REGULATED INFORMATION
INSIDE INFORMATION

Nyxoah Announces DREAM U.S. Pivotal Study Meets Primary Endpoints

Reports an Apnea-Hypopnea Index (AHI) responder rate of 63.5% on an intent to treat (ITT) basis (p=0.002)
Reports an Oxygen Desaturation Index (ODI) responder rate of 71.3% on an intent to treat (ITT) basis (p<0.001)
Median 12-month AHI reduction of 70.8%

Mont-Saint-Guibert, Belgium – March 19, 2024, 9:05pm CET / 4:05pm ET – Nyxoah SA (Euronext Brussels/Nasdaq: NYXH) ("Nyxoah" or the "Company"), a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea (OSA), today announced the DREAM U.S. pivotal study achieved a statistically significant reduction in the co-primary endpoints of 12-month AHI responder rate, per the Sher criteria, and ODI responder rate, both on an ITT basis.

The DREAM study is a pivotal trial, being conducted under an investigational device exemption (IDE) and is designed to support the marketing authorization of the Genio® hypoglossal nerve stimulation system (HGNS) in the United States. This multicenter, prospective, open-label, interventional study enrolled 115 patients and has co-primary efficacy endpoints of the Apnea-Hypopnea Index (AHI) responder rate, per the Sher criteria, and the Oxygen Desaturation Index (ODI) responder rate, both measured at 12 months*. Subjects also were required to sleep supine for at least 60 minutes at their 12-month polysomnography test (PSG). More information regarding the study can be found in section 1.5.4 of the Company's annual report regarding financial year 2022, which can be found on the Company's website using the following link: Nyxoah Annual Report 2022 EN.pdf.

Study participants entered the DREAM study with a mean AHI of 28.0, mean ODI of 27.0 and mean body mass index of 28.5. 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). Subjects demonstrated a median 12-month AHI reduction of 70.8%, with similar AHI improvements in supine and non-supine sleeping positions. The safety results for the investigational treatment were favorable, 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.

"DREAM is a pivotal, multicenter, international study of Genio, a next generation HGNS technology offering patients bi-lateral stimulation with a non-implanted battery solution powered and controlled by a wearable. With the DREAM data, Genio has demonstrated positive efficacy results that OSA patients, having failed traditional medical therapies, have come to expect. Notably, Genio's unique bilateral

*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.

stimulation provides the potential for improved outcomes for a wider spectrum of OSA patients. I am excited that Nyxoah and Genio are working towards expanding options and advancing HGNS therapy for OSA, and I look forward to offering it to my patients upon FDA approval," commented B Tucker Woodson, MD, Chief, Professor – Medical College of Wisconsin and Principal Investigator of the DREAM study."

"I am excited to report the positive DREAM results, as they pave the way for Genio to shift the OSA treatment paradigm in the U.S. With Genio's patient centric design, strong clinical data and commercial learnings from Europe, we are confident Nyxoah can become a leading OSA company." commented Olivier Taelman, Nyxoah's Chief Executive Officer. "We are finalizing the fourth and final module submission in the PMA application and I look forward to launching Genio in the U.S, pending FDA approval."

Conference call and webcast presentation

Company management will host a conference call to discuss the DREAM results today beginning at 9:30pm CET / 4:30pm ET. A webcast of the call will be accessible via the Investor Relations page of the Nyxoah website or through this link: DREAM Results Webcast. For those not planning to ask a question of management, the Company recommends listening via the webcast.

If you plan to ask a question, please use the following link: DREAM Results Call. After registering, an email will be sent, including dial-in details and a unique conference call access code required to join the live call. To ensure you are connected prior to the beginning of the call, the Company suggests registering a minimum of 10 minutes before the start of the call.

About Nyxoah

Nyxoah is a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea (OSA). Nyxoah's lead solution is the Genio® system, a patient-centered, leadless and battery-free hypoglossal neurostimulation therapy for OSA, the world's most common sleep disordered breathing condition that is associated with increased mortality risk and cardiovascular comorbidities. Nyxoah is driven by the vision that OSA patients should enjoy restful nights and feel enabled to live their life to its fullest.

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 which will be filed on March 20, 2024** 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, 2022, filed with the Securities and Exchange Commission ("SEC") on March 22, 2023, 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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