NeuroMetrix Reports that Quell® Wearable Neuromodulator to be Evaluated in Post-Acute COVID-19 Syndrome

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WOBURN, Mass., Feb. 24, 2022 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today announced that its Quell wearable neuromodulation technology will be evaluated for treatment of a fibromyalgia-like syndrome in individuals with post-acute COVID-19 syndrome (PACS, or "long COVID"). The trial will be conducted at the Baylor College of Medicine in collaboration with the National Science Foundation (NSF) funded Center to Stream Healthcare In Place (C2SHIP). The principal investigator is Dr. Bijan Najafi, Professor of Surgery, and clinical director at the Division of Vascular Surgery and Endovascular Therapy, Baylor College of Medicine.

Over 10 million Americans are estimated to be living with PACS. This condition is defined as persistent symptoms following an acute COVID-19 infection. It may affect over one-third of individuals who had COVID-19, even those whose initial disease was mild or asymptomatic. PACS is characterized by a constellation of symptoms that include fatigue, joint pain, muscle pain, memory and concentration issues, sleep problems, shortness of breath, cough, and heart rate abnormalities. Many of these symptoms are also characteristic of fibromyalgia. In a recently published study, 31% of individuals who experienced an acute COVID-19 infection met the American College of Rheumatology (ACR) criteria for fibromyalgia when surveyed an average of 6-months following infection. PACS treatment is challenging and there is an unmet need for effective therapies.

Quell is an advanced, non-invasive, neuromodulation technology that is covered by 22 U.S. utility patents and numerous international 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 U.S. Food and Drug Administration (FDA) is currently reviewing Quell under a De Novo request for treatment of fibromyalgia symptoms. NeuroMetrix received an FDA Breakthrough Designation for this indication in July 2021.

The PACS study is a double blinded, randomized, sham-controlled trial (RCT). A total of 40 patients with persistent symptoms of pain, fatigue, weakness, or poor gait and balance following COVID-19 infection will be enrolled. The subjects will be randomized to an active or sham Quell device for 4-weeks. Subjects in both arms will be instructed to use their device for at least 3-hours of nerve stimulation each day. The primary outcome measures are baseline to 4-week changes in pain, sleep and fatigue. Secondary outcomes measures include patient global impression of change, quality of life and objective assessments of gait, lower extremity muscle function and sural nerve conduction using the DPNCheck® device. Complete study details are available at clinicaltrials.gov.

“This project will test the potential effectiveness of Quell, which is a practical neuromodulation wearable technology, shown to be effective to manage pain and lower extremities symptoms, for clinical management of patients with PACS," said Professor Najafi, Co-Director of C2SHIP. "This wireless tool has the potential, not only to revolutionize PACS management, but also to significantly reduce the burden on the healthcare industry by reducing clinic visits while performing home-based therapy. This is aligned with the mission of C2SHIP to promote in-place care technologies that enable a patient engagement ecosystem.”

"The impact of COVID-19 appears to linger long after the acute infection, which may lead to a profound surge of chronic illness in the coming years. One of the likely manifestations will be an increase in a fibromyalgia-like syndrome. Unfortunately, like traditional fibromyalgia, the COVID-19 version is expected to be debilitating and difficult to treat," said Shai N. Gozani, M.D., Ph.D., CEO of NeuroMetrix. "We appreciate the opportunity to work with Professor Najafi and his colleagues at the Baylor College of Medicine to evaluate whether Quell has a therapeutic role in patients with PACS. Moreover, this project is a demonstration of the goals and potential of C2SHIP to address some of the most difficult healthcare challenges facing the country, and we are honored to be an industrial member. Another novel aspect of this study is that our DPNCheck device will be used to objectively detect and stage peripheral neuropathy. There have been several early reports that peripheral neuropathy is a neurological complication of long COVID.”

Note: The use of Quell for post-acute COVID-19 syndrome and fibromyalgia is investigational and neither indication has been cleared or approved by the FDA. The safety and effectiveness for these purposes 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.

Source: NeuroMetrix, Inc.

Thomas T. Higgins
SVP and Chief Financial Officer
781-314-2761
neurometrix.ir@neurometrix.com

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