

## Neural Stimulation for Drug Resistant Epilepsy

**SYNERGIA MEDICAL SUCCESSFULLY IMPLANTS  
FIRST PATIENTS WITH NAO.VNS™**

Brussels, 23 September 2024 – Synergia Medical, a leader in the development of optoelectronic medical devices, is pleased to announce the successful implantation of its groundbreaking NAO.VNS system in the first two patients as part of the AURORA study. These first-in-human implantations took place on September 6, 2024, at Cliniques Universitaires Saint-Luc and UZ Gent. Two weeks after surgery, both patients have fully recovered, allowing the initiation of stimulation therapy as planned.

The AURORA study is designed to evaluate the safety of the NAO.VNS™ system for patients with Drug-Resistant Epilepsy (DRE). The successful implantations, performed by Dr. Herbert Rooijackers at Cliniques Universitaires Saint-Luc and Dr. Frank Dewael at UZ Gent, mark a critical milestone in this first-in-human study.

"We are excited to be part of this optical revolution in neuromodulation," said Dr. Herbert Rooijackers and Dr. Frank Dewael, the lead surgeons at Cliniques Universitaires Saint-Luc and UZ Gent, respectively. "This technology has the potential to transform how we treat epilepsy and other neurological disorders, offering new hope to patients who have exhausted traditional options."

**Prof. Dr. Kristl Vonck, Principal Investigator at UZ Gent, and Dr. Riëm El Tahry, Principal Investigator at Cliniques Universitaires Saint-Luc**, emphasized the significance of the NAO.VNS system's MRI compatibility. "Ensuring full access to the benefits of MRI in healthcare is crucial, and this device offers that advantage to all our patients implanted with VNS," said Prof. Vonck. Dr. El Tahry added, "This compatibility allows us to better personalize and improve VNS therapy in the future by leveraging MRI imaging."

"We are thrilled with the success of these first implantations, which brings us one step closer to providing a new, innovative treatment option for patients with drug-resistant epilepsy," said **Attila Borbáth, CEO and co-founder of Synergia Medical**. "The full recovery of the first 2 patients and the commencement of stimulation therapy demonstrate the potential of the NAO.VNS™ system to improve patient safety and outcomes."



The NAO.VNS™ system, developed by Synergia Medical, is a new generation neural stimulator that can reduce epileptic seizures by stimulation of the vagus nerve (VNS). Neural stimulation is a clinically proven solution and the last resort for patients suffering from drug-resistant neurological diseases. It involves the implantation of a small pacemaker that delivers mild electric signals to targeted nerves or brain cells. NAO.VNS™ unique design allows for safe and easy MRI & fMRI scans which therefore enable a personalized treatment, adapted to each patient's needs. It is powered by a rechargeable battery, extending the device lifespan, as well as enabling continuous collection of patient data through dedicated biomarkers.

The AURORA study will continue to monitor the safety of the NAO.VNS™ system over a 24-month period, focusing on key safety endpoints such as the incidence of device-related adverse events and procedure-related adverse events. Following the successful completion of the AURORA study, Synergia Medical plans to initiate a pivotal trial across Europe, the USA, and Canada to assess the efficacy of the NAO.VNS™ system.

For more information about the AURORA study or the NAO.VNS™ system, please contact:

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### **About Epilepsy and Drug-Resistant Epilepsy**

Epilepsy is the 4<sup>th</sup> most common neurological disorder affecting over 10 million adults and children in the EU & US. The conventional medical treatment is with anti-epileptic drugs but 30% of the epilepsy population see their symptoms poorly controlled and continue to have seizures that impair their health and daily lives. Of the 220,000 new epilepsy patients diagnosed every year in the US and in Europe, 66,000 suffer from drug-resistant epilepsy and are in dire need for a safe treatment that will help them control their seizures. Overall, more than 1.15 million epilepsy patients are currently waiting for an effective therapy.

### **About NAO.VNS™ – Optoelectronics for Vagus Nerve Stimulation**

NAO.VNS™ is unique in its use of optoelectronic technology, which minimizes the use of metallic components by utilizing innovative materials such as quartz, polymer optical fibers, and miniaturized photovoltaic cells. These materials allow the device to deliver vagus nerve stimulation with several competitive advantages, including unconditional MRI compatibility, extended battery life with ultra-fast recharging, and enhanced cybersecurity through optical communication. Additionally, the optoelectronic platform paves the way for the development of future light-based therapies, which could offer more precise and less invasive treatment options.

### **About Synergia Medical**

Synergia Medical is a leader in the development of innovative optoelectronic medical devices focused on transforming patient care through advanced technology. Operational since 2015, the Company is based in Belgium, employing nearly 20 employees. Since its inception, Synergia Medical benefits from the support of a wide range of public, private, and independent investors. Synergia Medical is also financed by the Wallonia Region and by the European Union through the EIC program.

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