Quell® Demonstrates Encouraging Clinical Trial Results in Chemotherapy Induced Peripheral Neuropathy (CIPN)

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WOBURN, Mass., May 31, 2023 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) noted publication of an abstract describing partial results from a NIH-funded, multi-site randomized controlled trial of Quell titled "Wireless transcutaneous electric nerve stimulation (TENS) for chemotherapy-induced peripheral neuropathy (CIPN): A proof-of-concept, placebo-controlled, randomized clinical trial (RCT)." The abstract will be published at the 2023 American Society of Clinical Oncology (ASCO) annual meeting to take place June 2-6 in Chicago, IL. The principal investigator is Dr. Jennifer Gewandter of the University of Rochester School of Medicine and Dentistry. The trial leveraged the National Cancer Institute (NCI) Community Oncology Research Program (NCORP).

The study was a phase II, multi-site, double blinded, randomized, sham-controlled trial. A total of 142 subjects with CIPN were randomized to an active or sham Quell device for 6-weeks. Subjects in both arms were instructed to wear their device for 5 hours each day. As reported in the abstract, patients with moderate to severe CIPN symptoms of hot/burning pain, sharp/shooting pain or muscle cramping experienced about a 50% reduction in symptoms for active treatment compared to about 30% for sham treatment. The study authors concluded "A RCT of an app-controlled, wireless TENS device for chronic CIPN with excellent adherence and retention rates is feasible in NCORP. Preliminary efficacy evidence suggests that TENS [Quell] is promising for pain and cramping from CIPN ... A confirmatory RCT of TENS for painful CIPN is highly warranted." The abstract is available at link and the study details are available at NCT04367480.

"These efficacy results from a sham-controlled RCT of Quell in CIPN are exciting and consistent with an earlier published open-label study. CIPN is very difficult to manage, with no FDA approved treatments. As evidenced by its designation from the FDA as a breakthrough device for chronic CIPN, Quell offers the potential for a safe and effective treatment that can be administered at home," said Shai N. Gozani, M.D., Ph.D., President and CEO of NeuroMetrix. "We look forward to obtaining further details on the trial results over the coming months and will correspondingly finalize our regulatory strategy, potentially to include a near term regulatory submission for a Quell CIPN indication. We are also enthusiastic about continuing to support Dr. Gewandter and her colleagues at NCORP as they pursue a confirmatory trial that further investigates the clinical benefits of Quell in CIPN."

The use of Quell for chemotherapy induced peripheral neuropathy is investigational and has not been cleared or approved by the FDA. The safety and effectiveness for this purpose have not been reviewed by the FDA.

About Chemotherapy Induced Peripheral Neuropathy

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. CIPN is difficult to treat with few treatment options, and those that are used have limited effectiveness and may cause serious side effects.

About Quell Technology

Quell is an advanced, non-invasive, neuromodulation technology that is covered by 26 issued or granted U.S. utility patents. It is the only wearable neuromodulator that is enabled by a proprietary microchip to provide precise, high-power nerve stimulation in a form factor the size of a credit card. Quell utilizes position and motion sensing to automatically adjust stimulation for an optimal user experience both day and night. The device supports Bluetooth® low energy (BLE) to communicate with mobile apps for multiple smartphone platforms. Quell is currently indicated to reduce fibromyalgia symptoms in patients with high pain sensitivity and to reduce lower extremity chronic pain.

About NeuroMetrix

NeuroMetrix is an innovation-driven company with a mission to improve individual and population health through novel medical devices and technology solutions for neurological disorders and pain syndromes. The Company has three commercial products. Quell® is a prescription wearable neuromodulator that is the only FDA-authorized medical device to help reduce the symptoms of fibromyalgia. DPNCheck® is a diagnostic device that provides rapid, point-of-care detection of peripheral neuropathies. ADVANCE® is a legacy diagnostic device that provides automated, in-office nerve conduction studies for the evaluation of focal neuropathies. For more information, visit www.neurometrix.com.

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