



**PRESS RELEASE**

**First Patient Implanted in the DREAM US 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 – 17<sup>th</sup> November 2020** – 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 sleep disordered breathing conditions, today announces the successful implantation of the first patient in the DREAM US pivotal FDA study. The implantation took place at Hollywood Private Hospital in Perth, Australia and was performed by Dr. Richard Lewis, MBBS, FRACS, 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. Richard Lewis, implanting surgeon from Hollywood Private Hospital commented:** “ Our center has an extensive historical collaboration with Nyxoah. We took part in the BLAST OSA study that led to CE Mark approval of the Genio® system and we are the lead investigator center in the ongoing BETTER SLEEP study testing the effectiveness of hypoglossal nerve stimulation on Complete Concentric Collapse (CCC) patients who are currently excluded from this type of therapy. We are excited to be part of the DREAM IDE pivotal trial together with US and European physicians and are thrilled to build further clinical evidence on the Genio® system giving more patients across the globe access to this innovative OSA therapy.”

**Olivier Taelman, Chief Executive Officer of Nyxoah, added:** “The United States are the largest market in the world for the treatment of patients suffering from Obstructive Sleep Apnea. The DREAM study is designed to support the U.S. introduction of the Genio® system. Enabling US physicians to build their first experience with the Genio® system, combined with the knowledge of other already experienced international surgeons, is supporting Nyxoah’s mission to offer its disruptive therapy to more OSA patients around the world.

**- ENDS -**

**For further information, please contact:**

**Nyxoah**

Rémi Renard, VP Therapy Development and Education

[remi.renard@nyxoah.com](mailto:remi.renard@nyxoah.com)

+32 472 12 64 40

**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<sup>®</sup> system, a CE-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<sup>1</sup> 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<sup>®</sup> 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, 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<sup>®</sup> system.

For more information, please visit [www.nyxoah.com](http://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.

---

<sup>1</sup> 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.