Clinical Data Supports the Role of Ultrafiltration in Preventing Cardiac Surgery-Associated Acute Kidney Injury (AKI)

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New guidelines from cardiothoracic surgical societies emphasize the importance of volume maintenance during cardiac procedures

MINNEAPOLIS, Feb. 23, 2023 (GLOBE NEWSWIRE) -- A recent editorial published in *The Annals of Thoracic Surgery* provides additional clinical evidence to support the role that ultrafiltration plays in preventing cardiac surgery-associated acute kidney injury (CSA-AKI), according to leaders at Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload.

Written by Daniel T. Engelman, M.D. and Andrew D. Shaw, M.D., "A Turnkey Order Set for Prevention of Cardiac Surgery-Associated Acute Kidney Injury" compares protocols for preventing cardiac surgery-associated acute kidney injury (CSA-AKI) from leading cardiothoracic surgical societies. This topic is of critical importance to cardiac surgeons because as many as 80% of cardiac surgery patients may have stage 1 or greater CSA-AKI, according to guidelines published by Kidney Disease Improving Global Outcomes (KDIGO), the global nonprofit organization developing and implementing evidence-based clinical practices guidelines in kidney disease.[1]

The editorial examines the role of intravenous fluid overload in contributing to CSA-AKI and challenges the notion that diuretics are always the best management approach. Specifically, the authors wrote that greater attention is needed when maintaining intravascular volume – and said ultrafiltration should be considered when patients are unresponsive to diuretics.

"We're thrilled to have additional validation for the technology behind Aquadex ® in this new publication," said Dr. John Jefferies, Chief Medical Officer of Nuwellis. "We often hear about the need for alternatives to diuretics from clinicians. This publication validates ultrafiltration as a best practice when diuretics fall short in treating patients with fluid overload during and after cardiothoracic procedures."

This editorial also reinforces data published in the *Journal of Cardiac Surgery* by lead author Daniel Beckles, M.D., Ph.D., a cardiothoracic surgeon at Baylor Scott & White Health, which supported the use of ultrafiltration in high-risk postoperative coronary artery bypass grafting (CABG) patients. The study is a real-world retrospective review of postoperative isolated CABG patients. With an elevated mean Society of Thoracic Surgeons mortality score of 5.7% (range 0.6-50.0), the 30-day survival rate of patients treated with ultrafiltration in this study was 100%.

"Avoiding complications like CSI-AKI in cardiac surgery is critical, and ultrafiltration has a unique application to treat fluid overload in this space, especially when treating patients with diuretic resistance," said Dr. Beckles. "I'm encouraged to see additional evidence generated by leading societies supporting ultrafiltration technology for these patients."

Diuretics can play a key role in managing fluid overload for some patients but are also associated with mixed outcomes and even adverse events. For example, in heart failure, 40% of patients show poor diuretic response, and 68% demonstrate a suboptimal response.[2,3] Furthermore, loop diuretics provide unpredictable elimination, put patients at risk of developing low potassium and magnesium levels, and can ultimately lead to diuretic resistance that causes persistent congestion with no change to sodium levels.[4] Ultrafiltration, on the other hand, provides predictable removal of sodium and fluids, restores diuretic responsiveness, and offers more effective decongestion and fewer heart failure events compared to loop diuretics.[4]

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, Minnesota, with a wholly owned subsidiary in Ireland. For more information visit www.nuwellis.com or visit us on LinkedIn and Twitter.

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 2023 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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Source: Nuwellis, Inc.