PRESS RELEASE

Nyxoah receives FDA approval for full-body 1.5T and 3T MRI compatibility for the Genio® system to treat Obstructive Sleep Apnea (OSA)

Mont-Saint-Guibert, Belgium – 9th February 2021 – Nyxoah SA (Euronext: NYXH) ("Nyxoah" or the "Company"), a health-technology company focused on the development and commercialization of innovative solutions and services to treat Obstructive Sleep Apnea (OSA), today announces that the Company has received approval by the Food and Drug Administration (FDA) for the Magnetic Resonance Imaging (MRI) conditional labeling for the Genio® neurostimulation-based OSA therapy, currently being evaluated in the DREAM pivotal IDE study.

This revised labeling ensures that patients who receive the Genio® system and those already implanted can now undergo full-body 1.5T and 3T MRI diagnostic scans within approved parameters, and access the benefits of Genio® unique bilateral stimulation therapy.

The DREAM (Dual-sided Hypoglossal neRvE stimulAtion for the treatMent of Obstructive Sleep Apnea) study is an Investigational Device Exemption (IDE) trial designed to support the marketing authorization of the Genio® system in the United States. This is a multicenter study being conducted worldwide including sites in the United States, Germany, Belgium and Australia.

Olivier Taelman, Chief Executive Officer of Nyxoah, commented: "The approval by the Food and Drug Administration (FDA), received only a week after similar CE mark approval in Europe, confirms again the unique and unparalleled design of our technology. With the prevalence of MRI scans in the United States being one of the highest in the world, we are delighted that Nyxoah will be able to fulfil the currently unmet need for full-body 1.5T and 3T MR conditional labeling. Such an extensive labeling is unique to Nyxoah in the field of neurostimulation-based OSA therapies. Currently other therapies cannot fully address this need due to limitations to 1.5T MRI scans and body areas exclusion. As a company, Nyxoah always puts the patient first and seeks to ensure minimal disruption of their daily life and optimal Quality of Life (QOL)."

Prof. B. Tucker Woodson, MD, added: "As the Principal Investigator for the DREAM pivotal IDE study, I'm really pleased with the FDA approval for full-body 1.5T and 3T MRI compatibility for the Genio® system. MRI scans are often the preferred diagnostic imaging modality for comorbidities affecting OSA patients. This extensive MRI labeling will be a major benefit for all OSA patients who currently receive the Genio® therapy in the United States as part of the DREAM IDE clinical trial, ensuring that they can undergo MRI scans in full safety."

- ENDS -

For further information, please contact:
Nyxoah
Milena Venkova, Corporate Communications Manager
milena.venkova@nyxoah.com
+32 490 11 93 57

About Nyxoah
Nyxoah is a healthtech company focused on the development and commercialization of innovative solutions and services to treat Obstructive Sleep Apnea (OSA). Nyxoah's lead solution is the Genio® system, a CE-validated, patient-centered, next generation hypoglossal neurostimulation therapy for OSA, the world's most common sleep disordered breathing condition that is associated with increased mortality risk[1] and comorbidities including cardiovascular diseases, depression and stroke.
Following the successful completion of the BLAST OSA study in patients with moderate to severe OSA, the Genio® system received its European CE Mark in 2019. The Company is currently conducting the BETTER SLEEP study in Australia and New Zealand for therapy indication expansion, the DREAM IDE pivotal study for FDA approval and a post-marketing EliSA study in Europe to confirm the long-term safety and efficacy of the Genio® system.
For more information, please visit 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.

[1] Young T. et al: Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort, Sleep. 2008 Aug 1; 31(8): 1071–1078.