



Restoring Fluid Balance. Transforming Care.

Nuwellis Announces Peer-Reviewed Publication of Clinical Trials Analysis Advocating the Use of Ultrafiltration for Heart Failure Patients Resistant to Diuretics

March 21, 2023

MINNEAPOLIS, March 21, 2023 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload, today announced the peer-reviewed publication of an analysis of available ultrafiltration clinical trials with findings that support ultrafiltration as a safe and effective therapeutic option for acute decompensated heart failure (ADHF) patients who are resistant to diuretics or who have a history of multiple hospitalizations for fluid overload. The publication highlights the scale of clinical burden: "ADHF has the highest rate of hospital readmissions among all medical conditions and portends a significant financial burden on healthcare systems worldwide."¹

The [publication](#), "*Extracorporeal Ultrafiltration for Acute Heart Failure*," featured in *Cardiorenal Medicine Journal*, includes the review of pooled data from seven randomized controlled trials of ultrafiltration with a total of 771 patient participants. A. Kazory, et al, highlight the clinical application and value of ultrafiltration, including:

- Predictable, adjustable, and more efficient fluid removal with ultrafiltration compared to diuretics, without clinically adverse impact on renal function, leads to a reduction in hospital readmissions and financial burden;
- Applicability of ultrafiltration therapy in other clinical settings, such as cardiac surgery, burn and other specialty units, where active and prompt volume management is of utmost importance; and
- Expansion of use of ultrafiltration into outpatient centers and other ambulatory settings.

John Jefferies, M.D., Chief Medical Officer of Nuwellis, said, "Hospitalizations for ADHF are primarily driven by fluid overload, with nearly 50% of these patients leaving the hospital with inadequate or minimal weight loss, in part due to unpredictability of diuretic therapy. As such, it also has the highest rehospitalization rate among all medical conditions." Dr. Jefferies added, "Ultrafiltration, however, provides an opportunity to overcome the shortcomings of diuretics, as the Aquadex[®] system's decongestion technique safely provides for adjustable fluid and sodium removal. It can also be considered early after admission, with volume and rate of fluid removal specific to patient characteristics for more predictable results, which diuretics often times cannot achieve."

"We are excited to add this peer-reviewed analysis of ultrafiltration trials to our growing body of clinical evidence, which we are leveraging to change practice guidelines to make Aquadex the standard of care for fluid overload and increase its use across multiple specialty units in hospitals and outpatient centers," said Nestor Jaramillo, President and CEO of Nuwellis. "In the last six months we have announced various new publications demonstrating results that favor ultrafiltration over IV diuretics when using Nuwellis' Aquadex system. This publication is different because it outlines the reasons why healthcare providers should use ultrafiltration and the consequences of not using it to treat ADHF. We look forward to increased sales momentum as we expand awareness of the benefits of ultrafiltration over diuretics using the arguments presented by the authors."

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](#).

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 healthcare 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 as a result of new information, future events or otherwise.

CONTACTS

INVESTORS:

Vivian Cervantes

Gilmartin Group

ir@nuwellis.com

MEDIA:

Annika Parish

Health+Commerce

annika@healthandcommerce.com



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