CHF Solutions Announces First Patient Enrolled in the ULTRA-Peds Registry

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Registry will Support Real-World Efficacy of Fluid Management in Children

EDEN PRAIRIE, Minn., April 20, 2021 (GLOBE NEWSWIRE) -- More pediatric clinical evidence is essential in understanding the real-world benefits of medical devices in children. CHF Solutions is committed to expanding pediatric-specific data, and today announced Joe DiMaggio Children's Hospital in Hollywood, Florida has enrolled the first patient in the Ultrafiltration Therapy Registry Using Aquadex (ULTRA-Peds Registry).

ULTRA-Peds will collect real-world evidence on the safety, performance and utilization of Aquadex SmartFlow® in fluid overloaded children who weigh 20 kg or more. CHF Solutions is the sponsor of the registry alongside collaborator Acute Kidney Injury Critical Care Research Foundation.

Key clinical data to be collected from approximately 500 patients:

- Treatment course survival
- ICU survival
- ICU length of stay
- Change in kidney function
- Hemodynamic stability
- Change in percentage of fluid overload
- Complications and adverse events

"Maintaining fluid balance and hemodynamic stability are imperative to minimize the risk of increased morbidity and mortality. This involves selecting the appropriate treatment for fluid overload states" said Alex. R. Constantinescu, MD, Chief of Pediatric Nephrology, Joe DiMaggio Children's Hospital. "Because the majority of medical products are designed for and tested in adults, having clinical outcomes data supporting a device's use in children has an immeasurable value. I'm honored to support the collection of pediatric data on Aquadex because I know the therapy works, and data will support clinician adoption – meaning more kids can benefit from this therapy."

"We are grateful to partner with organizations like Joe DiMaggio Children's Hospital as part of our commitment to improve and customize pediatric care with the Aquadex SmartFlow® system," said Nestor Jaramillo, Jr., President and CEO of CHF Solutions. "As part of our continued growth, we are committed to finding ways to advance future technology and progress our pipeline, while demonstrating that this innovative and gentle therapy is safe, effective and beneficial for pediatric patients who are suffering from fluid overload."

About Fluid Overload in Pediatric Patients

Fluid overload (hypervolemia) occurs when there is too much fluid in the body and is a major issue among critically ill children and adults. When left untreated, it can lead to life-threatening consequences. Available therapies require very high relative extracorporeal blood volumes, which can be challenging for pediatric patients. In a retrospective, multi-center study, 32 critically ill pediatric patients weighing over 20 kgs and predominantly suffering from hypervolemia were treated with the Aquadex FlexFlow System and 97% (31/32) survived to the end of therapy.[1]

About CHF Solutions

CHF Solutions, Inc. (Nasdaq: CHFS) 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. CHF Solutions 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.

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 benefits of innovations contained in the patent application. 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. CHF Solutions 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.

[1] https://pubmed.ncbi.nlm.nih.gov/31462396/

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