



Nyxoah announces data demonstrating the benefits and safety of its Genio® system implantation technique for the treatment of Obstructive Sleep Apnea published in *Laryngoscope Investigative Otolaryngology*

- *Data show that the implantation procedure of the Genio® system is relatively non-invasive*
- *Implantation was safe, and its therapeutic benefit demonstrated in reducing apnea and hypopnea events in a single case study*

Mont-Saint-Guibert, Belgium – 27 November 2019, Nyxoah S.A., a healthtech company focused on the development of innovative solutions and services for sleep related disorders, today announces that data demonstrating the benefits and safety of its Genio® system implantation technique for the treatment of Obstructive Sleep Apnea (OSA) have been published in [*Laryngoscope Investigative Otolaryngology*](#).

Unlike other devices for OSA that comprise a cuff electrode wrapped around the hypoglossal nerve, the Genio® system offers bilateral stimulation of the hypoglossal nerve branches, which may lead to potentially greater airway opening. This study describes the surgical implantation of the Genio® nerve stimulator, which is minimally invasive, involving just one incision in the chin area, no tunnelling, and no long leads or internal battery. Other devices require additional incision sites for implanting sensing/stimulating leads and a pulse generator.

The recently completed [clinical study](#) (the BLAST OSA study) also provides evidence as to the acceptable safety profile and the therapeutic benefits of the Genio® system.

Dr. Richard Lewis, MBBS, FRACS, Head & Neck Surgeon and lead author of this publication commented: “Unlike other commercially available devices for OSA, which involve multiple incision sites, the Genio® system only requires a minimal surgical procedure, with one incision site beneath the chin. The results from the BLAST OSA study have been very encouraging, and the bilateral stimulation of the hypoglossal nerve, which is unique to the Genio® system, may provide a therapeutic advantage over unilateral stimulation. We are already well into our next, larger clinical study which is being conducted in Australia and New Zealand, and I look forward to continuing to support the Company with the development and improvement of the Genio® system for the benefit of OSA patients worldwide.”

Robert Taub, Co-Founder and Executive Chairman of Nyxoah, said: “We are pleased to announce the publication of these data demonstrating the safe implantation technique and therapeutic benefit of our Genio® system. Following the recent positive outcomes of the



BLAST OSA study, on which our CE Mark registration is based, we will continue to build a strong body of evidence to continue to support the positive results seen so far.”

The Genio® system is the world’s first and only battery-free, leadless and minimally invasive neurostimulator and is capable of delivering bilateral hypoglossal nerve stimulation in moderate to severe OSA patients who have not tolerated, have failed or refused Positive Airway Pressure (PAP) therapy.

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

OSA is the world’s most common sleep disorder, affecting almost one billion people globally.¹ OSA 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 associated with increased mortality risk and comorbidities, including cardiovascular diseases, depression and stroke. The current standard of care consists of Positive Airway Pressure (PAP) therapy, a treatment whereby air is pushed into the upper airway via a mask connected to a pump. Despite its proven efficacy, there are many limitations to this therapeutic option meaning compliance is a serious challenge.

The Genio® system is the world’s first and only, battery-free, leadless and minimally invasive implanted neurostimulator that helps keep the upper airway open, allowing patients to breathe better while sleeping. It offers a simple, convenient, safe and effective alternative to PAP, addressing the needs of patients seeking another treatment option.

About Nyxoah

Nyxoah is a healthtech company focused on the development of innovative, neurostimulation-based solutions and services for sleep related disorders. Nyxoah’s lead technology is the Genio® system, the world’s first and only, battery-free, leadless and minimally invasive implanted neurostimulator that treats the underlying cause of Obstructive Sleep Apnea (OSA), a market worth approximately \$10bn in the United States alone.

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 and a post-marketing ELISA study in Europe to assess long-term safety and efficacy of the Genio® system. The US trial programme for FDA approval is in preparation.

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

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



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