Nuwellis Initiates REVERSE-HF Study to Evaluate Ultrafiltration for Heart Failure Patients with Fluid Overload

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REVERSE-HF will evaluate rehospitalizations and survival when using the Aquadex therapy

MINNEAPOLIS, Feb. 17, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) today announced the company will evaluate the clinical outcomes and economic value of its Aquadex® therapy in comparison to intravenous diuretics for the treatment of fluid overload in patients with worsening heart failure through its randomized controlled trial, Ultrafiltration Versus IV Diuretics in Worsening Heart Failure, the REVERSE-HF Study.

REVERSE-HF is a multicenter, open-label, randomized controlled trial with an adaptive design that will be conducted across the United States. The study will be led by Sean Pinney, M.D., Professor of Medicine and Co-Director of the Heart and Vascular Center at The University of Chicago Medicine, and Maria V. DeVita, M.D., Professor of Medicine at Hofstra School of Medicine/Northwell and Chief of the Division of Nephrology at Lenox Hill Hospital. Enrollment in the trial will begin this year.

“Traditional diuretics can result in mixed outcomes, and people with heart failure who are experiencing fluid overload don’t always respond to them,” said Dr. Pinney. “We’re excited to further evaluate how ultrafiltration with Aquadex may optimally treat these patients.”

The primary effectiveness endpoint of REVERSE-HF will evaluate mortality and heart failure events within 30 days and 90 days as a comparison between Aquadex therapy and intravenous (IV) loop diuretics. The study will assess safety parameters, including but not limited to cardiovascular and renal related adverse events of special interest.

Heart failure can disrupt normal kidney functions and lower their ability to remove sodium from the body, which can cause excessive water retention resulting in fluid overload. Over 1 million heart failure hospitalizations occur annually in the United States, and fluid overload is the predominant cause. Furthermore, nearly one quarter of heart failure patients will be readmitted to the hospital within 30 days of their initial discharge, and half will be readmitted within 6 months.[1]

“Heart failure patients suffering from fluid overload are frequently readmitted to the hospital, resulting in a tremendous burden to both patients and our healthcare systems,” said Dr. DeVita. “We’re looking forward to learning more about how ultrafiltration can improve patient quality of life and prevent these readmissions.”

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical device company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The Company is focused on developing, manufacturing and commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly-owned subsidiary in Ireland.

About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically proven therapy using a simple, flexible and predictable method of removing excess fluid from patients suffering from hypervolemia (fluid overload). The Aquadex SmartFlow system is indicated for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a health care provider, within an outpatient or inpatient clinical setting, under physician prescription, both having received training in extracorporeal therapies.

Forward-Looking Statements

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding the new market opportunities and anticipated growth in 2022 and beyond. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risks associated with our ability to execute on our commercialization strategy, the impact of the COVID-19 pandemic, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. Nuwellis does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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[1] Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445.

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