



## NeuroMetrix Reports Encouraging Results from Pilot Clinical Trial of Quell® in Post-Acute COVID-19 Syndrome (Long COVID)

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WOBURN, Mass., Dec. 12, 2023 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) reported the recent presentation of data from a clinical trial of Quell wearable neuromodulation technology in patients with post-acute COVID-19 syndrome (PACS), commonly called Long COVID. The presentation was made at the National Science Foundation (NSF) funded Center to Stream Healthcare In Place (C2SHIP) annual meeting in Washington DC. The trial was conducted at the Baylor College of Medicine in collaboration with C2SHIP. The principal investigator was Dr. Bijan Najafi, Professor of Surgery, and clinical director at the Division of Vascular Surgery and Endovascular Therapy, Baylor College of Medicine.

According to the Centers for Disease Control and Prevention (CDC), about 10 million Americans have PACS. This condition is defined as persistent symptoms following an acute COVID-19 infection. It may affect 10-20% 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. As many as 30% of individuals who experienced an acute COVID-19 infection meet 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.

The Quell PACS study was a subject and investigator blinded, randomized, sham-controlled trial. A total of 30 subjects with persistent symptoms of pain, fatigue, weakness, or poor gait and balance following COVID-19 infection were enrolled. Subjects were randomized to an active (high dose) or sham (low dose) Quell device for 4-weeks. Subjects in both arms were instructed to use their device for at least 3-hours of nerve stimulation each day. The primary outcome measures were baseline to 4-week changes in pain (Brief Pain Inventory, BPI) and fatigue (Multidimensional Assessment of Fatigue, MAF). Secondary outcomes measures included objective assessments of gait. Complete study details are available at [clinicaltrials.gov \(NCT05200858\)](https://clinicaltrials.gov/NCT05200858).

Twenty-five subjects (12 active, 13 sham) completed the study. The trial met the BPI primary endpoint, with the pain interference subscale exhibiting a greater decrease in the active arm compared to the sham arm ( $p = 0.01$ , Cohen's  $d$  effect size = 1.1). In the 60% of subjects who met ACR criteria for fibromyalgia, the MAF showed a significant within-group decrease in fatigue for the active arm ( $p < 0.01$ ) but not for sham ( $p = 0.19$ ). The active group also demonstrated significant within-group improvements in gait quality.

"The impact of COVID-19 lingers long after the acute infection in many individuals, and may resemble a fibromyalgia-like syndrome. Unfortunately, like traditional fibromyalgia, the COVID-19 version is debilitating and difficult to treat," said Shai N. Gozani, M.D., Ph.D., CEO of NeuroMetrix. "This pilot trial suggests that Quell may alleviate fibromyalgia-like pain and other symptoms of Long Covid. We are conducting a regulatory review to determine if the data supports an expansion of the Quell fibromyalgia label. We appreciated the opportunity to work with Professor Bijan Najafi and his colleagues at the Baylor College of Medicine in this investigation. This project is a demonstration of the mission of C2SHIP to address some of the most difficult healthcare challenges facing the country."

**The use of Quell for post-acute COVID-19 syndrome is investigational and has not been cleared or approved by the FDA. The safety and effectiveness for this purpose has not been reviewed by the FDA.**

### About C2SHIP

The mission of the Center to Stream Healthcare In Place (C2SHIP) is to engage academic and industrial partners in joint efforts that develop healthcare technologies for in-place care and accelerate innovation through multi-specialty collaborations. The Center's strategy is to emphasize fundamental investigations that provide an in-depth understanding of the core disciplines needed for personalized technology that promotes in-place care, to establish effective interactions with Center members to promote innovation capacity and accelerate technology transfer, and to promote collaborations with other existing centers to create multi-center innovative technology for the involved core disciplines. C2SHIP is part of the U.S. National Science Foundation (NSF) Industry/University Cooperative Research Centers (I/UCRC) program. For more information visit [C2SHIP.org](https://C2SHIP.org).

### About Quell Technology

Quell is an advanced, non-invasive, neuromodulation platform that is covered by 26 issued U.S. utility patents. It is the only wearable neuromodulator that is enabled by a proprietary microchip to provide 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 user experience both day and night. The device supports Bluetooth® low energy (BLE) to communicate with mobile apps and the Quell Health Cloud. Quell is indicated to help reduce fibromyalgia symptoms in patients with high pain sensitivity and to reduce lower extremity chronic pain.

### About NeuroMetrix

NeuroMetrix is a commercial stage healthcare company that develops and commercializes neurotechnology devices to address unmet needs in the chronic pain and diabetes markets. The Company's products are wearable or hand-held medical devices enabled by proprietary consumables and software solutions that include mobile apps, enterprise software and cloud-based systems. The Company has two commercial brands. Quell® is a wearable neuromodulation platform. DPNCheck® is a point-of-care screening test for peripheral neuropathy. For more information, visit [www.neurometrix.com](https://www.neurometrix.com).

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