Abstract Title: Long-Term Safety of a Fully Implanted Endovascular Brain-Computer Interface for Severe Paralysis: Results of SWITCH, a First-in-Human Study

Authors: Bruce Campbell¹, Chiu Mun Sarah Lee², Peter Yoo³, Andrew Morokoff⁴, Rahul Sharma⁵, Christopher MacIsaac¹, Steven Bush¹, James Bennett³, Zafar Faraz², Edward Karst³, Natalie DeWitt¹, Lia Madariaga³, Gil Rind³, Ivan Vrljic¹, Anna Balabanski¹, Katharine Drummond¹, Patricia Desmond¹, Douglas Weber⁶, Timothy Denison⁷, Susan Mathers², Terence O'Brien⁸, J Mocco⁹, David Grayden⁴, Nicholas Opie³, Thomas Oxley³, Peter Mitchell¹

¹Royal Melbourne Hospital, ²Calvary Bethlehem Hospital, ³Synchron, ⁴University of Melbourne, ⁵Stanford University, ⁶Carnegie Mellon University, ⁷Oxford University, ⁸The Alfred Hospital Melbourne, ⁹Mount Sinai

Objective: To assess safety of an endovascular motor neuroprosthesis (MNP) and feasibility of using the implant to control a computer by thought.

Background: The MNP provides direct communication between the brain and an external device by recording and decoding signals from the precentral gyrus as the result of movement intention. To date, implantation of MNPs has required surgery involving removal of a portion of the skull and placement of electrodes on the brain. A recently developed minimally invasive MNP reaches the brain by vascular access, without need for a craniotomy.

Design/Methods: Subjects with paralysis were implanted with the endovascular device (Stentrode, Synchron, Brooklyn, NY) using a catheter to guide placement in the superior sagittal sinus. The device was attached to an electronics unit in a subcutaneous pocket to relay brain signals from the motor cortex into commands for a laptop computer. Safety endpoints were device-related serious adverse events resulting in death or increased disability during the 12-month post-implant evaluation period, and target vessel patency and incidence of device migration at 3 and 12 months. The study also recorded signal fidelity and stability over 12 months and use of the brain-computer interface to perform routine digital tasks.

Results: The study enrolled five subjects with amyotrophic lateral sclerosis; four had suitable anatomy and underwent the implant procedure. All four subjects successfully completed the 12-month follow-up with no serious adverse events. Post-operative imaging demonstrated patent blood vessels in all subjects and no device migration. All subjects learned to use the MNP with eye tracking for routine computer use. The decoder developed during the study allowed the final participant to control a computer independently without an eye tracker.

Conclusions: In a first-in-human study, four subjects were implanted with an endovascular brain-computer interface. The study met its safety endpoints, allowing subjects with paralysis to operate a computer for daily tasks.

Study Support: The study was supported by Synchron Inc., the maker of the device, the U.S. Defense Advanced Research Projects Agency, the Office of Naval Research, the National Health and Medical Research Council of Australia, the Australian Federal Government Foundation and the Motor Neurone Disease Research Institute of Australia.