



## **CHF Solutions Announces Registry for Fluid Overload Conditions in Pediatric Patients**

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EDEN PRAIRIE, Minn., July 16, 2020 (GLOBE NEWSWIRE) -- [CHF Solutions](#) (Nasdaq: CHFS), a medical device company dedicated to improving the lives of patients suffering from fluid overload, today announced the development of a pediatric registry through a partnership with the Acute Kidney Injury Critical Care Research Foundation and Watermark Research Partners. The registry will collect real-world evidence on the use of the Aquadex SmartFlow™ ultrafiltration system in pediatric patients with fluid overload.

The registry will include data on ultrafiltration utility, performance, and safety profile in pediatric patients from approximately ten research institutions over an anticipated time period of two and a half years. The parties anticipate collecting data on up to 500 patients, and the registry is expected to be operational by the end of this year.

“Fluid overload is associated with increased mortality and adverse outcomes in pediatric patients. Improving our understanding of ultrafiltration performance in clinical conditions, such as cardiac or renal diseases, will be critically important to effectively inform our treatment strategies,” said Dr. Stuart Goldstein, M.D., Professor of Pediatrics and Director, Center for Acute Care Nephrology at Cincinnati Children’s Hospital Medical Center and Chairman of the Acute Kidney Injury Critical Care Research Foundation. “To date there has not been a large prospective multicenter evaluation of the use of the Aquadex system in pediatric patients. We expect this registry to expand knowledge about fluid overload to help healthcare providers determine the best solutions available for their patients.”

“CHF Solutions is committed to supporting the collection of robust and current clinical data to allow medical professionals to make well-informed treatment decisions on behalf of their patients,” said John Erb, CEO of CHF Solutions. “We believe that this investment will lead to a broad database of important clinical information to support life-saving interventions to treat fluid overload in pediatric patients.”

#### **About Fluid Overload in Pediatric Patients**

Fluid overload (hypervolemia), which occurs when there is too much fluid in the body, is a major issue among critically ill children and adults, and 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.<sup>1</sup>

1. <https://pubmed.ncbi.nlm.nih.gov/31462396/>

#### **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.

#### **About CHF Solutions**

CHF Solutions, Inc. (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 wholly-owned subsidiaries in Australia and Ireland. The company has been listed on the Nasdaq Capital Market since February 2012.

#### **About Acute Kidney Injury Critical Care Research Foundation**

The Acute Kidney Injury Critical Care Research Foundation (AKI Foundation) is a non-profit organization dedicated to research and education in kidney injury over the last decade. The AKI Foundation is actively involved in multiple outcome registries as well as ongoing educational endeavors to help physicians stay on the cutting edge of patient care.

#### **About Watermark Research Partners, Inc**

Watermark Research Partners, Inc. (Watermark) is a company dedicated to regulatory support for DSMB and Adjudication Panels during clinical trials. In the post-market setting, Watermark establishes and manages Post Market Outcomes and Registry studies including the registry publication board. Watermark is providing management and support to the AKI Critical Care Research Foundation and their education and research activities. Watermark has provided services for pharmaceutical and medical device companies for nearly 20 years.

#### **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 development of the registry and value of the clinical data collected in the registry. 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, the risks associated with our expectations regarding the potential impacts of the COVID-19 pandemic on our business operations, the risks 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.

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