Nyxoah Announces Achievement of Key Clinical and Regulatory Milestones

March 6, 2023

INSIDE INFORMATION
REGULATED INFORMATION

Nyxoah Announces Achievement of Key Clinical and Regulatory Milestones
All 115 patients implanted in DREAM U.S. pivotal study
First DREAM PMA module submitted
First patient implanted in ACCCESS U.S. pivotal study

Mont-Saint-Guibert, Belgium – March 6, 2023, 7:30am CET / 1:30am 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 that the Company has completed all 115 implants in its DREAM U.S. pivotal study, submitted the first module in the modular PMA submission and implanted the first patient in the ACCCESS U.S. pivotal study.

The DREAM study is a pivotal, investigational device exemption (IDE) trial designed to support the marketing authorization of the Genio® hypoglossal nerve stimulation system (HGNS) in the United States. This multicenter, prospective, open-label, observational 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 at 12 months.

In the ACCCESS trial, Nyxoah will implant 106 complete concentric collapse (CCC) patients with co-primary efficacy endpoints of Apnea-Hypopnea Index (AHI) responder rate, per the Sher criteria, and Oxygen Desaturation Index (ODI) responder rate, both assessed at 12 months post-implant.

"The achievement of these key clinical and regulatory milestones brings us closer to offering our patient centric Genio solution to all OSA patients in the U.S. The DREAM and ACCCESS studies demonstrate Nyxoah's mission of providing Genio to patients regardless of CCC status and without the requirement for a CCC diagnosis," commented Olivier Taelman, Nyxoah's Chief Executive Officer.

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. 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 is currently conducting the DREAM IDE pivotal study for FDA and US commercialization approval.

For more information, please 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; future financial performance and market position; planned 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; and the Company's results of operations, financial condition, liquidity, performance, prospects, growth and strategies. 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, 2021, filed with the Securities and Exchange Commission ("SEC") on March 24, 2022, 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.

Contacts:
David DeMartino
Chief Strategy Officer
david.demartino@nyxoah.com
+1 310 310 1313

Attachment

- ENGLISH_ Nyxoah Announces a Clinical Update