

CYBERKINETICS PRESENTS INNOVATIVE DIRECT BRAIN-COMPUTER INTERFACE FOR CLINICAL USE IN MOTOR-IMPAIRED HUMAN PATIENTS

Company Debuts BrainGateTM Development Plans at Society for Neuroscience 33rd Annual Meeting

NEW ORLEANS and FOXBOROUGH, Mass. – **November 10, 2003 -** Cyberkinetics, Incorporated will debut its development plan for BrainGateTM, an innovative multielectrode implantable brain-computer interface device for proposed clinical use in human patients, at the Society for Neuroscience 33rd Annual Meeting in New Orleans, Louisiana. Cyberkinetics believes that the BrainGate technology platform may provide paralyzed or motor-impaired patients with a novel mode of communication through the translation of thought into direct control of a computer.

"The goal of the BrainGate program is to develop a fast, reliable and unobtrusive connection between the brain of a severely disabled person and a personal computer" stated Tim Surgenor, President and CEO of Cyberkinetics. "If we are successful in this effort we may be able to provide paralyzed individuals with a gateway through which they can access the broad capabilities of computers, control devices in the surrounding environment, and even move their own limbs. The presentation later this week describes our initial efforts to build a system for pilot trials of the initial safety and performance of the BrainGate system."

The poster presentation will be made on Tuesday, November 11, 2003 at 9:00 AM by John Donoghue, Ph.D., Cyberkinetics Chief Scientific Officer and Henry Merritt Wriston Professor, Chairman of the Department of Neuroscience, and Executive Director of the Brain Science Program at Brown University. Dr. Donoghue co-authored the abstract titled, BRAINGATETM: DEVELOPING A DEVICE TO PROVIDE MOTOR IMPAIRED PATIENTS WITH A NOVEL NEURAL OUTPUT, with researchers from Brown University and Cyberkinetics: M.D. Serruya, R.A. Van Wagenen, S. Guillory, A.H. Caplan, M. Saleh, B.W. Hatt.

John Donoghue, Ph.D. commented, "The development of the BrainGate program is the culmination of 10 years of research in my academic laboratory at Brown University. We have not only demonstrated in preclinical studies that BrainGate can remain safely implanted in the macaque brain for at least two years, but we have shown that it can safely be removed as well. ."

BrainGate[™]: Pilot Clinical Trial Proposed for 2004

Cyberkinetics plans to file an Investigational Device Exemption (IDE) with the Food and Drug Administration (FDA) for a pilot clinical trial to begin in 2004 with approximately five quadriplegic participants. In the proposed study, patients who meet Cyberkinetics' rigorous selection criteria would receive the implant and their ability to achieve direct neural output control over an attached computer explored. There are two proposed primary goals of the pilot clinical trial: the first is to characterize the safety profile of the device in humans and the second is to evaluate the amount, type, and usefulness of neural output control that patients can achieve.

About the BrainGateTM Device:

Cyberkinetics' BrainGate technology platform was designed to take advantage of the fact that many patients with motor impairment have an intact brain that can produce movement commands. This may allow the BrainGate system to create an output signal directly from the brain, bypassing the route through the nerves to the muscles that can not be used in paralyzed people. Cyberkinetics' BrainGate Neural Interface Device is a proprietary brain-computer interface that consists of an internal neural signal sensor and external processors that convert neural signals into an output signal under the person's own control. The sensor consists of a tiny chip smaller than a baby aspirin, with one hundred electrode sensors each thinner than a hair that detect brain cell electrical activity. The chip is intended to be implanted on the surface of the brain in the area that controls movement. In the pilot version of the device, a cable connects the sensor to an external signal processor in a cart that contains computers. The computers translate brain activity and create the communication output using custom decoding software.

Importantly, the entire BrainGate system was specifically designed for clinical use in humans and thus, its manufacture, assembly and testing are intended to meet human safety requirements. BrainGate will be the first human device that has been designed to record, filter and amplify multiple channels of simultaneously recorded neural activity at a very high spatial and temporal resolution. While one day such translated instructions might be used to stimulate muscles or move robotic limbs, Cyberkinetics is focused on achieving the critical first step in this process, which is to enable patients to master accurate, rapid control over a computer desktop. This achievement alone will help to restore many activities of daily living that are now difficult for many paralyzed humans and will provide a platform for the development of a wide range of other assistive devices and potentially to control paralyzed muscles

Previous research conducted in non-human primates using an early version of the Cyberkinetics technology was published by researchers at Brown University (Serruya et al., 2002 Nature 416:141). The study demonstrated that neural output signals from fewer than 30 motor cortex neurons (an area of the brain responsible for movement) could be decoded in real-time into signals that provided animals the ability to neurally control cursor movements via a computer interface.

About Cyberkinetics, Inc.

Cyberkinetics is a leader in neurotechnology, an emerging field driven by advances in neuroscience, computer science, and engineering that promises to revolutionize the medical treatment of nervous system dysfunction. Cyberkinetics' first product, BrainGateTM, is designed to give severely paralyzed patients a long term, direct braincomputer interface for the purpose of communication and control of a computer. Cyberkinetics' intellectual property features key technologies licensed from Brown University, the Massachusetts Institute of Technology, Emory University, and the University of Utah. Cyberkinetics is headquartered in Foxborough, Massachusetts and conducts engineering and research in Salt Lake City, Utah. More information is available at <u>www.cyberkineticsinc.com</u>.

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