NeuroMetrix Reports that Quell® is to be Evaluated for Chemotherapy-Induced Peripheral Neuropathy in NIH-Funded Clinical Trial

August 20, 2020

WOBURN, Mass., Aug. 20, 2020 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today announced that its Quell device will be used in an NIH-funded, multi-site randomized controlled trial (RCT) of the efficacy of transcutaneous electrical nerve stimulation (TENS) for chemotherapy-induced peripheral neuropathy (CIPN). The principle investigator is Dr. Jennifer Gewandter of the University of Rochester School of Medicine and Dentistry. The trial leverages the National Cancer Institute (NCI) Community Oncology Research Program (NCORP).

About 650,000 cancer patients receive chemotherapy annually in the United States. CIPN is a disabling complication that occurs in many patients treated with common chemotherapeutic drugs such as vincristine, paclitaxel and cisplatin. A recently published systematic analysis reported that CIPN prevalence was 68% the first month after chemotherapy and 30% six-months after chemotherapy. CIPN symptoms include burning/shooting pain, tingling, cramping, and numbness in the hands and feet. CIPN is also associated with impaired balance, walking, and sleep, decreased quality of life, and increased risk of falls. There are few treatment options and those that are used have limited effectiveness and may cause serious side effects.

TENS is a safe, non-pharmacologic pain relief approach. It has been shown to be effective for neuropathic pain but has not been extensively evaluated in CIPN. Quell is an advanced, wearable TENS device that is FDA cleared for symptomatic relief and management of chronic pain. In a recently published single-arm, open label pilot study by Dr. Gewandter and colleagues, a majority of CIPN patients reported improved symptoms following 6-weeks of Quell use. See https://www.ncbi.nlm.nih.gov/pubmed/30151681 for further details.

The current study is a phase II, multi-site, double blinded, sham-controlled RCT. A total of 150 patients with CIPN will be enrolled. The subjects will be randomized to an active or sham Quell device for 6-weeks. Subjects in both arms will be instructed to wear their device for 5 hours each day. The primary outcome measure is the baseline to 6-week change in the CIPN20, which is a composite measure of a cancer patients' experience of symptoms and functional limitations related to CIPN. Secondary outcomes include individual CIPN symptoms and objective measures of central descending pain inhibition, lower limb sensation threshold, and balance. Complete study details are available at https://clinicaltrials.gov/ct2/show/NCT04367480.

"We are pleased that Dr. Gewandter and her colleagues have chosen to use Quell for this important NIH-funded clinical trial. CIPN is a common dose-limiting side effect of chemotherapy that adversely impacts quality of life for many cancer survivors," said Shai N. Gozani, M.D., Ph.D., President and CEO of NeuroMetrix. "This rigorous RCT will inform future clinical research and use of TENS, and Quell in particular, for CIPN."

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

About Quell

Quell is a novel transcutaneous electrical nerve stimulator (TENS) for the symptomatic relief and management of chronic pain that is available over-the-counter. It is a wearable device that can be used during the day while active and at night while sleeping. Quell users can personalize and manage therapy discreetly via the Quell app. Quell also offers health tracking metrics relevant to chronic pain sufferers. Quell users can synchronize their data with the Quell Health Cloud®, which provides customized feedback and powers a large chronic pain outcomes database. Visit QuellRelief.com for more information.

About NeuroMetrix

NeuroMetrix is a leading developer and manufacturer of diagnostic and therapeutic neurostimulation-based medical devices that are 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 and is available over-the-counter. The Company maintains an active, industry-leading R&D program. For more information, visit NeuroMetrix.com.

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