# NeuroMetrix Announces That Top-Line Results from a Randomized Controlled Trial of Quell® for Treatment of Fibromyalgia to be Presented at Two Upcoming Pain Medicine Conferences

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WOBURN, Mass., June 09, 2021 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today reported that top-line results from a randomized controlled trial of Quell in patients with fibromyalgia will be presented at two upcoming pain medicine conferences.

The double-blind, randomized, sham-controlled trial was conducted at the Center for Pain Management, Brigham and Women's Hospital (Boston, MA); ClinicalTrials.gov identifier 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. The average age of study subjects was 50 years, 93% were female and the average duration of chronic pain was 18 years. Most subjects had moderate to severe fibromyalgia.

A poster titled "Outcome of TENS for Fibromyalgia: Randomized Sham-Controlled Trial" will be presented at the International Association for the Study of Pain (IASP) 2021 Virtual World Congress on Pain June 9-11 & 16-18. Key reported results include:

- In the intention-to-treat (ITT) population, the treatment difference in the Patient Global Impression of Change (PGIC, primary endpoint) was not significant (sham 3.24 ± 0.26, active 3.58 ± 0.25, p=0.351). However, in a pre-specified subgroup analysis of subjects with elevated baseline pain sensitivity, the active treatment group exhibited a significant and clinically meaningful improvement compared to sham (sham 3.09±0.40, active 4.24 ± 0.37, p=0.032).

- Several secondary endpoints were positive in the ITT population. The reduction in the mean FIQR Total Score was significantly greater for active treatment (-14.0 ± 2.1) compared to sham (-6.6 ± 2.2), p=0.001. The Brief Pain Inventory (BPI) interference subscale and the painDETECT questionnaire (PDQ) also exhibited significant improvements compared to sham.

- There were few TENS related adverse events, and all were minor and self-limited.

An oral presentation titled "Baseline Pain Sensitivity Predicts Responder Rates of Wearable TENS Use in Fibromyalgia: Analysis of a Double-Blinded Randomized Sham-Controlled Trial" will be given at the 3rd International Virtual Congress on Controversies in Fibromyalgia (Fibromyalgia2021) on June 24-25. Key reported results include:

- In the ITT population, the FIQR responder rate (≥15% reduction) was 56% for the active device compared to 35% for sham (p=0.029).

- In subjects with elevated baseline pain sensitivity, the PGIC responder rate was 58% (active) versus 30% (sham), p=0.024. The pain responder rate (≥30% reduction) was 58% (active) versus 18% (sham), p=0.001.

"I would like to thank Dr. Robert Jamison and his colleagues at Brigham and Women's Hospital for designing and successfully completing this trial study despite the COVID-19 pandemic. Fibromyalgia is a disabling chronic pain condition with an urgent need for effective treatments without the side effects of drugs currently used to manage the condition. We believe that Quell may be effective in fibromyalgia and the results of this study support this potential," said Shai N. Gozani, M.D., Ph.D., President and CEO of NeuroMetrix. "We are particularly pleased that subjects treated with Quell exhibited a significant improvement in FIQR over 3-months compared to sham. FIQR is a comprehensive health-related quality of life assessment specifically designed for fibromyalgia. The 21 clinical items comprising the FIQR have high everyday relevance to individuals with fibromyalgia. We are also pleased with the broad positive results in subjects with elevated pain sensitivity, because these are the patients expected to benefit most from nerve stimulation."

**Note: The use of Quell for fibromyalgia is investigational. The safety and effectiveness for this purpose has not been reviewed by the United States Food and Drug Administration (FDA).**

**About Fibromyalgia**

Fibromyalgia is a disorder characterized by widespread chronic pain accompanied by fatigue, sleep, cognitive, balance and mood disturbances. It affects an estimated 2 to 6 percent of the US population, or as many as 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.

**About Quell**

Quell is a novel transcutaneous electrical nerve stimulator (TENS) that is indicated for symptomatic relief and management of chronic lower extremity 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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