



NeuroMetrix Announces Peer-Reviewed Publication of Phase 2 Clinical Trial Showing that Quell® Improves Painful Symptoms of Chemotherapy Induced Peripheral Neuropathy (CIPN)

December 5, 2023

WOBURN, Mass., Dec. 05, 2023 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) noted publication of results from a NIH-funded clinical trial of Quell titled "Wireless transcutaneous electric nerve stimulation (TENS) for chronic chemotherapy-induced peripheral neuropathy (CIPN): a proof-of-concept randomized clinical trial." The paper has been electronically published in [The Journal of Pain](#).

The study was a phase 2, 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 wore their device for 5 hours each day. Only a small number of minor adverse events were reported, primarily mild skin irritation that self-resolved. The trial met its pre-specified primary endpoint of a significant least-squares between-group difference of the EORTC-CIPN20 total score. The EORTC-CIPN20 is a validated patient questionnaire measuring CIPN related quality of life. Of greater clinical relevance, patients with moderate to severe CIPN symptoms of hot/burning pain, sharp/shooting pain or muscle cramping experienced about a 50% reduction in these symptoms for active treatment compared to about 30% for sham treatment. The study authors concluded "The study supports the preliminary efficacy of the TENS device for painful CIPN symptoms."

"CIPN is very difficult to manage, with no FDA approved treatments. Painful CIPN affects about half of patients with CIPN and is associated with particularly low quality-of-life. Duloxetine is the only treatment recommended for painful chronic CIPN in the current American Society of Clinical Oncology (ASCO) guidelines. Therefore, these efficacy results from a sham controlled RCT of Quell in CIPN are clinically important and exciting," said Shai N. Gozani, M.D., Ph.D., CEO of NeuroMetrix." As evidenced by its designation from the FDA as a breakthrough device for chronic CIPN, Quell has potential as a safe and effective treatment that can be administered at home. We believe that these clinical trial results along with earlier studies support a pre-market notification (510(k)) which we expect to submit to the FDA before the end of the year."

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 700,000 cancer patients receive chemotherapy annually in the United States, and worldwide the number is 10 million. 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 manage 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 platform that is covered by 26 issued 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 and the Quell Health Cloud. Quell is indicated to help reduce fibromyalgia symptoms in patients with high pain sensitivity and to reduce lower extremity chronic pain.

About NeuroMetrix

NeuroMetrix is a commercial stage healthcare company that develops and commercializes neurotechnology devices to address unmet needs in the chronic pain and diabetes markets. The Company's products are wearable or hand-held medical devices enabled by proprietary consumables and software solutions that include mobile apps, enterprise software and cloud-based systems. The Company has two commercial brands. Quell® is a wearable neuromodulation platform. DPNCheck® is a point-of-care screening test for peripheral neuropathy. For more information, visit www.neurometrix.com.

Source: NeuroMetrix, Inc.

Thomas T. Higgins
SVP and Chief Financial Officer
neurometrix.ir@neurometrix.com



Source: NeuroMetrix, Inc.