Nuwellis Announces the Activation of New Sites for Its Pivotal REVERSE-HF Trial

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REVERSE-HF will evaluate ultrafiltration therapy in comparison to IV diuretics to treat heart failure patients with fluid overload

MINNEAPOLIS, Sept. 27, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a commercial-stage company focused on transforming the lives of people with fluid overload, today announced the activation of three additional sites for its pivotal REVERSE-HF (Ultrafiltration Versus IV Diuretics in Worsening Heart Failure) clinical study. Jefferson Abington Hospital in Pennsylvania, the University of California San Francisco (UCSF), and Baycare Morton Plant Hospital in Florida are now eligible to enroll patients and evaluate the clinical outcomes and economic value of the Aquadex® ultrafiltration therapy in comparison to intravenous (IV) diuretics for the treatment of fluid overload in patients unresponsive to diuretics with worsening heart failure.

"We have significant experience providing ultrafiltration therapy to patients with acute decompensated heart failure and our recent 10-year retrospective study showed that it compares favorably in reducing heart failure rehospitalizations, renal function response, and weight and fluid volume loss[1]," said Dr. Donald Haas, M.D., Medical Director, Mechanical Circulatory Support and Director, Comprehensive Heart Failure Program at Jefferson Abington Hospital. “The REVERSE-HF study has the potential to yield the highest level of evidence yet demonstrating the clinical, economic, and quality-of-life benefits of using ultrafiltration to treat heart failure patients who are unresponsive to diuretics.”

Heart failure can disrupt normal kidney function and lower their ability to remove sodium from the body, resulting in excessive water retention that can ultimately lead to fluid overload. Over 1 million heart failure hospitalizations occur annually in the United States, and fluid overload is the predominant cause in 90% of the patients. Furthermore, 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.[2] Clinical studies have shown that ultrafiltration can reduce these readmissions by half.

“Fluid overload is a significant contributor to morbidity and mortality in heart failure patients. In addition, the frequent hospital readmissions to treat these patients result in a tremendous burden to our healthcare system,” said Dr. Liviu Klein, M.D., Professor of Clinical Medicine and Director, Cardiology Clinical Research at the University of California San Francisco. “Ultrafiltration has the potential to more adequately decongest heart failure patients that are unresponsive to diuretics, thus reducing readmissions, improving clinical and economic outcomes, and patient quality of life. We look forward to participating in the REVERSE-HF study.”

REVERSE-HF is a multicenter, open-label, randomized controlled trial that is being conducted across the United States. The study is 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.

“The current standard of care for treating fluid-overloaded heart failure patients has led to mixed outcomes due to a significant number of them not responding to traditional diuretics,” said Dr. Leslie Miller, Director of Heart Failure at BayCare Morton Plant. “Early application of ultrafiltration therapy in the appropriate patients could improve their outcomes and quality of life by more adequately decongesting them, thus reducing the risk of rehospitalizations. We’re excited to further evaluate the benefits of ultrafiltration with Aquadex in treating these patients.”

“We are excited about the activation of Jefferson Abington Hospital, the University of California San Francisco, and BayCare Morton Plant as REVERSE-HF study sites,” said Nestor Jaramillo, Jr., President and CEO of Nuwellis. “All three institutions have a long history of clinical excellence and experience that will contribute to its successful enrollment. We are grateful to Drs. Haas, Klein, Miller, and their clinical teams for their contributions in gathering additional evidence supporting the benefits of ultrafiltration therapy in heart failure 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 IV loop diuretics. The study will assess safety parameters, including, but not limited to, cardiovascular and renal-related adverse events of special interest.

REVERSE-HF uses a statistical method that increases precision in demonstrating significant differences in clinical outcomes between treatment arms. This statistical method, called the Finkelstein-Schoenfeld method of Win-Ratios, has also been used recently to re-evaluate data obtained during the AVOID–HF (Aquapheresis Versus Intravenous Diuretics and Hospitalization for Heart Failure) prospective, multicenter, randomized controlled trial, which was the first to propose that patients should be treated with adjustable ultrafiltration when compared to those receiving adjustable loop diuretics. The AVOID-HF trial tested the hypothesis that patients hospitalized for heart failure and treated with ultrafiltration would have a longer time to their first heart failure event within 90 days after hospital discharge compared to those receiving IV loop diuretics. AVOID-HF was trending favorably when it was terminated before reaching full enrollment for reasons unrelated to patient safety or clinical futility. The Win-Ratio analysis of AVOID-HF will be presented as a late-breaking abstract at the Heart Failure Society of America Annual Scientific Meeting in Washington D.C., on September 30. This paper is also expected to be published in a peer reviewed journal later this year.

In addition to Jefferson Abington, USCF, and BayCare Morton Plant, Nuwellis is currently partnering with other clinical institutions that will soon be enrolling patients for the REVERSE-HF study as well. The Company anticipates at least 12 clinical institutions will participate in the study.

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, Minn., 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.

1. Watson R, et al. J Card Fail. 2020; 26(10): S56.

2. Costanzo MR, et al. J Am Coll Cardiol. 2017;69(19)2428-2445

CONTACTS

INVESTORS:
George Montague, CFA
Chief Financial Officer, Nuwellis, Inc.
ir@nuwellis.com

Leigh Salvo
Gilmartin Group LLC
leigh@gilmartinir.com

MEDIA:
Sarah Lundberg
Health+Commerce
sarahlundberg@healthandcommerce.com

Source: Nuwellis, Inc.