Nyxoah Receives European CE Mark Approval for the Genio® System, a Disruptive Neurostimulation Solution for Obstructive Sleep Apnea Therapy

Mont-Saint-Guibert, Belgium – March 20th, 2019

Nyxoah S.A., a healthtech company focusing on the development of innovative solutions and services for sleep related disorders, today announced that the company has received CE Mark approval for the Genio® system in Europe.

The Genio® system is the world's first and only battery-free, leadless and minimally invasive neurostimulator, capable of delivering bilateral hypoglossal nerve stimulation for moderate to severe OSA patients who have failed conventional Positive Airway Pressure (PAP) therapy.

The CE Mark approval was based on data from the Nyxoah BLAST OSA (BiLAteral Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea) clinical study. The BLAST OSA trial is a prospective study that evaluated the safety and performance of the Genio® system in 7 centers in France and Australia. The BLAST OSA study results will be published in a leading medical journal later in 2019.

Robert Taub, Chairman of the Nyxoah Board said: "Obstructive Sleep Apnea (OSA) is the most common Sleep Disordered Breathing condition. International sleep experts recently estimated that nearly 1 Billion people worldwide suffer from sleep apnea. Existing therapeutic solutions are often not accepted or are poorly tolerated by patients. The sleep community is looking for alternative solutions for OSA patients who refuse currently available therapies or are not compliant. The Genio® system will help many OSA patients in need for a better solution. Having now received CE mark, the Nyxoah Genio® system is well on its way to fulfil this need".

"Patients from the BLAST OSA study show a major improvement in their sleep apnea symptoms and their Quality of Life" said Enrique Vega, Chief Executive Officer of Nyxoah S.A. "The BLAST OSA study results and the continuous dedication of the whole Nyxoah team were instrumental in obtaining CE approval, which marks a major milestone for Nyxoah."

Nyxoah is now focusing on gathering additional clinical evidence on the Genio® system, initiating European market development activities and working toward gaining approval by the US Food and Drug Administration (FDA).

About Nyxoah

Nyxoah S.A., headquarted in Mont-Saint-Guibert – Belgium, is a healthtech company focused on the development of innovative, neurostimulation-based solutions and services for sleep related disorders. Nyxoah S.A. was co-founded in 2009 by Robert Taub.

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

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SOURCE: Nyxoah S.A.