



## **FDA GRANTS HUMANITARIAN USE DEVICE DESIGNATION TO CYBERKINETICS' ANDARA™ OFS DEVICE FOR ACUTE SPINAL CORD INJURIES**

### **Designation Marks Critical Regulatory Step Toward Commercialization**

**FOXBOROUGH, MA– September 6, 2006** – Cyberkinetics Neurotechnology Systems, Inc. (OTCBB: CYKN; "Company;" "Cyberkinetics"), a neurotechnology company focused on neurostimulation and neural sensing, announced today that it has received notification from the Food and Drug Administration (FDA) that the Company's Andara™ Oscillating Field Stimulator (OFS) Device has been designated as a Humanitarian Use Device (HUD) for use immediately after (within 18 days) certain types of spinal cord injuries.

This special FDA designation will allow Cyberkinetics to file a Humanitarian Device Exemption (HDE) application with the FDA to use Cyberkinetics' Andara™ OFS Device to treat patients with acute, or recent, spinal cord injuries. Cyberkinetics expects to file the HDE application later this year.

"The HUD designation is a critically important step in our effort to make the Andara™ OFS Device available as soon as possible for people who have suffered spinal cord injuries," said Timothy R. Surgenor, President and Chief Executive Officer of Cyberkinetics. "We plan to base our HDE application on extensive preclinical data, as well as a published pilot clinical study, which indicate the potential for the device to allow patients with spinal cord injuries to regain some sensation and motor function.

"This is also an important step in our overall commercialization plan for the Andara™ technology. In addition to seeking accelerated approval to use the OFS Device to treat acute spinal cord injuries, we are planning to expand the use of the OFS Device to include the treatment of peripheral nerve injuries, strokes and traumatic brain injuries. Our goal is to develop the Andara™ OFS Device into a platform product applicable to a wide range of nervous system injuries."

According to the Center for Disease Control, approximately 11,000 Americans are hospitalized for spinal cord injuries each year. The most severe of these injuries result in devastating and permanent paralysis. These individuals are likely to be the primary beneficiaries of the Andara™ OFS Device. There are currently no accepted treatments for acute spinal cord injury that have been shown to return motor or sensory function. Because of the severity of disability that spinal cord injuries can cause, the cost to treat these injuries during the first year after injury can be as high as \$650,000 per patient.

### **About the Andara™ OFS Device**

Cyberkinetics' Andara™ OFS Device is based on initial research by the Center for Paralysis Research at Purdue University and is intended to improve or restore tactile sensation and some movement in those with quadriplegia and tetraplegia due to recent spinal cord injuries by promoting nerve fiber regeneration. The Andara™ OFS Device has been shown in published randomized controlled preclinical studies to

restore sensation and some motor function in a large animal model. Results of a ten-patient clinical study were published in the *Journal of Neurosurgery: Spine* in January of 2005.

### **About Humanitarian Use Devices (HUD) and Humanitarian Device Exemptions (HDE)**

Based upon FDA criteria, devices with HUD designation are used in the treatment of rare medical conditions, or those that affect less than 4,000 new patients annually in the United States. Following HUD designation, the FDA then determines if the device meets specific safety and probable benefit standards for the affected population. If the FDA determines the device meets these criteria, it may grant an HDE, which would allow for qualified distribution and use of the device for the specific indication.

### **About Cyberkinetics Neurotechnology Systems, Inc.**

Cyberkinetics Neurotechnology Systems, Inc., a leader in the neurotechnology industry, is developing neural stimulation, sensing and processing technology to improve the lives of those with severe paralysis resulting from spinal cord injuries, neurological disorders and other conditions of the nervous system. Cyberkinetics' product development pipeline includes: the Andara™ Oscillating Field Stimulator (OFS) Device, an investigative device designed to stimulate regeneration of the neural tissue surrounding the spinal cord; the BrainGate System, an investigative device designed to provide communication and control of a computer, assistive devices, and, ultimately, limb movement; and the FDA cleared-to-market NeuroPort™ System, a neural monitor designed for acute inpatient applications and labeled for temporary (less than 30 days) recording and monitoring of brain electrical activity. Additional Information is available at Cyberkinetics' website at <http://www.cyberkineticsinc.com>.

### **Forward-Looking Statements**

This announcement contains forward-looking statements, including statements about Cyberkinetics' product development plans and progress, potential development of proprietary inventions and benefits that may be realized by certain research programs. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, and can be identified by the use of forward-looking terminology such as "may," "will," "believe," "expect," "anticipate" or other comparable terminology. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected in forward-looking statements and reported results shall not be considered an indication of our future performance. Factors that might cause or contribute to such differences include our limited operating history; our lack of profits from operations; our ability to successfully develop and commercialize our proposed products; a lengthy approval process and the uncertainty of FDA and other governmental regulatory requirements; clinical trials may fail to demonstrate the safety and effectiveness of our products; the degree and nature of our competition; our ability to employ and retain qualified employees; compliance with recent legislation regarding corporate governance, including the Sarbanes-Oxley Act of 2002; as well as those risks more fully discussed in our public filings with the Securities and Exchange Commission, all of which are difficult to predict and some of which are beyond our control.

### **CONTACT**

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