Nyxoah Announces U.S. FDA Breakthrough Device Designation Granted for the Genio® System for Obstructive Sleep Apnea and Complete Concentric Collapse

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INSIDE INFORMATION
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Mont-Saint-Guibert (Belgium), September 14, 2021, 8:00 am CET / 2:00 am 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 granted the Genio® bilateral hypoglossal nerve stimulation system Breakthrough Device Designation for the treatment of adult patients with moderate to severe OSA and Complete Concentric Collapse (CCC) of the soft palate.

The FDA's Breakthrough Designation Program was created to help patients and healthcare providers receive faster access to innovative technologies that hold the potential to provide more effective treatment of irreversibly debilitating diseases or conditions. According to the FDA, OSA is an irreversibly debilitating human disease for patients with sleep apnea. Under the Program, the FDA will provide the Genio® system with priority review and interaction with FDA's experts throughout the premarket review phase until the product is commercialized in the US.

"We are pleased to have received Breakthrough Device Designation for our proprietary Genio® system for OSA patients with CCC, recognizing that Obstructive Sleep Apnea is an irreversibly debilitating condition." said Olivier Taelman, CEO of Nyxoah. "This Breakthrough Designation accelerates our market authorization process in the US and expands our total addressable market to include CCC patients currently contraindicated for hypoglossal nerve stimulation."

The Breakthrough Designation is supported by data from the Company's BETTER SLEEP trial, aimed at addressing the long-term safety and performance of the Genio® system in adult OSA patients with and without CCC.

About BETTER SLEEP Trial
BilatEral Hypoglossal Nerve StimulaTion for TreatmEnt of ObstRuctive SLEEP Apnoea, or BETTER SLEEP, is a multicenter, prospective, open-label, two-group clinical trial, designed to assess the safety and performance of the Genio® system for the treatment of OSA in adult patients with and without CCC. Top-line BETTER SLEEP results showed primary safety and performance endpoints were met, with statistically significant mean reduction in the AHI score in full patient population including CCC patients. Nyxoah will submit full BETTER SLEEP study data to a medical journal for publication and announce results following further analyses.

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 in September 2020 and NASDAQ in July 2021. Following the positive outcomes of the BETTER SLEEP study, Nyxoah is seeking 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.

Contacts:
Nyxoah
Fabian Suarez, Chief Financial Officer
corporate@nyxoah.com
+32 10 22 24 55

Gilmartin Group
Vivian Cervantes
IR@nyxoah.com

Attachment

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