Successful first implantation of two patients in Benelux with the Genio® system, a novel Obstructive Sleep Apnea solution by Nyxoah

- ***The Genio® system is an innovative hypoglossal neurostimulator (HGNS) developed and marketed by Nyxoah, a Belgian company, to treat Obstructive Sleep Apnea***
- ***Implanted in two patients suffering from Obstructive Sleep Apnea (OSA) who failed conventional OSA therapy***
- ***Implantations were conducted by the team of ENT, Head and Neck surgeon and Sleep Apnea expert Prof. Dr. Olivier Vanderveken, MD, PhD, at Antwerp University Hospital UZA in Edegem, Antwerp, Belgium***

Mont-Saint-Guibert, Belgium – 9 March 2020, Nyxoah S.A., a healthtech company focused on the development and commercialisation of innovative solutions and services to treat sleep disordered breathing conditions, today announces the successful first two implantations of its Genio® system in the Benelux region.

The procedures were performed at the Antwerp University Hospital (UZA) in Belgium and were led by internationally renowned ENT surgeon and OSA expert, Prof. Dr. Olivier Vanderveken, MD, PhD.

Prof. Dr. Olivier Vanderveken, MD, PhD, Head of the ENT Department at UZA, commented: "I am excited to have led the very first implantations of this unique therapy in Benelux. OSA is a very serious condition which, if left untreated, can lead to severe co-morbidities and even death. There are many patients in need of alternative therapeutic solutions to the conventional Continuous Positive Airway Pressure (CPAP) therapy and my team at UZA is a leader in this field. The Genio® system is minimally invasive, involving just one incision in the chin area, and doesn't require tunnelling, long leads or an internal battery. Moreover, thanks to its unique design and features, the Genio® system offers bilateral stimulation of the hypoglossal nerve branches, which may lead to a potentially greater airway opening. I am looking forward to continuing to work with Nyxoah to bring this much needed innovation to more patients suffering from moderate to severe OSA in Belgium and internationally."

Olivier Taelman, CEO of Nyxoah, added: "We are delighted to have introduced the Genio® system in Nyxoah's home country. This is a key milestone for Nyxoah as we continue to accelerate our efforts to bring this disruptive solution to the market and address a significant current unmet medical need. This, and further implantations in Belgium, will also add to Nyxoah's body of data as we develop long-term clinical evidence on the Genio® system, prepare for the IDE pivotal trial in the United States and accelerate the ongoing market access and commercialisation activities."

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 commercialisation 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. The IDE pivotal study to prepare for US market entrance is currently in discussion with the FDA.

For more information, please visit www.nyxoah.com.

Caution *– CE marked since 2019. Investigational device in the United States. Limited by 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.