Nyxoah receives IDE approval from the U.S. Food and Drug Administration (FDA) for its DREAM study

June 24, 2020

Study supporting the approval of Nyxoah's Genio ® system in the U.S. to be initiated in the coming months

Nyxoah S.A., a healthtech company focused on the development and commercialization of innovative solutions and services to treat sleep disordered breathing conditions, today announces that the U.S. Food and Drug Administration (FDA) has approved its Investigational Device Exemption (IDE) application to allow Nyxoah to commence its pivotal DREAM study of its Genio® system to support its approval in the U.S. Nyxoah will initiate the DREAM study in the coming months.

"We are delighted with the FDA approval of our IDE application. This is a significant milestone for Nyxoah that allows us to bring forth our plans for the U.S. introduction of the Genio® system and further increase our global footprint alongside our existing presence in Europe and Australia." said Olivier Taelman, CEO of Nyxoah.

"This major step will allow us to give the first U.S. patients suffering from Obstructive Sleep Apnea (OSA) access to Genio ® therapy under the DREAM study and to provide U.S. physicians with the opportunity to build expertise with our solution. We are excited to partner with the selected DREAM study centers in the U.S. and internationally."

The DREAM study is a prospective multicenter trial that will enroll 134 moderate to severe OSA patients who failed first line CPAP therapy in approximately 25 centers in the U.S. and internationally. The study aims to confirm the safety and effectiveness of the Genio® system.

About Obstructive Sleep Apnea (OSA) and the Genio® system

OSA is the world's most common sleep disordered breathing condition, affecting almost one billion people globally [1]. It makes a person stop breathing during sleep, while the airway repeatedly becomes partially (hypopnea) or totally (apnea) blocked, limiting the amount of air that reaches the lungs. OSA is a chronic condition that is associated with increased mortality risk and comorbidities, including cardiovascular diseases, type 2 diabetes, obesity, depression and stroke. The current standard of care consists of Continuous Positive Airway Pressure (CPAP) therapy, a treatment whereby air is pushed into the upper airway to keep it open.

The Genio® system is the world's first and only, battery-free, leadless and minimally invasive implanted neurostimulator designed to keep the upper airway open during sleep for certain people with OSA by bilateral stimulation of the hypoglossal nerve.

About Nyxoah

Nyxoah is a healthtech company focused on the development and commercialization of innovative solutions and services for sleep disordered breathing conditions. Nyxoah's lead solution is the Genio ® system, a validated, user-centered, next generation hypoglossal neurostimulation therapy for OSA, the world's most common sleep disordered breathing condition that is associated with increased mortality risk [2] and comorbidities including cardiovascular diseases, depression and stroke.

Following successful completion of the BLAST OSA study in patients with moderate to severe OSA, the Genio® system received its European CE Mark in March 2019. The Company is currently conducting the BETTER SLEEP study in Australia and New Zealand for therapy indication expansion, 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 United States federal law to investigational use.*

1 Benjafield, Adam V et al. Estimation of the global prevalence and burden of obstructive sleep apnea: a literature-based analysis. Lancet Respir Med 2019 Published Online July 9, 2019 http://dx.doi.org/10.1016/S2213-2600(19)30198-5

2 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.