PRESS RELEASE

First US patient implanted in the DREAM pivotal IDE study, with the Genio® system for the treatment of Obstructive Sleep Apnea (OSA)

DREAM is a pivotal, Investigational Device Exemption (IDE) study, designed to support marketing authorization in the United States

Mont-Saint-Guibert, Belgium – 5th January 2021 – Nyxoah S.A. (EBR: 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 successful implantation of the first US patient in the DREAM pivotal IDE study. The implantation took place at the Nose and Sinus Institute Boca Raton, Florida and was performed by Dr. Melyssa Hancock, Otolaryngology-Head & Neck surgeon.

The DREAM (Dual-sided Hypoglossal neRvE stimulAtion for the treatMent of Obstructive Sleep Apnea) study is a pivotal, Investigational Device Exemption (IDE) trial designed to support the marketing authorization of the Genio® system in the United States. This multicenter, prospective, open-label, observational study will enroll 134 patients, who will undergo the implantation procedure in up to 26 centers worldwide including sites in the United States, Germany, Belgium and Australia.

Dr. Melyssa Hancock, implanting surgeon from the Nose and Sinus Institute Boca Raton commented: " We are very excited to be chosen as the first center in the United States to implant the Genio system in a patient for treatment of obstructive sleep apnea. The teaming of the Nose and Sinus Institute of Boca Raton with the innovators at Nyxoah represents the collaboration of some of the most experienced surgeons in the United States today treating nose and airway issues with a team of brilliant international engineers. During this time of COVID-19 and virtual adaptation to everything we do, the fact that we were able to communicate in real-time during the procedure with other surgeons globally who have extensive experience with this device made it a truly extraordinary and successful endeavor."

Olivier Taelman, Chief Executive Officer of Nyxoah, added: "I'm really proud of Nyxoah's team reaching another key milestone despite all challenges due to the Covid-19 pandemic and would like to congratulate Dr. Hancock and her team for implanting the first US patient with the Genio® system. Enabling US physicians to build their experience with the Genio® system, combined with the existing expertise of other international surgeons participating in the DREAM study, is supporting Nyxoah's timeline for the pivotal IDE study enrollment closing by the end of Q2 2021.

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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.