New Study Published in Current Problems in Cardiology Highlights Statistically Significant Reduction in Heart Failure Readmissions at 60 days when using the Aquadex Ultrafiltration Therapy

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MINNEAPOLIS, Aug. 27, 2024 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company dedicated to transforming the lives of patients with fluid overload, is pleased to announce the publication of a new study in *Current Problems in Cardiology* demonstrating the effectiveness of Aquadex® ultrafiltration therapy in reducing 60 day hospital readmission rates for patients with acutely decompensated heart failure (ADHF) who are otherwise resistant to diuretic treatment.

The study, conducted by Viswanath R. Chinta, MD, Dr. John L. Jefferies, MD, MBA, MPH, and fellow researchers, is titled “Outcomes of Ultrafiltration in community-based hospitals” and sought to evaluate and validate the role of a newly implemented Aquadex ultrafiltration therapy program in a community hospital setting. The study analyzed data from 30 patients who underwent this therapy during the program's first year. The primary objective was to assess whether ultrafiltration with Aquadex could reduce the high readmission rates commonly observed in patients with refractory ADHF.

Key findings from the study include:

- **Significant Volume Loss and Weight Reduction:** Patients experienced significant volume loss and weight reduction without adverse renal effects.
- **Significant Reduction in Heart Failure Readmissions:** The study found a statistically significant reduction in rehospitalization rates for heart failure at 60 days from the initiation of ultrafiltration therapy compared to the pre-ultrafiltration period (16.7% vs. 26.7%, p=0.013). The total number of ADHF readmissions in the 30 days following ultrafiltration therapy decreased by 40%, and by 59% in the subsequent 60 days.
- **Stable Renal Function:** Serum creatinine levels at 72 hours post-ultrafiltration did not change significantly (-0.01 mg/dL, 95% CI -0.26, 0.23).

Dr. Jefferies expressed his enthusiasm for the study's findings, stating, "The results of our study showed success with ultrafiltration in the mainstream setting with reproducible results of significant volume loss without adverse effect, mitigation of recurrent HF admissions and remarkable subjective clinical benefits. The significant reduction in rehospitalization rates, combined with the safety profile observed, marks a notable advancement in the management of acutely decompensated heart failure."

"This study underscores the value of ultrafiltration therapy with Aquadex in managing fluid overload in hospitalized heart failure patients," commented Nestor Jaramillo, President and CEO of Nuwellis. "The positive outcomes reported in this community-based hospital setting demonstrate the broader applicability and effectiveness of Aquadex, which is critical as we continue to expand access to this life-saving therapy in multiple academic and community healthcare centers across the country."

Mr. Jaramillo added, "These study results should be of interest to the many physicians and hospital administrators seeking to reduce the losses associated with heart failure patient care. The statistically significant outcomes reported in this study further reinforce the value of Aquadex. This new evidence comes as we marked 30% revenue growth in our core business, as reported in our second quarter earnings release."

Treating heart failure patients is a complex and costly endeavor. In the U.S., over 6.5 million people suffer from this condition, leading to $60 billion in annual healthcare costs.[1] One million of these patients are hospitalized each year due to fluid overload, spending an average of 8 days in the hospital at a cost of $24,000 per patient.[1,2] DRGs do not fully cover these costs, and a 24% national readmission rate can result in a 2-3% penalty on all Medicare expenses for hospitals. The results of this new research highlight the crucial role that Aquadex ultrafiltration therapy can play in reducing hospitalization and readmission rates, as well as patient length of stay. By doing so, hospitals can save approximately $3,975 per patient and reduce hospitalization mortality.[3,4]

The full study is available in the October issue of *Current Problems in Cardiology*. While certain authors of this paper have disclosed selected financial interests in the Company, Nuwellis did not provide any financial support to any of the authors or the hospital in connection with this research.

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.

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 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 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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4. Costanzo, et. al., ISPOR 23rd Annual Int'l Mtg., May 19 -23, 2018, Baltimore, MD, USA

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