NeuroSigma Announces Publication of Randomized Controlled Trial of eTNS for Treatment of Drug Resistant Epilepsy in the Leading Journal, Neurology@

The Associated Press

NeuroSigma, Inc., a California-based medical device company, today announced the publication of a positive Phase II clinical study for the use of external Trigeminal Nerve Stimulation (eTNST) for the treatment of drug-resistant epilepsy. The study, led by Christopher M. DeGiorgio, M.D., Professor of Neurology at the University of California, Los Angeles (UCLA) and Vice President of Neurology at NeuroSigma, was published online in the January 30, 2013 issue of Neurology@, the medical journal of the American Academy of Neurology. NeuroSigma is the exclusive worldwide licensee of UCLA's entire TNS intellectual property portfolio.

Drug resistant epilepsy (DRE) is a serious medical disorder, and affects approximately 30% of the estimated 50 million people with epilepsy worldwide. Today's publication details the results of a double-blind randomized controlled trial of eTNS in 50 subjects with DRE. The trial demonstrated that among patients receiving eTNS there were significant reductions in seizure frequency over the course of the 18-week study. Patients receiving eTNS also demonstrated significant improvements in mood, making eTNS unique among epilepsy therapies. The clinical trial was conducted at UCLA and the University of Southern California (USC).

"This randomized controlled trial provides Level II evidence that eTNS may be effective at decreasing seizures in patients with epilepsy.

Based on these results, we believe eTNS is a promising new therapy which is non-invasive, well tolerated, and also helps depression, a major co-morbidity in epilepsy," said Dr. DeGiorgio.

At the beginning of the trial, subjects were extremely drug resistant.

eTNS was well tolerated throughout the trial without any serious adverse events reported. Patients in the treatment group experienced significant improvements in responder rate, where a responder is defined as a patient with a greater than 50% reduction in seizure frequency. Use of eTNS was also associated with significant improvements in mood as measured by the Beck Depression Inventory.

"We congratulate all the investigators at USC, UCLA, and Olive View/UCLA medical centers," said Leon Ekchian, Ph.D., NeuroSigma's President & CEO. "The results provide a foundation for the design and execution of a pivotal trial of eTNS for the treatment of epilepsy.

NeuroSigma has completed its Pre-Investigational Device Exemption (Pre-IDE) meeting with the FDA and is preparing to submit its IDE application for authorization to proceed with the pivotal trial." eTNS in Europe NeuroSigma's first TNS product, the MonarchT eTNST System, is currently being sold to patients in the European Union, with a physician's prescription. In September 2012, NeuroSigma received CE Mark approval for the adjunctive treatment of epilepsy and major depressive disorder, for adults and children 9 years and older. The Monarch System was recently unveiled in London at the 10th European Congress on Epileptology.

Background - TNS The trigeminal nerve is the largest cranial nerve, offering a high-bandwidth pathway for signals to enter the brain. The trigeminal nerve projects to specific areas of the brain, such as the locus coeruleus, nucleus tractus solitarius, thalamus and the cerebral cortex, which are involved in epilepsy, depression, PTSD, ADHD and other disorders. TNS is the electrical stimulation of branches of the trigeminal nerve, which are located very close to the surface of the skin in the forehead. The low-energy stimulus is confined to the soft tissues of the forehead without direct penetration into the brain.

PET imaging studies in humans confirm that eTNS activates or inhibits key regions implicated in these disorders and the changes were observed within minutes of therapy.

There are two embodiments of TNS: eTNST (external electric patches and pulse generator) and sTNST (subcutaneous electrodes and implantable pulse generator). The eTNS system is composed of an external pulse generator and electric patches placed on the forehead, which need to be replaced daily. The patches can be worn primarily in the evening while asleep. The eTNS system is currently being marketed in the European Union and the sTNS system is being developed at NeuroSigma.

Together they offer an integrated and complimentary platform where eTNS could serve as a means to screen for sTNS candidates. Once sTNS is approved by regulatory agencies, patients could first commence with the eTNS treatment. Those that respond to eTNS, and wish to transition to an implantable version, could be implanted with an sTNS system.

CAUTION: In the United States, both eTNST and sTNST are investigational devices and are limited by Federal (or United States) law to investigational use.

eTNS , sTNS, Monarch, and the Monarch eTNSare trademarks of NeuroSigma, Inc.

About NeuroSigma, Inc. NeuroSigma is a Los Angeles-based medical device company established to develop early stage technologies with the potential to transform medical practice and patients' lives.

Currently, NeuroSigma is focused on neuromodulation therapies and has amassed significant intellectual property licensed on an exclusive basis from the University of California, Los Angeles (UCLA), including potential TNS therapies for epilepsy, depression, post-traumatic stress disorder (PTSD) and attention-deficit hyperactivity disorder (ADHD). For more information about NeuroSigma, please visit

www.neurosigma.com.

Forward-Looking Safe Harbor Statement: This press release contains forward-looking statements, including but not limited to, research and development outcomes, efficacy, adverse reactions, market and product potential, product availability and other statements regarding our eTNST and sTNST systems. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Risks and uncertainties include, among other things, general industry and medical device market conditions; technological advances and patents attained by competitors; challenges inherent in the research and development and regulatory processes; challenges related to new product marketing, such as the unpredictability of market acceptance for new medical device products; inconsistency of treatment results among patients; potential difficulties in manufacturing a new product; general economic conditions; and governmental laws and regulations affecting domestic and foreign operations.

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