FDA Approves Genio® 2.1 For Use in DREAM U.S. IDE Pivotal Study

New smartphone application, upgraded activation chip, improved user interface, and stimulation amplitude trimming enhance patient experience and comfort

Mont-Saint-Guibert, Belgium – June 1, 2022, 10:30pm CET / 4:30pm 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 U.S. Food and Drug Administration (FDA) has approved the use of Nyxoah's next generation Genio® 2.1 system for use in the Company's DREAM U.S. IDE pivotal study. Genio® 2.1's upgrades are entirely related to the external components of the Genio® system, as the implantable stimulator remains unchanged.

Genio® 2.1 further demonstrates Nyxoah's patient-centric approach to addressing the needs of those suffering from moderate-to-severe OSA. The system features updates to the Genio® activation chip and a new smartphone application to enable daily reporting of therapy usage, which will support therapy acclimation and long-term compliance. Additional features of Genio® 2.1 include an improved user interface and the ability for clinicians to make more incremental stimulation adjustments. This is particularly meaningful for patients who are more sensitive to neurostimulation, as with Genio® 2.1 physicians can fine-tune stimulation amplitude to determine the optimal level of comfort for patients without compromising therapy efficacy.

"Genio® 2.1's features, along with existing full-body 3.0T MRI compatibility, illustrate Nyxoah's patient-first mission in OSA product development," commented Olivier Taelman, Nyxoah's Chief Executive Officer. "The updated activation chip and new smartphone app, combined with our upgraded user interface and increased stimulation resolution, represent key next steps in optimizing patient outcomes. We are excited to make these important new features available to patients in our DREAM trial."

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 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.

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