

Nuwellis Provides More Children in Texas With Access to Its Unique Fluid Management Technology

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Gentle Ultrafiltration with Aquadex SmartFlow® Expands Options for Pediatric Patients

EDEN PRAIRIE, Minn., May 13, 2021 (GLOBE NEWSWIRE) -- Reaffirming its commitment to expanding access to life-saving ultrafiltration therapies for adult and pediatric patients suffering from fluid overload, Nuwellis, Inc. (Nasdaq: NUWE), formerly CHF Solutions, Inc., today announced that its Aquadex SmartFlow® System is now available at Driscoll Children's Hospital in Corpus Christi, Texas.

Aquadex enables gentle, precise and adjustable fluid removal, helping achieve the desired fluid balance with only 35 mL (around 2.5 tablespoons) of blood outside of the body. This is particularly important for pediatric patients, who have a small amount of blood in their bodies. Aquadex is clinically proven¹ to be safe and effective in children weighing 20 kg or more. The expansion into pediatric hospitals like Driscoll Children's Hospital further validates the benefit if this technology offers children.

"Aquadex allows us to remove excess fluid according to each patient's specific needs, with very high precision, while using a very small circuit which helps minimize hemodynamic instability in very sick patients," said Dr. Samhar Al-Akash, Medical Director of Dialysis and Transplantation at Driscoll Children's Hospital. "Having the flexibility to customize therapy for each unique patient is especially advantageous in smaller pediatric patients who have a smaller margin of error. We are excited to offer this innovative treatment to our patients."

Fluid overload is associated with adverse outcomes in multiple disease states including heart failure, kidney failure and critical care. Alleviating the burden that fluid overload has on vital organs helps mitigate poor outcomes and reduces the need for re-hospitalization, leading to better efficiency, reduced costs and improved outcomes.²

"We continue to deliver on our promise to expand access to life-saving fluid management technology," said Nestor Jaramillo, Jr., President and CEO of Nuwellis. "Ensuring that providers have the technology they need to help patients recover and thrive is what motivates us most, and we're doing it one hospital at a time."

About Nuwellis

Nuwellis, Inc. (Nasdaq:NUWE), formally CHF Solutions, Inc., is a medical device company dedicated to changing 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, Minn., with a wholly-owned subsidiary in Ireland. The Company has been listed on the Nasdaq Capital Market since February 2012, previously branded as CHF Solutions (Nasdaq:CHFS).

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 about the anticipated use of the net proceeds. 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 risk associated with our ability to execute on our commercial 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 as a result of new information, future events or otherwise.

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¹ Menon S, et al. Clin J Am Soc Nephrol. 2019 Oct 7;14(10):1432-1440.

² Watson, Ret al (2020). Journal of Cardiac Failure, 26(10).

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