

NeuroMetrix Reports Positive Pilot Data for Use of its Wearable Pain Relief Technology in Restless Leg Syndrome

WALTHAM, Mass.--(BUSINESS WIRE)-- NeuroMetrix, Inc. ([NURO](#)), an innovative health-care company that develops wearable medical technology and point-of-care tests that help patients and physicians better manage chronic pain, nerve diseases, and sleep disorders, today announced preliminary results from a pilot study of its wearable pain relief technology in subjects with restless leg syndrome (RLS).

RLS, which is also known as Willis-Ekbom Disease, is a common sleep disorder characterized by a strong urge to move the legs at night. It affects up to 14% of the US adult population at varying levels of severity. In addition to its direct impact on sleep, RLS may increase the risk of cardiovascular disease and is associated with an overall higher risk of mortality. It is currently managed using various pharmacological agents, some of which worsen the symptoms over time. Many RLS patients remain under treated.

The pilot study was an open-label, single-arm, flexible dosing, 4-week trial. The objective of the study was to determine if transcutaneous electrical nerve stimulation (TENS), when delivered using a wearable intensive nerve stimulation device (NeuroMetrix SENSUS®), is an effective and safe treatment for RLS, and to explore its effect on sleep in subjects with RLS. The principal investigator was John W. Winkelman MD, PhD, Chief, Sleep Disorders Clinical Research Program, Departments of Psychiatry and Neurology, Massachusetts General Hospital (a Harvard Medical School teaching hospital).

A total of nine subjects were evaluated. Two-thirds of the subjects were responders to the therapy according to the Clinical Global Impression of improvement (CGI-I) scale. Overall RLS severity decreased by 32%, as assessed by the International Restless Leg Syndrome (IRLS) scale, which was statistically significant. Similarly, several sleep related outcomes measures (MOS Sleep Scale) showed statistically significant (or a trend towards) improvement. A complete set of results and analyses will be published by Dr. Winkelman who stated, "Pharmacologic treatments, though an important advance over the past 20 years for patients with RLS, leave much to be desired. Effective non-pharmacological treatments would be of great value, and these are encouraging preliminary results that must now be confirmed in a sham-controlled study."

"We are encouraged by the results of our wearable intensive nerve stimulation (WINS) technology in restless leg syndrome. Importantly, this pilot study represents the first evaluation of wearable transcutaneous electrical nerve stimulation in RLS and suggests that WINS may be a viable non-pharmacologic option," said Shai N. Gozani, M.D., Ph.D. President and CEO of NeuroMetrix, Inc. "The next step is to conduct a formal sham-controlled randomized clinical trial of WINS using our Quell™ platform in subjects with RLS. We believe that an eventual RLS indication would substantially expand the market for Quell beyond chronic pain."

About NeuroMetrix

NeuroMetrix is an innovative health-care company that develops wearable medical technology and point-of-care tests that help patients and physicians better manage chronic pain, nerve diseases, and sleep disorders. The company is located in Waltham, Massachusetts and was founded as a spinoff from the Harvard-MIT Division of Health Sciences and Technology in 1996. For more information, please visit www.NeuroMetrix.com.

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