

Press Release

Neural Stimulation for Drug-Resistant Epilepsy

SYNERGIA MEDICAL ANNOUNCES:

FIVE PATIENTS NOW IMPLANTED WITH NAO.VNS™

LEADERSHIP CHANGE: CHARLES NOLET TO SUCCEED ATTILA BORBATH AS CEO

Brussels, January 13, 2025. Synergia Medical SA, a leader in developing optoelectronic medical devices, is pleased to announce the successful implantation of its groundbreaking NAO.VNS™ system in three more patients, bringing the total to five, as part of the AURORA study. These First-In-Human implantations took place at Cliniques Universitaires Saint-Luc and UZ Gent, Belgium. All patients have fully recovered, allowing the initiation of stimulation therapy as planned.

Early patient responses are highly promising, and full results from these first clinical trials are expected in the next few weeks.

The Board of Directors of Synergia Medical has appointed Mr. Charles Nolet as the new Chief Executive Officer, effective February 1, 2025, succeeding Mr. Attila Borbath.

Mr. Charles Nolet holds an MBA from MIT Sloan focused on Medtech, advanced analytics, and private equity. He brings significant strategic and operational expertise, including from his tenure at McKinsey & Company. Following this, he served as Investment Manager at Lumine Capital Advisors, where he supported entrepreneurs and start-ups, particularly in the MedTech sector, enhancing value for private equity stakeholders. Most recently, he served as Chief Strategy Officer for Synergia Medical, where he played a key role in refining the company's strategy and guiding management during a pivotal phase.

"I am honored to lead the next exciting phase in Synergia Medical's development. As we transition from R&D to full clinical trials, following the successful First-In-Human implantations, our immediate priority is to put in place a scalable manufacturing process and financing to meet the product needs for pivotal clinical trials and future commercial launch," **said Charles Nolet, CEO.** "I am looking forward to working with our talented team on the transformation, which is so important to providing a new, innovative treatment option for patients with drug-resistant epilepsy."

The Board of Directors thanks Mr. Attila Borbath for his substantial contribution to Synergia Medical's research and development phase, which culminated in the start of clinical trials. During his tenure, Synergia Medical developed its breakthrough innovation using optoelectronics for Vagus Nerve Stimulation. It has built a solid IP portfolio, carried out pre-clinical studies, and most recently successfully implanted five FIH patients.



About the AURORA study

The AURORA study¹ 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. The Principal Investigators are Prof. Dr. Kristl Vonck, Principal Investigator at UZ Gent, and Dr. Riëm El Tahry, Principal Investigator at Cliniques Universitaires Saint-Luc.

To date, no reportable safety events have been identified from the device implantation or therapy delivery. The AURORA study will continue to monitor the safety of the NAO.VNS™ system over 24 months, 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.

About Epilepsy and Drug-Resistant Epilepsy²

Epilepsy is the 4th 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 have drug-resistant epilepsy and are in dire need of a safe treatment that will help them control their seizures. Overall, more than 1.15 million epilepsy patients are currently waiting for effective therapy.

About NAO.VNS™ – Optoelectronics for Vagus Nerve Stimulation

NAO.VNS™ is unique in its optoelectronic technology, which minimizes the use of metallic components by utilizing innovative materials such as quartz, polymer optical fibers, and miniaturized photovoltaic cells. The NAO.VNS™ system, developed by Synergia Medical, is a new-generation neural stimulator that can reduce epileptic seizures by stimulating 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 tiny pacemaker that delivers mild electric signals to targeted nerves or brain cells. The unique design of NAO.VNS™ 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's lifespan and allowing continuous patient data collection through dedicated biomarkers.

About Synergia Medical

Synergia Medical is a leader in the development of innovative optoelectronic medical devices focused on transforming patient care through advanced technology. The company has been operational since 2015 and is based in Belgium. It employs c.20 people. Since its inception, Synergia Medical has received support from many public, private, and independent investors. The Wallonia Region and the European Union also finance Synergia Medical through the EIC program.

1. <https://clinicaltrials.gov/study/NCT06340802>

2. Sources: <https://www.cdc.gov/epilepsy/data/index.html> & International Bureau for Epilepsy

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