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# Nyxoah BETTER SLEEP Trial Reaches its Primary Endpoints

**Mont-Saint-Guibert, Belgium – 7 June 2021, 7:00 am CET / 1:00 am ET – Nyxoah SA (Euronext Brussels: NYXH)** ("Nyxoah" or the "Company"), a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea (OSA), today announced that the BETTER SLEEP trial reached its primary safety and performance endpoints.

The BETTER SLEEP trial was designed to assess the long-term safety and performance of the Genio® bilateral hypoglossal nerve stimulation system (the "Genio® system") in 42 adult OSA patients with and without Complete Concentric Collapse (CCC) of the soft palate.

Top-line results from the BETTER SLEEP study showed:

- A statistically significant mean reduction in Apnea Hypopnea Index (AHI) from baseline to six months post implantation in the whole cohort (CCC and non-CCC patients)
- A statistically significant mean reduction in AHI from baseline to six months post implantation in the CCC patient subgroup
- 42.9% of the study population had CCC

The Company expects to announce additional data with respect to the study as further analyses are conducted.

Dr. Richard Lewis, MBBS, FRACS, Principal Investigator of the BETTER SLEEP study, from Royal Perth Hospital and the University of Western Australia commented: "The top-line results of the BETTER SLEEP study are extremely encouraging. The most impressive aspect of the results is the responder rate of the CCC patient subgroup. These patients are excluded from unilateral hypoglossal nerve stimulation, but the BETTER SLEEP results showed a significant reduction in AHI in these patients following treatment with the Genio® system, which is the first device designed to deliver bilateral stimulation of the hypoglossal nerve. Overall, we have achieved a very high responder rate in both CCC and non-CCC patients, and the treatment with the Genio® system was well tolerated. We look forward to publishing this data in a leading medical journal."

Olivier Taelman, CEO of Nyxoah, stated: "We are excited by the top-line data, with the primary performance and safety endpoints met, supporting our belief that the Genio® system's bilateral stimulation of the hypoglossal nerve, has the potential to provide positive clinical outcomes for patients with CCC. We already engaged with the EU Notified Body to review these study data, with the goal of expanding the CE-marked indication to include CCC patients. In parallel, we plan to initiate dialogue with the FDA to further discuss the Genio® system as a potential treatment option for patients with CCC." Mr.

Taelman continued, “Additionally, we observed a 70% responder rate in the non-CCC patient subgroup based on the Sher criteria, which strengthens our confidence in ongoing study outcomes.”

**About BETTER SLEEP Trial**

BilatEral Hypoglossal Nerve StimulaTion for TreatmEnt of ObstRuctive SLEEP Apnoea, or BETTER SLEEP, is a multicenter, prospective, open-label, two-group clinical trial, designed to assess the safety and performance of the Genio® system for the treatment of OSA in adult patients with and without CCC. The BETTER SLEEP trial includes a subgroup of CCC patients who are currently contraindicated for unilateral hypoglossal nerve stimulation. The trial was authorized by the Australian and New Zealand regulatory authorities and is being conducted in nine local medical centers. The primary safety endpoint was the incidence of device-related serious adverse events six months post-implantation. The primary performance endpoint was the change in the AHI score from baseline to six months post-implantation measured by counting the number of events (apnea or hypopnea) that occur per hour collected during an overnight sleep study. Patients with moderate to severe AHI scores between 15 and 65 and aged between 21 and 75 years were eligible for enrollment if they failed, refused, or did not tolerate PAP treatment. Patients with a body mass index above 32 kg/m² were excluded.

**About Nyxoah**

Nyxoah is a medical technology company focused on the development and commercialization of innovative solutions to treat OSA. Nyxoah’s lead solution is the Genio® system, a CE-marked, patient-centered, minimally invasive, next generation hypoglossal neurostimulation therapy for treatment of moderate to severe OSA. OSA is the world’s most common sleep disordered breathing condition that is associated with increased mortality risk and comorbidities including cardiovascular diseases, depression and stroke.

Following the successful completion of the BLAST OSA study in patients with moderate to severe OSA, the Genio® system received its European CE Mark in 2019. The Company is currently conducting the BETTER SLEEP study in Australia and New Zealand for potential CE-mark indication expansion, the DREAM IDE pivotal study for potential FDA approval and the post-marketing EliSA study in Europe to evaluate 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 U.S. federal law to investigational use in the United States.

**Forward-Looking Statements**

This press release includes certain disclosures that contain “forward-looking statements,” including, without limitation, statements regarding Nyxoah’s expectations regarding the Genio® system; planned and ongoing clinical studies of the Genio® system; the potential advantages of the Genio® system; Nyxoah’s goals with respect to the development, regulatory pathway and potential use of the Genio® system; and the utility of prior clinical data, including data from the BETTER SLEEP study, in potentially

obtaining FDA approval of the Genio® system. Forward-looking statements are based on Nyxoah's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict and could cause actual results to differ. Forward-looking statements contained in this announcement are made as of this date, and Nyxoah undertakes no duty to update such information except as required under applicable law.

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