patient Monitoring (RPM) device for Obstructive Sleep Apnea (OSA). Data from the pilot study demonstrated that an oximeter embedded in a precision medical device can accurately, safely, and continuously monitor SpO_2.

"This pilot study validation represents a step toward bringing sleep medicine into the P4 medicine era. The ProSomnus® $RPMO_2$ OSA Device enables sleep medicine to be more personalized, predictive, preventative, and participatory," commented Len Liptak, Chief Executive Officer for ProSomnus Sleep Technologies. "Although we have more work to do in terms of FDA clearances, market access and commercialization, I am very proud that team ProSomnus is in the process of bringing this potentially life changing innovation to the millions of people suffering from OSA."

An intraoral medical device capable of performing RPM of physiologic parameters relevant to OSA such as arterial oxygen saturation and pulse rate would be beneficial, as it would enable healthcare providers to monitor the residual risks associated with any OSA treatment. Few treatments for OSA offer the healthcare provider real-time information about treatment status. Even fewer, if any, offer the healthcare provider access to metrics predictive of cardiovascular morbidity and mortality such as sleep apnea-specific hypoxic burden (SASHB) or sleep apnea specific-pulse rate response. The calculation of such predictive metrics requires, at minimum, full night pulse oximetry.

Healthy adult volunteers were fitted with a ProSomnus $RPMO_2$ OSA Device and an FDA-cleared reference oximeter. Each volunteer then underwent a standard controlled desaturation protocol in accordance with FDA and medically accepted parameters to achieve six desaturation plateaus between 70% and 100% SaO_2. Five matched data pairs between the ProSomnus $RPMO_2$ and FDA-cleared reference oximeter from each desaturation plateau were pooled to determine the accuracy of the ProSomnus $RPMO_2$ Device. Based on the FDA's requirements for accuracy, a performance goal of root mean square error ("RMSE") less than 3.5% was selected.

Eighty-five matched data pairs were included in the analysis. The RMSE for the ProSomnus $RPMO_2$ OSA Device was 2.32%. The minimum and maximum SpO_2 values recorded by the ProSomnus $RPMO_2$ OSA Device were 71.8% and 100%, respectively. Bland-Altman analysis showed a bias of 0.24 and lower and upper 95% limits of agreement of -4.31 and 4.79, respectively.

"The results of our pilot studies are impressive and demonstrate that ProSomnus has the capability to implement an intraoral oximeter," stated Dr. John E. Remmers, MD, Chief Scientist for ProSomnus Sleep Technologies. "We believe that this technology, following further validation testing and obtaining the necessary regulatory approvals, has the potential to meaningfully advance the role of oral appliances in treating OSA; oxygen monitoring provides ongoing assessment of the efficacy of oral appliance therapy."

"Pilot testing was a crucial step in the development and preliminary validation of the ProSomnus $RPMO_2$ OSA Device," commented Dr. Erin Mosca, PhD, Director of Scientific and Medical Affairs for ProSomnus Sleep Technologies. "The results of the pilot testing hold tremendous promise for the formal validation testing, in which the ProSomnus $RPMO_2$ OSA Device will be compared against a gold standard."

About ProSomnus
ProSomnus (NASDAQ: OSA) is the leading non-CPAP therapy 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.

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 timing, outcome and effects from the pilot testing for the $RPMO_2$ OSA Device and the potential impacts of the $RPMO_2$ OSA Device, are forward-looking statements. The words "expect," "believe," "estimate," "intend," "plan" and similar expressions indicate forward-looking statements, although not all forward-looking statements contain these or similar identifying words.

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: effectiveness of the ProSomnus's products; ProSomnus's ability to raise additional funds to continue operating under its existing business plan; ProSomnus's ability to comply with its debt obligations; changes in the timelines and potential outcomes of regulatory clearance and/or approval processes; securing and maintain regulatory clearances, approvals and compliance in jurisdiction in which the Company intends to offer its products, competitive industries in which the Company operates and variations in operating performance across competitors; changes in laws and regulations affecting ProSomnus's business; the risk of downturns in the market and ProSomnus's industry; risks related to ProSomnus's limited operating history and history of losses; 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; the understanding and adoption by dentists and other healthcare professionals of

ProSomnus oral devices for severe OSA if clearance for such indication be secured from the FDA; 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; 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 adoption of its devices; 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; the extent of patient reimbursement by medical insurance in the United States and internationally; and the outcome of any legal proceedings that may be instituted against the Company. A further list and description of risks and uncertainties can be found in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 14, 2023. 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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