Nyxoah Announces ACCCESS U.S. Pivotal Study Meets Primary Safety and Efficacy Endpoints in Complete Concentric Collapse Patients

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REGULATED INFORMATION
INSIDE INFORMATION

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Reports an Apnea-Hypopnea Index (AHI) responder rate of 77.2% on a Full Analysis Set basis (p<0.001)

Zero device-related serious adverse events through 12 months

Mont-Saint-Guibert, Belgium – September 2, 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 ACCCESS U.S. pivotal study achieved statistically significant outcomes on its co-primary efficacy endpoints of 12-month AHI responder rate, per the Sher criteria*, and 12-month Oxygen Desaturation Index (ODI) responder rate, and met its safety endpoints, in patients with Complete Concentric Collapse (CCC) of the soft palate. The ACCCESS study was designed to support the expansion of the Genio® system's U.S. indication for CCC patients, who are today contraindicated for commercially available unilateral hypoglossal nerve stimulation in this geography.

As announced in August 2025, the Company closed enrollment ahead of the planned maximum of 106 patients, reflecting its confidence that the enrolled population would deliver statistically significant results. Today's results confirm that confidence.

At 12 months, patients demonstrated an AHI responder rate, per the Sher criteria, of 77.2% (p<0.001) and an ODI responder rate of 87.7% (p<0.001), both on a Full Analysis Set basis. On safety, zero device-related serious adverse events were reported through 12 months post-implant.

The results were generated in line with the prespecified statistical analyses planned in the study protocol as approved by the U.S. Food and Drug Administration (FDA). The primary analysis was performed on the Full Analysis Set of 47 patients, being all patients who were implanted, activated and completed at least one in-study sleep test (polysomnography). Missing data points were addressed through a multiple imputation model, the recognized statistical method prespecified as primary analysis in the protocol and statistical analysis plan.

"A significant number of patients with OSA are found to have CCC and, until this point, hypoglossal nerve stimulation has not been an option for this population. The ACCCESS results demonstrate that Genio delivers a strong responder rate with an excellent safety profile in patients with this pattern of airway collapse. These findings could give U.S. physicians a new treatment option for the vast number of OSA patients with CCC who have struggled with positive airway pressure," commented Colin Huntley, MD, Professor, Department of Otolaryngology Head & Neck Surgery, Thomas Jefferson University, and Co-principal Investigator of the ACCCESS study.

"ACCCESS delivers on the promise we made to CCC patients. With a 77.2% AHI responder rate and zero device-related serious adverse events, Genio demonstrated both the efficacy and the safety this underserved patient population deserves. We are preparing our FDA submission to bring Genio to CCC patients in the United States, as we already do in Europe, and to deliver on our mission to make sleep simple," commented Olivier Taelman, Nyxoah's Chief Executive Officer.

The complete 12-month dataset and detailed results are expected to be presented at the upcoming International Surgical Sleep Society (ISSS) annual meeting in Los Angeles, October 15-16, 2026.

Nyxoah is preparing a premarket approval (PMA) supplement submission to the FDA to expand Genio's indication to CCC patients under FDA Breakthrough Device Designation.

*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 polysomnography (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.

About the ACCCESS study

ACCCESS is a multicenter, prospective, open-label pivotal study conducted in the United States, designed to assess the safety and efficacy of the Genio system in adult patients with moderate to severe OSA and CCC of the soft palate who have failed, do not tolerate, or refused positive airway pressure treatment. The study's co-primary efficacy endpoints are the AHI responder rate, per the Sher criteria, and the ODI responder rate, both assessed at 12 months post-implant, with patients followed for three years. CCC patients are currently contraindicated for unilateral hypoglossal nerve stimulation in the United States. Genio has been approved for CCC patients in Europe since 2021, following the positive outcomes of the BETTER SLEEP study, while in the United States, no commercially available neurostimulation treatment option exists for this population today.

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, with the treatment of CCC patients included in the warning section of our indications for use.

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 ACCCESS study and the results thereof; the potential advantages of the Genio system; Nyxoah's goals with respect to the potential use of the Genio system; the planned PMA supplement submission to the FDA and the timing of any FDA review; 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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Attachment

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