Nyxoah Announces First Patient Implanted in BREATHE, the U.S. Post-Approval Study of the Genio® System

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BREATHE is scheduled to implant up to 229 patients at up to 25 U.S. centers, followed for up to five years, to evaluate the long-term safety and effectiveness of the Genio therapy in real-world clinical practice

First implant performed by Rolando Molina, MD, South Florida ENT Associates, with Edward Mezerhane, MD, of PharmaDev Clinical Research Institute as Site Principal Investigator

Mont-Saint-Guibert, Belgium – September 7, 2026, 10:05 pm CET / 4:05 pm 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 that the first patient has been implanted in BREATHE, the Company's U.S. post-approval study of the Genio® system. The procedure was performed by Rolando Molina, MD, otolaryngologist at South Florida ENT Associates. Edward Mezerhane, MD, FAASM, FACP, DABOM, CPI, sleep medicine physician at PharmaDev Clinical Research Institute (Miami, Florida), serves as the BREATHE Site Principal Investigator.

BREATHE is a multicenter, prospective, single-arm post-approval study designed to assess the long-term safety and effectiveness of the Genio system in adults with moderate to severe OSA. Up to 229 patients will be implanted at up to 25 clinical centers across the United States and followed for up to five years after implantation. The co-primary effectiveness endpoints are the Apnea-Hypopnea Index (AHI) and Oxygen Desaturation Index (ODI) responder rates at 12 months. Safety endpoints assess device- and procedure-related serious adverse events at 12 months and annually thereafter.

BREATHE will generate real-world evidence on how Genio performs in routine clinical practice across a broad set of U.S. centers bringing together sleep medicine physicians and ENT surgeons and will contribute to the ongoing evaluation of long-term patient outcomes.

"As an otolaryngologist dedicated to the treatment of sleep-disordered breathing, I have seen firsthand the significant impact obstructive sleep apnea has on patients' health and quality of life. The BREATHE study represents an exciting milestone in the evolution of sleep surgery and neurostimulation therapy. By performing the first implant in this study, we have the opportunity to help shape the future of sleep apnea treatment while offering eligible patients access to an additional therapeutic approach. Advancing innovation through clinical research remains central to our mission of improving outcomes for patients with obstructive sleep apnea," said Rolando Molina, MD, South Florida ENT Associates, implanting surgeon.

"Obstructive sleep apnea affects millions of people, yet many patients continue to struggle despite available therapies. The launch of the BREATHE study marks an exciting step forward in the evolution of sleep medicine, allowing us to evaluate an innovative bilateral hypoglossal nerve stimulation therapy in a real-world setting. Being the first site to implant a patient in this study reflects our commitment to bringing cutting-edge research and new treatment possibilities to patients who need alternatives," said Edward Mezerhane, MD, PharmaDev Clinical Research Institute.

"The first BREATHE implant marks the start of the largest prospective study of Genio to date and the next step in building the long-term, real-world evidence base for bilateral hypoglossal nerve stimulation in the United States," said Olivier Taelman, Chief Executive Officer of Nyxoah. "As adoption of Genio accelerates across U.S. centers, BREATHE will document how the therapy performs in everyday practice, in the hands of both sleep physicians and surgeons, over five years. This is the evidence that patients, physicians and payors expect, and it reflects our commitment to clinical rigor beyond approval."

About Nyxoah

Nyxoah is a medical technology company focused on the development and commercialization of innovative solutions to treat 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 in 2024 and received approval from the FDA in August 2025.

For more information, please visit http://www.nyxoah.com.

Caution – CE marked since 2019. FDA approved in August 2025 as prescription-only device.

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 management's current expectations regarding the Genio system; the potential advantages of the Genio system; Nyxoah's goals with

respect to the potential use of the Genio system; the BREATHE post-approval study, including its enrollment, timing, conduct and outcomes; the Company's commercialization strategy and entrance to the U.S. market; the Company's results of operations, financial condition, liquidity, performance, prospects, growth, future revenue 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. 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, 2025, filed with the Securities and Exchange Commission (“SEC”) on March 26, 2026 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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