INSIDE INFORMATION
REGULATED INFORMATION

Nyxoah Announces CE-Mark Indication Approval to Treat Complete Concentric Collapse (CCC) Patients

Notified Body DEKRA approves IFU changes to remove warning regarding CCC patients

Mont-Saint-Guibert, Belgium – October 4, 2021, 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 DEKRA Notified Body has approved the Company's proposed indication for the Genio® system to treat patients with a Complete Concentric Collapse ("CCC"). DEKRA attributed the updated Genio® therapeutic indication to the BETTER SLEEP study data presented by the Company, concluding that "the effectiveness results and safety profile for both CCC and non-CCC patients are comparable". Patients, therefore, do not have to undergo a Drug-Induced Sleep Endoscopy (DISE) procedure to determine if they have CCC at the soft palate level prior to Genio® implantation.

"We are thrilled that the Notified Body has approved the Genio® system as a treatment option for the large population of CCC patients. This will expand our total addressable market by at least 30%.", said Olivier Taelman, CEO of Nyxoah. "Combined with the Breakthrough Device Designation granted by the U.S. FDA last month, the DEKRA approval provides further validation that our bilateral approach is well suited for both non-CCC and CCC patients. This broader indication will help accelerate our commercial activities in key European markets while we continue to pursue a clinical and regulatory pathway to make Genio® available to both non-CCC and CCC patients in the U.S."

Prof. Dr. med. Clemens Heiser, MD, PhD – Head of ENT Sleep Laboratory at Klinikum Rechts der Isar – Technical University of Munich and worldwide recognized Key Opinion Leader in sleep surgery commented: "Until now, Obstructive Sleep Apnea (OSA) patients presenting a CCC were not suitable for marketed unilateral hypoglossal nerve stimulation systems and had to be excluded from this technique. With previous research from my group, bilateral stimulation seems to open the soft palate even with CCC. Bilateral neurostimulation solution is a new hope for these patients in need for a safe and efficient therapy. A full-body 1.5T and 3T MRI compatibility combined with CCC indication for the Genio bilateral stimulation solution will change a lot in the future for hypoglossal nerve stimulation therapy."

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 received CE-Mark indication approval to treat 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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