NeuroMetrix Receives FDA Breakthrough Device Designation for Treatment of Chronic Chemotherapy Induced Peripheral Neuropathy (CIPN) with its Wearable Neurostimulation Technology

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WOBURN, Mass., Jan. 18, 2022 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today announced that its Quell® technology has received Breakthrough Designation from the U.S. Food and Drug Administration (FDA) for reducing moderate to severe symptoms of chemotherapy induced peripheral neuropathy that have persisted for at least 6-months following the end of chemotherapy.

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. 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. Approximately 30% of patients experience chronic CIPN, defined as symptoms lasting longer than 3-6 months after the last chemotherapy treatment. There are no FDA approved treatments for CIPN, and those that are used have limited effectiveness and have side effects.

Quell is an advanced, non-invasive, neuromodulation technology that is covered by 19 U.S. utility patents. It is the only wearable neuromodulator that is enabled by a proprietary microchip that provides precise, high-power nerve stimulation in a form factor the size of a credit card. The Quell device utilizes position and motion sensing to automatically adjust stimulation for an optimal patient experience both day and night. The device supports Bluetooth® low energy (BLE) to communicate with smartphone and smartwatch apps that help the patient personalize and control their treatment.

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide NeuroMetrix with priority review and interactive communication regarding device development, through to commercialization.

The data submitted by NeuroMetrix in support of the Breakthrough Designation included results from a 6-week open label study that evaluated the safety and effectiveness of Quell used at home for treatment of patients diagnosed with CIPN (study publication available here). The study enrolled 29 patients who had completed chemotherapy with a neurotoxic agent at least 3-months earlier, had a clinical diagnosis of CIPN, and reported lower extremity symptoms of pain, tingling, numbness, or cramping. The primary outcome measure was EORTC-CIPN20, which is a composite measure of CIPN symptoms and functional impairments. There were statistically significant group improvements in the EORTC-CIPN20 and other outcome measures, with the relative improvements ranging from 13 to 52%. All adverse effects were mild and self-limited.

A National Cancer Institute (NCI) funded, multi-center, double blind, randomized, sham-controlled trial of Quell in CIPN is currently ongoing (see ClinicalTrials.gov for details). A total of 150 patients will be enrolled, with subjects randomized to an active or sham Quell device for 6 weeks. The primary outcome measure is the baseline to 6-week change in the EORTC-CIPN20. Other outcomes include individual CIPN symptoms and objective measures of central descending pain inhibition, lower limb sensation threshold, and balance. The study is expected to complete by the end of 2022.

"This Breakthrough Device Designation is an important step in our effort to make Quell technology available to patients suffering from the debilitating effects of CIPN," said Shai N. Gozani, M.D., Ph.D., CEO of NeuroMetrix. "We are looking forward to completion and subsequent reporting of the results from the ongoing multi-center RCT of Quell in CIPN. Depending on the outcome of the trial, we hope to be positioned for an FDA filing in 2023. Following on our first Breakthrough Designation for fibromyalgia, this new designation for CIPN advances our effort to build a portfolio of Quell based prescription wearable neurotherapeutics."

Note: 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 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 entrapment neuropathies. Quell® is a wearable neurostimulation device currently indicated for treatment of lower extremity chronic pain. For more information, visit NeuroMetrix.com.

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