



NeuroMetrix Reports Quell® Technology to be Used in NIH-Funded Trial Evaluating Effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) for Fibromyalgia

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WOBURN, Mass., April 16, 2020 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today announced that Quell technology has been selected for use in a large, NIH-funded, randomized, pragmatic clinical trial of TENS for fibromyalgia.

Fibromyalgia is a disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep and mood disturbances. It affects an estimated 2 to 4 percent of the US population, or as many as 6 to 12 million people, and is most often diagnosed between the ages of 30 and 50. The cause of fibromyalgia remains unclear, but scientific studies point to abnormalities in the way the brain processes normal sensations and pain.

Although several drugs are approved for treating fibromyalgia pain, there is an unmet need for safe, non-pharmacological options.

TENS is a non-invasive pain relief approach. In a recently published sham-controlled, double-blind, randomized controlled trial (RCT), TENS using frequency and charge modulated pulses was shown to improve movement-evoked pain and additional clinical outcomes in patients with fibromyalgia (see <https://www.ncbi.nlm.nih.gov/pubmed/31738014>).

The new study is titled "Fibromyalgia TENS in physical therapy study (FM-TIPS): An embedded pragmatic clinical trial." The trial is supported by NIH's Helping to End Addiction Long-termSM Initiative, or NIH HEAL InitiativeSM. The principle investigators are Drs. Kathleen Sluka of the University of Iowa and Leslie Crofford of Vanderbilt University. It is a center-randomized, pragmatic trial of routine physical therapy with or without TENS. The objectives of the trial are to assess the feasibility of using TENS in addition to physical therapy for treatment of patients with fibromyalgia and to determine if TENS use improves symptoms, increases adherence to physical therapy, increases the likelihood of meeting therapeutic goals, and reduces medication use. A total of 660 patients will be enrolled. Further study information is available at https://projectreporter.nih.gov/project_info_description.cfm?aid=9869089.

Quell technology is an advanced TENS platform that is enabled by a proprietary neurostimulation microchip that provides flexible, precise, high-power nerve stimulation in small wearable devices. Quell supports Bluetooth low energy (BLE) to communicate with mobile applications. The Company is creating a custom Quell device and mobile application in collaboration with the study investigators for use in the FM-TIPS trial.

"We are honored that Drs. Sluka and Crofford and their colleagues have chosen to use Quell technology for this first-of-its-kind TENS clinical trial. Fibromyalgia is a common chronic pain condition that is difficult to manage and can benefit from new treatment options," said Shai N. Gozani, M.D., Ph.D., President and CEO of NeuroMetrix. "This novel pragmatic study will inform the clinical use of TENS for fibromyalgia. We also expect that our experience with this and other ongoing studies will guide development of a new fibromyalgia focused Quell device."

Note: The use of Quell technology for fibromyalgia is investigational only. The safety and effectiveness for this purpose has not been reviewed by the United States Food and Drug Administration.

Note: The FM-TIPS trial is supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health under Award Number UG3AR076387. The contents of this press release are solely the responsibility of NeuroMetrix and do not necessarily represent the official views of the National Institutes of Health.

About the NIH Heal Initiative

The NIH Heal Initiative is an aggressive, trans-NIH effort to speed scientific solutions to stem the national opioid public health crisis. Launched in April 2018, the initiative is focused on improving prevention and treatment strategies for opioid misuse and addiction, and enhancing pain management. For more information, visit: <https://heal.nih.gov>.

About NeuroMetrix

NeuroMetrix is a leading developer and manufacturer of diagnostic and therapeutic neurostimulation-based medical devices used throughout the world. The Company has three FDA cleared commercial products. DPNCheck[®] is a point-of-care test that is used to evaluate peripheral neuropathies. ADVANCE[™] is a point-of-care device that provides nerve conduction studies as an aid in diagnosing and evaluating patients suspected of having focal or systemic neuropathies. Quell[®] 2.0 is a wearable, mobile app enabled, neurostimulation device indicated for symptomatic relief and management of chronic pain that is available over-the-counter. For more information, visit NeuroMetrix.com.

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