New Evidence on Aquadex Ultrafiltration Therapy to be Presented at HFSA 2024 Conference

July 9, 2024

MINNEAPOLIS, July 09, 2024 (GLOBE NEWSWIRE) -- Nuwellis, Inc. Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company dedicated to transforming the lives of patients with fluid overload, is pleased to announce that new clinical evidence demonstrating the efficacy of its Aquadex® system will be presented at the Heart Failure Society of America (HFSA) Annual Scientific Meeting, taking place September 27-30, 2024, in Atlanta, Georgia.

The study, conducted by Dr. Wayne Old, MD, an advanced heart failure cardiologist at Sentara Health, based out of Sentara Norfolk General Hospital in Norfolk, Va., highlights the benefits of Aquadex ultrafiltration therapy for heart failure patients experiencing fluid overload who have not responded to traditional diuretic treatments. The research underscores Aquadex's ability to effectively manage fluid levels, providing a critical therapeutic alternative for this challenging patient population.

"We are excited to share our findings at the upcoming HFSA conference," said Dr. Wayne Old. "Our research demonstrates the efficacy of Aquadex in improving patient outcomes where diuretics have failed. This data supports the integration of ultrafiltration therapy via the Aquadex system into standard practice for managing fluid overload in heart failure patients, providing a new therapy option for patients needing decongestion."

Nestor Jaramillo, President and CEO of Nuwellis, expressed his gratitude to Dr. Old and his team for their dedicated research efforts. "We extend our deepest appreciation to Dr. Old and his research team for their invaluable work in validating the effectiveness of Aquadex," said Jaramillo. "Nuwellis is committed to providing robust clinical data to support the use of our therapy. There are many heart failure patients hospitalized due to the symptoms of fluid overload who continue to be treated with diuretics despite their known inefficacy. Aquadex not only offers a more effective solution but also presents significant economic savings to hospitals by reducing the length of hospital stays and associated healthcare costs."

Sentara Health is also actively participating in REVERSE-HF, a pivotal clinical study on ultrafiltration using Aquadex. REVERSE-HF (Ultrafiltration Versus IV Diuretics in Worsening Heart Failure) is evaluating the clinical outcomes and economic value of Aquadex ultrafiltration therapy in comparison to intravenous (IV) diuretics for the treatment of fluid overload in patients with worsening heart failure.

Dr. Amin Yehya, MD, MS, FACC, FHFSA is the site principal investigator for the REVERSE-HF trial, the medical director of the durable mechanical circulatory support at Sentara Health, and an advanced heart failure and transplant cardiologist. "We are excited to participate in REVERESE-HF and examine Aquadex SmartFlow therapy in our heart failure patients experiencing fluid overload," stated Dr. Yehya. "We are looking forward to confirming the efficacy of ultrafiltration for our patients who do not respond to diuretics. Currently, diuretics are the sole treatment available for the acute relief of heart failure congestion with over 40% of the patients unresponsive to the therapy. Simplified ultrafiltration has demonstrated that it has the potential to change that and offer long-term benefits for heart failure management. REVERSE-HF is set to provide the evidence."

Additional details on Dr. Old's research will be forthcoming from HFSA. Nuwellis invites attendees of the HFSA 2024 Annual Scientific Meeting to attend the presentation and learn more about the clinical advancements and benefits of Aquadex ultrafiltration therapy. Neither Dr. Old nor Sentara Health received any financial support from Nuwellis in support of his research initiatives. The REVERSE-HF clinical study is sponsored by Nuwellis.

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 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.

CONTACTS

Investors:
Vivian Cervantes
Gilmartin Group
ir@nuwellis.com

Source: Nuwellis, Inc.