NEURO**Metrix**®

NeuroMetrix Reports that Quell® Technology is to be Evaluated for Neuromyelitis Optica Spectrum Disorder (NMOSD) in a Randomized Controlled Trial

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WOBURN, Mass., June 15, 2021 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today announced that Quell technology will be used in a double-blinded, randomized, sham-controlled trial to determine whether transcutaneous electrical nerve stimulation (TENS) is an effective, acceptable and feasible method of pain relief in patients with NMOSD. The principal investigator is Michael Levy, M.D., Ph.D., Director, NMO Clinic and Research Laboratory, Massachusetts General Hospital, Boston, MA.

NMOSD is a rare, chronic relapsing autoimmune disease of the central nervous system that targets the optic nerves and spinal cord and can cause paralysis and vision loss. Central neuropathic pain (CNP), characterized by chronic burning, shooting or tingling sensations in the arms, torso and legs, occurs in many cases. CNP can be debilitating and current pharmacological treatments have limited efficacy and significant side effects.

TENS is a safe, non-pharmacologic pain relief approach. It has been shown to be effective in some forms of neuropathic pain, but has not been extensively evaluated for NMOSD. 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 trial will use a modified Quell device and mobile app that allow for an alternative electrode placement and stimulation pattern. The same system is being used in a large, NIH-funded pragmatic clinical trial of TENS for fibromyalgia.

The current trial will enroll 46 patients with NMOSD. The subjects will be randomized to an active or sham Quell device for 4 weeks. All subjects will then proceed into a 4-week open-label active treatment phase. The primary outcome measure is the baseline to 4-week change in pain intensity using the 11-point numerical pain scale. Study details are available <u>here</u>.

"We are pleased to support Dr. Levy and his colleagues in this clinical trial. NMOSD is a disabling disease without safe and effective treatment options," said Shai N. Gozani, M.D., Ph.D., President and CEO of NeuroMetrix. "This rigorous randomized controlled trial will add to the growing body of clinical data on the utility of Quell technology in chronic pain conditions with a neuropathic pain component. There are significant unmet clinical needs in the treatment of neuropathic pain that Quell may be able to eventually address."

Note: The use of Quell for NMOSD and neuropathic pain is investigational only. The safety and effectiveness for these purposes has not been reviewed by the United States Food and Drug Administration.

About NeuroMetrix

NeuroMetrix is an innovation-driven company focused on the development and global commercialization of non-invasive medical devices for the diagnosis and treatment of pain and neurological disorders. The Company has three commercial products. DPNCheck[®] is a diagnostic device that provides rapid, point-of-care detection of peripheral neuropathies. ADVANCE[®] is a diagnostic device that provides automated, in-office nerve conduction studies for the evaluation of focal neuropathies. Quell[®] is a wearable neurostimulation device indicated for symptomatic relief of lower extremity chronic pain that is available over-the-counter. For more information, visit <u>www.NeuroMetrix.com</u>.

Source: NeuroMetrix, Inc.

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