synchron

Press Release, July 28, 2021

Synchron receives green light from FDA to begin breakthrough trial of implantable brain computer interface in US

Clinical trial to pave the way for Synchron's Stentrode™ to become first commercially available implantable brain computer interface

NEW YORK, NY July 28, 2021 – Synchron, a venture-backed brain data transfer company, today announced that the U.S. Food and Drug Administration (FDA) has approved its Investigational Device Exemption (IDE) application for its flagship product, the *Stentrode*™ motor neuroprosthesis. This early feasibility study (EFS) of the device will begin later this year at Mount Sinai Hospital, New York, and will assess the safety and efficacy in patients with severe paralysis. Outcomes will include the use of the brain data to control digital devices and achieve improvements in functional independence. The FDA granted Breakthrough Device designation to Synchron in August 2020.

"The approval of this IDE reflects years of safety testing performed in conjunction with FDA. We have worked together to pave a pathway forward, towards the first commercial approval for a permanently implanted BCI for the treatment of paralysis. We are thrilled to finally be launching a U.S. clinical trial this year," said Synchron CEO Thomas Oxley, MD, PhD.

Synchron's technology solves multiple challenges that have restricted the commercial translation of BCIs out of the experimental laboratory. Other implantable BCI approaches involve drilling into the skull and placing needle electrodes directly into the brain tissue, which can result in long term brain inflammation. The Stentrode device is delivered into the brain via the blood vessels in a minimally invasive 2-hour procedure, similar to the insertion of stents in the heart. No robotic assistance is required for the procedure, which can be performed in widely available angiography suites. The implant is fully internalized with no wires coming out of the head or body.

Patients begin using the device at home soon after implantation and may wirelessly control external devices by thinking about moving their limbs. The system is designed to facilitate better communication and functional independence for patients by enabling daily tasks like texting, emailing, online commerce and accessing telemedicine.

"Synchron's north star is to achieve whole-brain data transfer," continued Oxley. "The blood vessels provide surgery-free access to all regions of the brain, and at scale. Our first target is the motor cortex for treatment of paralysis, which represents a large unmet need for millions of people across the world, and market opportunity of $20B."

Synchron is collaborating with Carnegie Mellon University, the University of Pittsburgh Medical Center and Mount Sinai Health System, New York City, on the new study, the COMMAND trial. A total of six patients are planned for the trial, with enrollment beginning later this year.

Synchron continues to evaluate the device in the SWITCH clinical trial currently underway in Australia. Four patients have received the Stentrode implant and are utilizing this neuroprosthesis for data transfer from motor cortex to control digital devices. Data from the first two patients in this study, which were published in the *Journal of NeuroInterventional Surgery* (JNIS) in October 2020, demonstrated each patient was able to control their devices to text and type through direct thought. Following implantation and a short period of machine learning-assisted training, they were able to use the system unsupervised in their homes to send text messages, do online shopping and manage their finances.

About the Stentrode™

Synchron's foundational technology, a motor neuroprosthesis (MNP), is implanted via the jugular vein using neurointerventional techniques. The system is designed for patients suffering from paralysis as a result of a broad range of conditions, and aims to be user friendly and dependable for patients to use autonomously.

About Synchron, Inc.

Synchron is a venture-backed brain data transfer company headquartered in New York City. It is a leader in the field of implantable neural interface technology. The company is in the clinical stage with a commercial neuroprosthesis for the treatment of paralysis and is developing the first endovascular implantable neuromodulation therapy. Future applications of the brain data transfer technology include epilepsy, depression, and sleep. Synchron has offices in Silicon Valley, California and R&D facilities in Melbourne, Australia.

###

Media Contact

Tara DiMilia
908-369-7168
media@synchron.com