Nyxoah Announces Commercial Launch of Genio® Innovative Therapy in England

December 13, 2024

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First patients implanted with Genio at UCLH, London

Mont-Saint-Guibert, Belgium – December 13, 2024, 8:05am CET / 2:05am 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, today announced the commercial launch of its Genio system in England, marked by the first successful implants performed at University College London Hospitals (UCLH).

Genio is now covered under the NHS Specialised Services Devices Programme (SSDP), enabling access to innovative therapies through specialized centers of excellence.

The first two patients were successfully implanted by Mr. Ryan Chin Taw Cheong, Consultant ENT and Sleep Surgeon at UCLH. Commenting on the milestone, Mr. Cheong said: "We are proud to be the first hospital in the UK to offer Genio to our OSA patients. Genio is a groundbreaking, clinically proven therapy that addresses the unmet needs of individuals suffering from Obstructive Sleep Apnea."

Olivier Taelman, CEO of Nyxoah, added: "Today represents an important milestone for Nyxoah as we introduce our Genio neurostimulation solution to treat Obstructive Sleep Apnea in England. Congratulations to Mr. Cheong and his team on this remarkable achievement. We look forward to expanding our collaboration with UCLH and other leading hospitals in England as we continue our mission to make sleep simple for OSA patients."

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.

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, reflecting Nyxoah's current expectations and beliefs regarding the Genio® system; 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 potential receipt of FDA approval and entrance into 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 Nyxoah'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 Nyxoah 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, Nyxoah 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 Nyxoah 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:

Nyxoah
John Landry, CFO
IR@nyxoah.com

For Media
In UK
Kinfolk Communications
rebecca@wearekinfolk.co.uk
gemma@wearekinfolk.co.uk

In United States
FINN Partners – Glenn Silver
glenn.silver@finnpartners.com

In Belgium/France
Backstage Communication – Gunther De Backer
gunther@backstagecom.be

In International/Germany
MC Services – Anne Hennecke
nyxoah@mc-services.eu

Attachment

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