

Nuwellis Initiates Its Outpatient Heart Failure Strategy Using Aquadex Ultrafiltration Therapy

July 12, 2022

MINNEAPOLIS, July 12, 2022 (GLOBE NEWSWIRE) -- <u>Nuwellis, Inc.</u> (Nasdaq: NUWE), a commercial-stage company focused on improving the quality of life for people with fluid overload, today announced key takeaways from its recent physician-led webinar discussing the benefits of treating fluid overloaded heart failure (HF) patients with Aquadex® ultrafiltration (UF) in the outpatient setting – the first step toward commercializing this opportunity.

The webinar featured perspectives from leading heart failure clinicians from across the U.S.:

- Ramesh Emani, MD, Interventional Heart Failure Cardiologist and Associate Professor of Clinical Medicine, Division of Cardiology, The Ohio State University – Columbus, OH
- Detlef Wencker, MD, Advanced Heart Failure Specialists Dallas, TX
- Pat Correlli, PA-C, Chief Outpatient Physician's Associate and Lead Clinician of Outpatient Congestive Heart Failure at MedStar Good Samaritan Hospital – Baltimore, MD

Panelists discussed the clinical and economic challenges associated with the current standards of care for managing fluid overload among heart failure patients, explored strategies for treating these patients in the outpatient setting, and shared their experiences with outpatient Aquadex UF therapy. Under the current standard of care, patients often have long hospital stays and hospitals are typically only partially reimbursed for the cost of care. Furthermore, hospitals receive no reimbursement for patients that are readmitted within 30 days of initial discharge. According to Premier Applied Sciences data, the average total unreimbursed cost per inpatient encounter is \$24,027, which highlights the importance of reducing unscheduled 30-day readmissions. While reimbursement for ultrafiltration varies from state to state, panelists said, in their experience, reimbursement for the administration of Aquadex in the outpatient setting has been favorable for their hospitals.

"Outpatient ultrafiltration treatment with Aquadex presents a unique opportunity to break the cycle of heart failure readmissions, reducing the associated financial burden to healthcare systems, and improving patient quality of life," said Nestor Jaramillo, Jr., President and CEO of Nuwellis. "In addition, it represents a new patient segment with the same call point as our regular heart failure segment. Treating heart failure patients with the Aquadex System in the outpatient setting is similar to how other patients receive dialysis in outpatient clinics. We appreciate the panelists sharing their extensive experience and thank them for their continued dedication to expanding medical knowledge on the benefits of effective fluid management."

According to the panelists, heart failure patients with fluid overload are often caught in a cycle where they are hospitalized, inadequately decongested, sent home, and then rehospitalized when congestion issues resurface. In fact, national data suggests that 24% of these patients will be rehospitalized within 30 days of discharge, and 50% within 90 days. In a study conducted by Lin et al., investigators evaluated the impact of repeat HF hospitalizations on all-cause mortality and determined the risk variables related to patient mortality. They found that mean survival time was 2.6, 1.8, 1.5, and 1.3 years after the first, second, third, and fourth hospitalization, respectively, and concluded that repeat hospitalizations were a strong predictor of mortality for existing patients with HF¹.

The webinar panelists also shared how ultrafiltration with Aquadex therapy is being used in the outpatient setting to effectively address this challenge. According to Dr. Emani, ultrafiltration adequately decongests patients without significant injury to the kidneys, as evidenced by a reduction in unscheduled 30-day readmissions (up to 79%), significant weight loss, and stable serum creatinine levels in patients studied at The Ohio State University.

Panelist Patrick Correlli described the impact of ultrafiltration on heart failure patients in his hospital as a paradigm shift. "Now we're finding we can really have a lot of success in doing this for outpatients, and this doesn't have to be captive to the inpatient world," said Correlli.

Patient satisfaction is another key benefit of ultrafiltration. "The feedback we've received has been almost universally positive. Patients really like having this as an option. And when we can tell them, you are going to get this treatment and then go home, it is all that much better," said Dr. Emani.

The full webinar is available on the Nuwellis website and YouTube channel.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical device company dedicated to transforming 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, with a wholly-owned subsidiary in Ireland.

About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically proven therapy using a simple, flexible and predictable 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 2022 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.

¹Andrew H Lin et al. Mil Med. 2017 Sep.

CONTACTS

INVESTORS: George Montague, CFA Chief Financial Officer, Nuwellis, Inc. ir@nuwellis.com

Matt Bacso, CFA Gilmartin Group LLC Matt.Bacso@gilmartinir.com

MEDIA: Sarah Lundberg Health+Commerce sarahlundberg@healthandcommerce.com



Source: Nuwellis, Inc.