NeuroSigma Awarded Fast Track SBIR Grant for Development of Implantable sTNS System for Drug Resistant Epilepsy

The Associated Press

NeuroSigma, Inc., a California-based medical device company, today announced it received a Notice of Award, for a Fast Track Small Business Innovation Research (SBIR) grant, from the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH). Phase I of the project is budgeted in the amount of $600,000, with $3 Million budgeted for Phase II, subject to the availability of funds and satisfactory progress by NeuroSigma.

The funding supports further development of NeuroSigma's implantable subcutaneous trigeminal nerve stimulation (sTNSTM) System, culminating in a pilot human trial of sTNS in patients with drug resistant epilepsy (DRE). The project builds on the positive results from the randomized controlled trial of NeuroSigma's non-invasive, external TNS (eTNSTM) System, as reported online in the January 30, 2013 issue of Neurology@. The eTNS System is composed of an external pulse generator and electric patches placed on the forehead, primarily while the patient is asleep.

Together, eTNS and sTNS offer a complementary platform. Some patients may choose to remain on eTNS whereas others may opt to transition to sTNS. eTNS may serve as a means to screen for sTNS candidates prior to committing to sTNS surgery.

(Photo: http://photos.prnewswire.com/prnh/20130204/LA53356 [1]) Once both sTNS and eTNS are approved by regulatory agencies the following integrated therapy path would be available. First, patients could commence with the eTNS treatment. Responders to the eTNS therapy could be identified with the relatively low cost and minimal risk afforded by eTNS. Then, those that respond to eTNS, and wish to transition to an implantable version, could be implanted with the more permanent, minimally-invasive, extra-cranial (under the skin but outside the skull) sTNS System. The sTNS electrodes would be implanted under the skin of the forehead while the pulse generator would be implanted pectorally.

In addition to this SBIR grant, NeuroSigma is currently performing under a separate Small Business Technology Transfer (STTR) grant from NINDS focused on optimization of its eTNS external electric patches.

Christopher M. DeGiorgio, M.D., Vice President of Neurology at NeuroSigma and Professor of Neurology at the University of California, Los Angeles (UCLA), will serve as the Principal Investigator (PI).

Colin Kealey, M.D., Manager of Product Development at NeuroSigma, will serve as

co-PI. "We are extremely pleased by the recognition and continuing support of the NINDS, knowing that its highly regarded peer review process includes a rigorous review by leading medical experts," said Dr. DeGiorgio. "We look forward to working closely with the NINDS Project Scientists in this Cooperative Program in Translational Research," added Dr. Kealey.

"This is our third NIH grant. As a small business we applaud the support of the NIH in transitioning promising technologies from the laboratory to the clinic," said Leon Ekchian, Ph.D., President & CEO of NeuroSigma.

eTNS in the European Union NeuroSigma's first TNS product, the MonarchT eTNST System, is currently being marketed to patients in the European Union (EU), 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 in the EU. 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. Trigeminal Nerve Stimulation (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.

NeuroSigma is the exclusive worldwide licensee of UCLA's entire TNS intellectual property portfolio and continues to develop additional technologies and target additional indications.

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

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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 [2].

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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[1] http://photos.prnewswire.com/prnh/20130204/LA53356
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