DREAM Pivotal Study Data Presented at the International Surgical Sleep Society 2024 Educational Update

Additional clinical data on patients suffering from Obstructive Sleep Apnea (OSA) demonstrate a clinically significant 71.0% median reduction in Apnea-Hypopnea index (AHI) while sleeping supine at 12 months compared with baseline.

82.0% of patients who completed a polysomnography at 12 months had an AHI below 15, and 67.4% of patients who completed a polysomnography at 12 months had an AHI below 10.

Mont-Saint-Guibert, Belgium – September 27, 2024, 10:30pm CET / 4:30pm ET – Nyxoah SA (Euronext Brussels/Nasdaq: NYXH) ("Nyxoah" or the "Company"), a medical technology company that develops breakthrough treatment alternatives for Obstructive Sleep Apnea (OSA) through neuromodulation, announced that data from the DREAM U.S. pivotal study were presented in an oral session at the International Surgical Sleep Society (ISSS) 2024 Educational Update, taking place from September 26 -27 in Miami, Florida.

Additional data were presented for AHI reduction in supine and non-supine positions. Genio bilateral stimulation resulted in a clinically meaningful 71.0% median reduction in supine AHI at 12 months compared with baseline. This reduction compares to a median 12-month AHI reduction of 70.8% across all sleeping positions.

With respect to secondary endpoints reported at ISSS, subjects demonstrated significant improvements in quality-of-life outcomes. Specifically, a mean increase of 2.3 points was observed in the Functional Outcomes of Sleep Questionnaire (FOSQ) assessment. Additionally, the Epworth Sleepiness Score was reduced by a mean of 3.4 points from baseline.

The presentation included previously announced data demonstrating that the study achieved its co-primary endpoints of 12-month AHI responder rate, per the Sher criteria, and Oxygen Desaturation Index (ODI) responder rate, both on an Intent-To-Treat (ITT) basis. In the DREAM U.S. pivotal study, 115 patients received the Genio® implant and were included in the safety analysis. These patients had a mean AHI of 28.0, mean ODI of 27.0 and mean body mass index of 28.5 at baseline. At 12 months, 73 subjects were determined to be AHI responders, per the Sher criteria*, resulting in an ITT AHI responder rate of 63.5% ($p=0.002$), and 82 subjects were determined to be ODI responders, resulting in an ODI responder rate of 71.3% ($p<0.001$). Safety results were in line with other neuromodulation therapies, with 11 serious adverse events, or SAEs, in ten subjects resulting in an SAE rate of 8.7%. Out of the 11 SAEs, three were device related, and there were three explants.

*An AHI responder, per the Sher criteria, is defined as a subject with an AHI reduction of at least 50% from baseline and an AHI score of less than 20 events per hour on the 12-month PSG. An ODI responder is defined as a subject which demonstrates an ODI reduction of at least 25% from baseline on the 12-month PSG.

"The DREAM study demonstrated efficacy of bilateral hypoglossal nerve stimulation using Genio for the treatment of obstructive sleep apnea. Clinically significant improvements in primary and secondary endpoints were observed," said B. Tucker Woodson, MD, Chief, Professor – Medical College of Wisconsin and Principal Investigator of the DREAM study. "Genio has the potential of helping us advance neuromodulation therapy for the treatment of OSA."

"Achieving meaningful AHI reductions regardless of sleep position is a clinical validation of our patient-centric approach," said Olivier Taelman, CEO of Nyxoah. "Genio bilateral stimulation also enabled more than 80% of patients to hit 12 months with an AHI below 15, positively impacting their overall quality of life and reducing sleepiness. Nyxoah is now entering the final regulatory phase and is progressing toward FDA approval. This will be a huge milestone in our mission to make Genio available to OSA patients in the US."

About Nyxoah

Nyxoah is reinventing sleep for the billion people that suffer from obstructive sleep apnea (OSA). We are a medical technology company that develops breakthrough treatment alternatives for OSA through neuromodulation. Our first innovation is Genio®, a battery-free hypoglossal neuromodulation device that is inserted through a single incision under the chin and controlled by a wearable. Through our commitment to innovation and clinical evidence, we have shown best-in-class outcomes for reducing OSA burden.

Following the successful completion of the BLAST OSA study, the Genio® system received its European CE Mark in 2019. Nyxoah completed two successful IPOs: on Euronext Brussels in September 2020 and NASDAQ in July 2021. Following the positive outcomes of the BETTER SLEEP study, Nyxoah received CE mark approval for the expansion of its therapeutic indications to Complete Concentric Collapse (CCC) patients, currently contraindicated in competitors' therapy. Additionally, the Company announced positive outcomes from the DREAM IDE pivotal study for FDA and U.S. commercialization approval.

For more information, please see the Company's annual report for the financial year 2023 and visit http://www.nyxoah.com/.

Caution – CE marked since 2019. Investigational device in the United States. Limited by U.S. federal law to investigational use in the United States.

Forward-looking statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations regarding the Genio® system and ongoing clinical studies of the Genio® system; the potential advantages of the Genio® system; Nyxoah's goals with respect to the development, regulatory pathway and potential use of the Genio® system; the utility of clinical data in potentially obtaining FDA approval of the Genio® system; reporting data from Nyxoah's DREAM U.S. pivotal trial; filing for FDA approval; and entrance to the U.S.

market. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. Additionally, these risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the "Risk Factors" section of the Company's Annual Report on Form 20-F for the year ended December 31, 2023, filed with the Securities and Exchange Commission ("SEC") on March 20, 2024, and subsequent reports that the Company files with the SEC. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.

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