NeuroMetrix Announces Submission of FDA De Novo Request for Treatment of Fibromyalgia Symptoms with the Quell® Wearable Neuromodulation Device

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WOBURN, Mass., Oct. 06, 2021 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today announced that it has submitted a De Novo request to the U.S. Food and Drug Administration (FDA) for Quell as a prescription treatment for the symptoms of fibromyalgia in adults. The Company received FDA Breakthrough Designation for this indication in July.

Fibromyalgia is a chronic pain condition that is accompanied by fatigue, sleep, cognitive and mood disturbances. It affects an estimated 2 to 6 percent of the U.S. population (5 to 15 million people). The cause of fibromyalgia remains unclear, but scientific studies point to abnormalities in the way the brain processes normal sensations and pain. Although several drugs are FDA approved for managing fibromyalgia pain, there is an unmet need for safe and effective non-pharmacological treatments. There are currently no medical devices with FDA clearance or approval for treating fibromyalgia.

The De Novo pathway for marketing authorization is available to low-to-moderate risk medical devices that do not have a cleared predicate device, and are therefore not eligible for the pre-market notification process (i.e., 510(k)). Unlike traditional TENS devices that are narrowly cleared for pain relief, NeuroMetrix is seeking a novel intended use for Quell to treat fibromyalgia symptoms.

The data submitted by NeuroMetrix in support of the De Novo request includes results from a double-blind, randomized, sham-controlled trial (NCT03714425). A total of 119 subjects with fibromyalgia were enrolled and randomized to a standard (active) or modified (sham) Quell device for 3-months of at-home use. In an intention-to-treat (ITT) analysis of all randomized subjects, 57% of those on active treatment exhibited a clinically meaningful improvement in health-related quality-of-life (Fibromyalgia Impact Questionnaire, FIQR) compared to 34% that received sham treatment (p=0.014). Subjects in the active treatment arm reported statistically significant improvements in 19 of the 21 symptoms comprising the FIQR instrument, including pain, sleep, fatigue, balance and the ability to carry out typical daily activities. There were additional positive outcomes in both the ITT population and in a pre-specified subgroup analysis of subjects with elevated pain sensitivity based on Quantitative Sensory Testing (QST). A subset of the trial results were recently published in the Journal of Pain Research.

“Submission of this De Novo request is an important milestone in the Company's effort to make Quell technology available as a prescription treatment for people living with fibromyalgia,” said Shai N. Gozani, M.D., Ph.D., President and CEO of NeuroMetrix. “We look forward to working with the FDA as they proceed through their review, which we are optimistic will be facilitated by the device's breakthrough status. Subject to a successful and timely process, we hope to commercially launch Quell for this indication in the second half of 2022.”

NeuroMetrix was advised by MCRA, LLC in this submission.

Note: The use of Quell for fibromyalgia is investigational and has not been cleared or approved by the U.S. Food and Drug Administration (FDA).

About Quell

Quell is an advanced, non-invasive, neuromodulation device that is covered by 18 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. Quell 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 the Quell app, which is available for iOS and Android mobile devices. Quell is currently indicated for symptomatic relief and management of chronic lower extremity (knee, foot and leg) pain. It is available over-the-counter for this use. Visit QuellRelief.com for more information.

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 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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