Results of Pediatric Clinical Trial of External Trigeminal Nerve Stimulation for the Treatment of ADHD

PR Newswire

LOS ANGELES, April 18, 2013 /PRNewswire/ -- NeuroSigma, Inc., a California-based medical device company, today announced that the results of the first-ever pediatric clinical trial of external Trigeminal Nerve stimulation (eTNS™) for the treatment of attention-deficit hyperactivity disorder (ADHD) will be presented at the American Psychiatric Association annual meeting in San Francisco on May 20, 2013. The clinical trial was conducted at the University of California, Los Angeles (UCLA) with funding provided by NeuroSigma.

This study, which began in November 2011, was a Phase I open-label trial of children ages 7 to 14 who had a DSM – IV diagnosis of ADHD. Subjects received eTNS nightly as monotherapy for the 8-week study period. ADHD symptom severity and cognitive performance were assessed at baseline, four weeks and eight weeks. The *a priori* outcome metric was the investigator-completed ADHD rating scale (ADHD-RS scale).

The results will be presented by James McGough , M.D., M.S., principal investigator for the study and Professor of Clinical Psychiatry at the Semel Institute for Neuroscience and Human Behavior and David Geffen School of Medicine at UCLA, and director of clinical teaching programs in both Child and Adolescent Psychopharmacology and ADHD at UCLA. Dr. McGough is a leading researcher in the field and has worked to understand ADHD's causes and develop new treatments for nearly two decades.

"PET scan data that showed the immediate effects of eTNS on activity in centers in the brain associated with attention prompted our interest in exploring eTNS as a treatment for ADHD in children," said Dr. McGough. "There is a pressing need for non-stimulant options to manage ADHD given parental and patient preferences to avoid medication use as well as the possible side effects of these drug therapies."

"The results of this study are eagerly awaited by the treatment community, especially by pediatricians, child psychologists and child psychiatrists who not only see severe side effects from current drug therapies but also worry about the significant risks for diversion and abuse of these drugs," said Ian Cook , M.D., Director of the UCLA Depression Research & Clinic Program, where initial studies of eTNS began in psychiatric conditions. Dr. Cook is also one of the inventors of eTNS and a Senior Scientific Advisor to NeuroSigma.

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