



PRESS RELEASE

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

Mont-Saint-Guibert, Belgium – 26th January, 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 the Company has received CE Mark Magnetic Resonance Imaging (MRI) conditional labeling for the current Genio® neurostimulation-based OSA therapy to treat Obstructive Sleep Apnea.

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.

Olivier Taelman, Chief Executive Officer of Nyxoah, commented: “We are delighted to announce full-body 1.5T and 3T MR conditional CE mark approval for the Genio® system, resulting from the unique and unparalleled design of our technology. 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. Dr. Clemens Heiser, MD, MHBA, PhD, ENT surgeon from Klinikum Rechts der Isar – Munich added: “Prevalence of MRI scans as diagnostic modality is growing, especially for OSA patients, as this condition is being associated with increased risk of comorbidities, such as cardiovascular diseases. The addition of 1.5T and 3T full-body MR conditional labeling for the Genio® system will be another critical benefit for my patients and will help me ensure those who may need an MRI can benefit from Nyxoah’s innovations with no fear for themselves and their implant during the exam”.

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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 risk¹ 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 – Genio[®] is 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.