Press Release

Vagus Nerve Stimulation for Drug Resistant Epilepsy

SYNERGIA MEDICAL ANNOUNCES STRONG RESULTS FOR NAO.VNS™ FIRST-IN-HUMAN STUDY

- **Primary safety endpoint met - No serious adverse events reported over 3-months**
- **Robust device performance - No device failure reported over 3-months**

Brussels, February 24, 2025 – Synergia Medical announces that its NAO.VNS™ device, successfully implanted in five patients at UZ Gent and Cliniques universitaires Saint-Luc in Belgium, has met the primary safety endpoint in the AURORA first-in-human clinical study. **Synergia Medical's technology is a next-generation neuromodulation platform** that eliminates the main metal components of traditional devices, ensuring immunity to electromagnetic interference (EMI). It **enhances patient safety and care** with full compatibility across MRI and other EMI sources (e.g., electrosurgery, defibrillators) and features a fast-recharge battery with an expected lifetime of 15 years with just one minute of daily charging. The NAO platform holds the potential to **optimize therapy** by remaining fully active during imaging, allowing physicians to adjust treatment in real time while observing brain responses, while its long-lasting battery supports energy-intensive stimulation for more effective therapeutic outcomes. Synergia is pursuing its first indication to treat drug-resistant epilepsy (DRE) via vagus nerve stimulation (VNS). **Three months post-implantation, results confirm strong safety, robust device performance, and positive patient outcomes. Synergia plans to now move into a pivotal FDA and CE trial.**

AURORA FIH study results - At 3 months post-implantation, the **study met its primary endpoint** and had very low incidence of minor procedure/device-related adverse events, along with the following **key findings:**

- **Strong safety profile** – No serious adverse events reported. Minor device-related events included coughing, intermittent voice alteration and mild skin numbness near the site of insertion, all typical of current VNS.
- **Robust device performance** – 100% successful implantation and titration, with effective therapy delivery confirmed via physiological and clinical markers. Reliable performance confirmed with device self-check. Zero implant failures were observed during the 3 months post-implantation.
- **Favorable early clinical outcomes** – Encouraging therapeutic response with 40% responder rate (≥50% seizure reduction) at 3 months post-implantation, in line with current VNS. Notably, the first implanted patient reports seizure freedom at six months, with other 6-month follow-ups still pending. Positive trends were observed in quality-of-life, seizure severity and depression. Patients reported benefits from activating additional magnet stimulation to manage ongoing seizures.
- **Positive user experience** – Recharge efficiency was ~1 min daily or ~7 min per week.

"*We are thrilled by the strong safety and reliability of our NAO.VNS™ device*," said **Charles Nolet, CEO of Synergia Medical**. "*The promising results and positive patient feedback bring us closer to a breakthrough for drug-resistant epilepsy. Building on this success, we are preparing to submit our request for a pivotal clinical study in the U.S. and Europe.*"

Prof. Dr. Kristl Vonck, Principal Investigator at UZ Gent, commented: *"These results demonstrate both safety and reliability in real-world settings for this innovative technology. The MRI access without restriction represents a major leap forward in neuromodulation. Seeing already therapeutic benefits is promising and we look forward to the long-term impact."*

Prof. Dr. Riëm El Tahry, Principal Investigator at Cliniques universitaires Saint-Luc, added: *"Patients were particularly appreciative of the extended battery life, which reduces the need for frequent surgical replacements. The ease of recharging has also been well received by both patients and caregivers, making long-term management more convenient."*

About Synergia Medical technology – Neuromodulation Advanced with Optoelectronic (NAO)

Synergia Medical pioneers optoelectronic technology to advance neuromodulation therapies. Its next-generation platform addresses the limitations of traditional neurostimulators. By replacing metal components with biocompatible materials such as quartz, polymer optical fibers, and miniaturized photovoltaic cells, the technology ensures unparalleled EMI immunity while delivering key advantages over traditional metal-based devices:

- **Full MRI compatibility** – No restrictions on MRI scans (100–150M annually worldwide[2]), eliminating patient care limitations and burdens. Full activity during imaging enables physicians to adjust therapy in real time while observing brain responses—an approach many neurologists believe could enhance VNS efficacy.
- **EMI immunity** – Groundbreaking protection against widely used medical EMI sources such as electrosurgery (utilized in 80% of surgeries[3]) and defibrillators, ensuring greater safety in patient care.
- **Extended battery life & fast recharging** – EMI-related power inefficiencies are eliminated, allowing for a rapid recharge—just 1 minute daily—for an expected long-term battery lifetime of 15 years. This significantly reduces replacement surgeries and supports energy-intensive stimulation modes that could enhance therapy.
- **Enhanced cybersecurity** – Closed-loop optical communication minimizes exposure to external and remote hacking, providing a highly secure system.

Synergia Medical, a Belgium-based company, has been supported by both public and private investors since its founding in 2015, including funding from the Wallonia Region and the European Union's EIC program.

For more information, visit www.synergiamedical.com

About drug resistant epilepsy (DRE) and vagus nerve stimulation (VNS)

Synergia Medical primary indication is Epilepsy affects **50 million people** globally and is the **4th most common neurological disorder**[4]. When two anti-epileptic drugs fail, **DRE (Drug-Resistant Epilepsy)** is diagnosed, affecting **30% of patients** with severe health, personal, and economic impacts[5,6]. **DRE patients face a 10x higher risk of premature death** and increased depression[7,8]. Vagus nerve stimulation (VNS), which involves the implantation of a small pacemaker that delivers mild electric signals to the vagus nerve, is a clinically proven solution for DRE that **helps reduce seizures, improve mood, and enhance quality of life**[9-11].

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