



Restoring Fluid Balance. Transforming Care.

Nuwellis Announces Launch of Ultrafiltration Therapy Using Aquadex Smartflow® System at Henry Ford Health

April 9, 2024

MINNEAPOLIS, April 09, 2024 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) today announced that Detroit, Michigan-based health system, Henry Ford Health, has begun offering ultrafiltration therapy to heart failure patients suffering from fluid overload using the company's Aquadex SmartFlow system as part of Nuwellis' pivotal REVERSE-HF clinical study.

"We are excited to study the impact of Aquadex SmartFlow therapy on our heart failure patients who are suffering from severe fluid overload," said Dr. Jennifer Cowger, Section Head of the heart failure program at Henry Ford. "We are eager to see if ultrafiltration can affect clinical outcomes of our heart failure patients resistant to diuretics. Presently, diuretics are the only options in the field for acute symptoms relief of heart failure congestion. This intervention may change that and could have a longer-term beneficial impact on heart failure too."

"The heart failure patient population continues to expand in the U.S. and worldwide, and Nuwellis is dedicated to addressing the therapy needs of these patients while helping health systems reduce the overall cost of care," said Nestor Jaramillo, Jr., President and Chief Executive Officer of Nuwellis. "We are proud and honored to be working with Henry Ford Health and look forward to partnering with Dr. Cowger and the team of heart failure experts through the REVERSE-HF trial. We currently have 130 patients enrolled in the randomized multicenter trial and Henry Ford is the only site in Michigan offering this study intervention."

The Michigan-based Henry Ford Health Advanced Heart Failure Program is one of the nation's leading academic heart failure centers, recognized for clinical excellence in heart failure, heart transplant, and left ventricular assist device patient outcomes, offering patients the additional option of access to novel and potentially life-saving clinical trials in heart failure. The Henry Ford Advanced Heart Failure Program is one of the largest programs in Michigan and is proud to be a key contributor to advancing heart failure clinical research and care standards in the U.S.

About REVERSE-HF Clinical Study

[REVERSE-HF](#) is a prospective, multicenter, open label, randomized controlled trial that is being conducted across the U.S. to evaluate clinical outcomes of adjustable ultrafiltration including heart failure events, mortality, and quality of life within 30 and 90 days, as compared to IV Loop Diuretics. The study is led by Sean Pinney, M.D., Icahn School of Medicine at Mount Sinai Morningside, New York, 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. Currently, 16 medical centers are actively enrolling patients in the study and these centers have doubled the monthly rate of enrollment so far in 2024.

About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically proven therapy using a simple, flexible and smart 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.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical technology company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The company is focused on commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information visit www.nuwellis.com or visit us on [LinkedIn](#) or [X](#).

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 2024 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 due to new information, future events or otherwise.

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