NeuroMetrix Receives FDA Breakthrough Device Designation for Treatment of Fibromyalgia with its Wearable Neurostimulation Technology

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WOBURN, Mass., July 20, 2021 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today announced that its Quell® device has received Breakthrough Designation from the U.S. Food and Drug Administration (FDA) for treating the symptoms of fibromyalgia in adults.

Fibromyalgia is a common form of chronic pain that is also 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) and is most often diagnosed between the ages of 30 and 50. 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.

Quell is an advanced, non-invasive, nerve stimulation device that is covered by 18 U.S. utility patents. It is the only wearable neurostimulator that is enabled by a custom designed microchip that provides flexible, 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.

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. In addition, there are government policies and programs under consideration that, if eventually adopted, may facilitate Medicare reimbursement for FDA Breakthrough Devices following marketing authorization.

The data submitted by NeuroMetrix in support of the Breakthrough Designation included 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 subjects, 56% of those on active treatment exhibited a clinically meaningful improvement in health-related quality-of-life (Fibromyalgia Impact Questionnaire, FIQR) compared to 35% that received sham treatment (p=0.029). 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).

“The Breakthrough Device Designation is an important milestone in the Company's effort to make Quell technology available to people living with fibromyalgia,” said Shai N. Gozani, M.D., Ph.D., President and CEO of NeuroMetrix. “We are moving forward with a regulatory filing that could position us to launch Quell for this indication in the second half of next year.”

Note: The use of Quell for fibromyalgia is investigational and has not been cleared or approved by the U.S. FDA. The safety and effectiveness for this purpose have not been reviewed by the FDA.

About Quell

Quell is a novel transcutaneous electrical nerve stimulator (TENS) that is indicated for symptomatic relief and management of chronic lower extremity (knee, foot and leg) pain and is available over-the-counter. It is a wearable device that can be used during the day while active and at night while sleeping. Quell users can personalize and manage therapy discreetly via the Quell app. Quell also offers health tracking metrics relevant to chronic pain sufferers. Quell users can synchronize their data with the Quell Health Cloud®, which provides customized feedback and powers a large chronic pain outcomes database. 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 focal neuropathies. Quell® is a wearable neurostimulation device indicated for treatment of lower extremity chronic pain. For more information, visit www.NeuroMetrix.com.

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