



NIH Study to Utilize NeuroPace RNS® System for Research on the Brain's Reward System

July 10, 2019

Study Aims to Assess Whether Closed-Loop Neuromodulation Could Help Manage Medically Refractory Obesity

MOUNTAIN VIEW, Calif. — July 10, 2019— NeuroPace, Inc., a Silicon Valley-based medical technology company, today announced that the company's RNS[®] System, a closed-loop neuromodulation technology approved to treat adults with medically refractory focal onset epilepsy, will be used in a [clinical investigation](#) that will examine whether neuromodulation could be effective as a means of managing loss-of-control eating for patients with body mass index (BMI) of 45-60 kg/m² for whom medication and gastric bypass surgery have not been effective treatments, and for whom loss-of-control eating is a contributing factor.

"Loss-of-control eating" refers to a feeling that one cannot control what or how much one is eating. This typically takes one of two forms, either eating objectively large amounts of food or eating continuously, and can compromise even the most aggressive of obesity treatments, such as bariatric surgery. There is evidence to suggest that long-term alterations in brain function, particularly in the reward and impulse control circuitry, occur with eating disorders, including loss-of-control eating. In addition, there is growing evidence to suggest that there are discrete changes in brain activity, or biomarkers, which immediately precede loss-of-control eating events.

A recent research study [published](#) in the Proceedings of the National Academy of Sciences demonstrated that applying stimulation to the nucleus accumbens when a specific pattern of brain activity was detected could suppress binge-eating behavior in mice. The pioneering study also observed similar changes in activity in the homologous brain region in people when they were anticipating a reward, opening up the possibility of using a closed-loop therapeutic approach in humans.

"We have long known that the neural recording and personalized interventional capability of the RNS System provides an unprecedented window to the brain, resulting in an effective treatment that works by identifying the precursors of seizures and treating them immediately and automatically," said NeuroPace Chief Medical Officer Martha Morrell, M.D. "We're pleased to support this new research, which will be among the first to explore additional applications of the RNS System beyond epilepsy. This may help lead to the treatment of other conditions where there may be signals or biomarkers that can be identified and used to time therapy delivery, and where there is also a real clinical need."

The five-year study will be conducted at Stanford University School of Medicine. The study will use NeuroPace's first-of-its-kind closed-loop neurostimulation system to interrupt brain activity patterns in the nucleus accumbens, a key component of the brain's reward circuit and a region believed to be involved in loss-of-control eating. The study is supported by a grant from the National Institutes of Health's (NIH) Brain Research through Advancing Innovative Neurotechnologies[®] (BRAIN) Initiative, a public-private research initiative supporting research to revolutionize the understanding of the human brain.

"Obesity is a disease with many contributing factors. Unfortunately, obesity is often associated with multiple comorbidities that can lead to reduced quality of life and even premature death. For some patients, loss-of-control while eating can be a significant contributor to their condition," said Tara Skarpaas, Ph.D., Principal Scientist at NeuroPace and one of the study's researchers. "This study will evaluate whether neurostimulation can automatically respond to the signals that occur immediately before a loss-of-control eating episode to help patients regain control, a potentially groundbreaking intervention for the most severely affected patients. The RNS System's ability to continuously monitor brain activity and respond with therapy when these biomarkers are detected makes the system an ideal fit for this research."

Neuromodulation has shown promise in treating many conditions, including depression, Alzheimer's, and obsessive-compulsive disorder. Most commercially available neuromodulation devices deliver stimulation continuously or on a fixed schedule, independent of the underlying brain activity. In contrast, NeuroPace's RNS System, a first-of-its-kind technology, treats focal onset seizures by continuously monitoring brainwaves, recognizing each patient's unique "seizure fingerprint," and automatically responding with imperceptible electrical pulses to stop seizures before they occur.

As part of the study, the RNS System will provide the first long-term ambulatory recordings of human brain activity from this key area of the reward circuit, the nucleus accumbens. Data captured by the system will be analyzed using artificial intelligence and machine learning to provide initial insights into the function of the human reward circuit as well as to initiate development of algorithms that can individualize treatment in the future.

A multi-disciplinary team of investigators at the Stanford University School of Medicine and NeuroPace will oversee the research including: Casey Halpern, M.D., Assistant Professor of Neurosurgery; Robert Malenka, M.D., Ph.D., the Pritzker Professor of Psychiatry and Behavioral Sciences, Director Pritzker Laboratory, and Deputy Director of the Stanford Neurosciences Institute; James Lock, M.D., Ph.D., Associate Chair and Director of the Eating Disorder Service in the Department of Psychiatry and Behavioral Sciences; and Tara Skarpaas, Ph.D., Principal Scientist at NeuroPace.

The NIH BRAIN Initiative is a collaborative, public-private research initiative with a goal of supporting the development and application of innovative technologies that can create a dynamic understanding of brain function. Founded in 2013, the BRAIN Initiative supports neuroscience research to help find innovative treatments for brain diseases and disorders and seeks to accelerate our understanding of the human brain through applied innovative technologies and cutting-edge scientific research.

About the RNS[®] System

The RNS System is the world's first and only closed-loop brain-responsive neurostimulation system designed to prevent epileptic seizures at their source. The RNS System is composed of a neurostimulator, leads that are placed at the seizure foci, a remote monitor used by patients to upload their data, and a RNS Tablet and Patient Data Management System (PDMS) used by physicians. Physicians can view their patient's electrographic data on a secure website and program the device to personalize therapy for each individual. Unlike anti-epileptic drugs or resective surgery, brain-responsive neuromodulation outcomes typically improve with time and do not cause the cognitive side effects that can be associated with those alternatives. The

RNS System is now available at nearly all comprehensive epilepsy centers in the United States and is widely covered by private and government insurance.

The RNS[®] System is an adjunctive therapy for adults with refractory, focal onset seizures with no more than 2 epileptogenic foci. See important safety information at <https://neuropace.com/safety/>. The RNS System is an investigational device for the treatment of loss of control eating in refractory obesity.

About NeuroPace

NeuroPace is the global leader in the emerging field of brain-computer interface technologies, which is projected to become a \$1.2 billion market by 2024. We are dedicated to developing groundbreaking technology and advancing brain science to improve the quality of life for millions of individuals who suffer from neurological disorders. The company's first product, the RNS System, is the only FDA-approved brain-responsive neurostimulator for the treatment of focal onset refractory epilepsy. In addition to treating epilepsy, brain-responsive neuromodulation holds the promise of treating other brain disorders that impact quality of life for millions of patients throughout the world.

###

Individuals who would like to find out if they are eligible to participate in the study should contact the [study coordinators](#).

Media contact

Durae Hardy

durae@healthandcommerce.com