ACC 2021 Presentation Adds to Body of Evidence Supporting Nuwellis Ultrafiltration to Treat Patients with Heart Failure

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Treatment with Aquadex therapy showed significant weight decrease, clinical symptom improvement and decreased readmissions among heart failure patients.

EDEN PRAIRIE, Minn., May 17, 2021 (GLOBE NEWSWIRE) -- Data supporting the effectiveness of Aquadex FlexFlow® system in the treatment of acutely decompensated heart failure (ADHF) patients was presented May 16th at the 2021 American College of Cardiology conference (ACC). The single-center study evaluated 30 ADHF patients in mainstream setting (i.e., step-down unit, not critical care) who were treated with Aquadex therapy. The Aquadex FlexFlow is developed by Nuwellis, Inc. (Nasdaq: NUWE), formerly CHF Solutions, Inc., a company dedicated to changing the lives of people suffering from fluid overload.

The study showed 83% of patients treated with Aquadex therapy experienced clinical symptom improvement (50% moderate, 33% markedly) and significant weight decrease – the mean fluid removed was 9.40L. In addition, heart failure related readmissions were significantly reduced at 60 days (p=0.017) and moderately at 90 days (p= 0.094).

Findings from this study compared favorably to several randomized controlled trials on ultrafiltration as well as the ten-year results published by Abington-Jefferson Health last fall.[1,2] All found that ultrafiltration using the Aquadex system:

- Is effective in driving fluid removal and weight loss in ADHF patients
- Decreases heart failure readmissions
- Has no significant impact on renal function

“We saw outstanding results with Aquadex in our first year of aquapheresis ultrafiltration, which is particularly meaningful considering the disease state of the patients,” said Dr. James Stamper, Medical Director of Aquapheresis, and lead clinical investigator. “The patients had serious medical conditions including cardiac and renal dysfunction, and failed standard therapeutic approaches. The prognosis is usually guarded in these situations. Aquadex achieved gratifying symptom improvement by fluid removal without worsening renal function, and reduced heart failure readmission rates in this cohort of our most challenging patients. Our data confirms a new aquapheresis ultrafiltration program can achieve safe and effective results, with impressive benefits to the patients and to the health system, even in the first year.”

“Nuwellis has a strong history in the heart failure space, and this data makes it evident why,” said Nestor Jaramillo Jr., President and CEO of Nuwellis. “Our gentle ultrafiltration therapy is built to effectively remove fluid at a customizable rate, which is beneficial for fragile patients such as those with heart failure. The positive results presented by Dr. Stamper support our foundational corporate focus. Despite expansions to other vulnerable patients, heart failure is a core area where ultrafiltration is beneficial and needed.”

About Nuwellis

Nuwellis, Inc. (Nasdaq:NUWE), formally CHF Solutions, Inc., is a medical device company dedicated to changing 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. The Company has been listed on the Nasdaq Capital Market since February 2012, previously branded as CHF Solutions (Nasdaq:CHFS).

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.

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 efficacy of Aquadex FlexFlow ultrafiltration therapy. 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 commercial 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.

Sources: 1. Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445. 2. Watson RA, et al. Poster 155. Presented at: Heart Failure

Society of America Scientific Meeting; Sept. 30-Oct. 6, 2020 (virtual meeting).

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