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First Study to Reduce Depression with Cortical Neuromodulation Implant Announced at International Neuromodulation Society World Congress

- Implant Designed to Deliver Electrical Pulses to Dorsolateral Prefrontal Cortex Shows Promise in Major Depression Disorder -

ACAPULCO, MEXICO (December 11, 2007) – A study presented today at the International Neuromodulation Society's (INS) eighth world congress demonstrated promising results for the use of cortical stimulation to treat major depressive disorder (MDD). These results were presented for the first time during the year's largest conference on neuromodulation, the alteration (or modulation) of nerve activity by delivering electrical or pharmaceutical agents directly to a target area.

Brian Harris Kopell, MD with the department of neurosurgery, Medical College of Wisconsin shared the outcomes from this multi-center feasibility study, which is the first to use an epidural cortical stimulation (CS) system on the dorsolateral prefrontal cortex (DLPFC). Epidural cortical stimulation delivers electrical pulses to the cortex using an electrode implanted over the protective outer layer of the brain.

"Nearly 10 percent of the U.S. population lives with major depression and it affects people of nearly all age groups and demographic backgrounds," said Dr. Kopell. "This novel use of a Cortical Stimulation system takes advantage of our growing understanding of the role of brain metabolism in depression. These results are promising for MDD patients whose depression is resistant to other antidepressant treatment options."

In this multi-center study, 12 patients with treatment-resistant MDD received investigational implantable Cortical Stimulation systems (*Renova™*, Northstar Neuroscience, Seattle, WA) after an initial observation period. For eight weeks, patients were randomly assigned to active or sham stimulation; following this period, all patients received active stimulation. The CS system targets the left DLPFC, an area of the brain that is hypometabolic in patients with MDD, and increases glucose metabolism in this region to antidepressive effects. Using the Hamilton Depression Rating Scale (HDRS) and the Global Assessment of Function (GAF) as assessment tools, Dr. Kopell and colleagues measured the patients' baseline and post-treatment levels of depression.

The data showed that active cortical stimulation lowered patients' levels of depression and also indicated that CS may have a treatment effect that increases over time. The study was conducted at the Medical College of Wisconsin (Milwaukee, WI), Massachusetts General Hospital (Boston, MA) and the University of Pittsburgh (Pittsburgh, PA).

According to the National Institute of Mental Health (NIMH), major depression is a serious medical illness affecting more than 20 million American adults, or approximately 9.5 percent of the adult population in a given year. Antidepressant medications and psychotherapies are commonly used to treat depressive disorders. While some patients do respond to these traditional therapies, about 10 to 20 percent of all depressed patients do not have satisfactory sustained responses. New therapies, such as cortical stimulation, offer hope for these patients.

About the International Neuromodulation Society

The International Neuromodulation Society (INS) is a non-profit group of clinicians, scientists and engineers dedicated to the scientific development and awareness of neuromodulation – the alteration of nerve activity through the delivery of electrical stimulation or chemical agents to targeted sites of the body. Founded in 1989 and based in San Francisco, CA, the INS educates and promotes the field through meetings, its journal *Neuromodulation: Technology at the Neural Interface* and chapter websites. For more information, please visit www.neuromodulation.com/. For conference information-conference-in-acapulco.htm

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