New Publication Highlights Transient Increases in Creatinine or Tubular Injury Markers in Heart Failure Patients Should Not Dissuade Use of Ultrafiltration

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EDEN PRAIRIE, Minn., Aug. 08, 2019 (GLOBE NEWSWIRE) -- CHF Solutions, Inc. (Nasdaq: CHFS) announced today the publication of a study in Circulation Heart Failure[1] highlighting the benefits of decongestion outweigh concerns from previous studies that showed a rise in creatinine levels or tubular injury markers.

The study, titled, “Renal Effects of Intensive Volume Removal in Heart Failure Patients With Preexisting Worsening Renal Function” further analyzed data on renal tubular injury biomarkers from a subset of 105 participants in the CARRESS-HF trial. The study supports that increases in serum creatinine should not be the major factor to dissuade decongestion by ultrafiltration or diuretics in patients where a therapeutic advantage may exist. Even if creatinine worsened and tubular biomarkers increased, renal function usually recovered by 60 days. In fact, participants with an increase in urinary biomarkers (who had 12-fold-increase odds of worsening renal function defined by a 20% change in serum creatinine) had the greatest improvement in kidney function at 60 days. Thus, changes in serum creatinine or kidney injury biomarkers should be discouraged as a surrogate endpoint in heart failure trials. Study authors concluded that modest or transient increases in creatinine levels, or increases in renal tubule injury biomarkers were outweighed by the benefits of decongestion, which aligns with the review conducted by Drs. Costanzo and Kazory published in the European Journal of Heart Failure, which stated, “It follows that the foremost aim of therapy to improve outcomes of fluid overloaded heart failure patients must be to achieve effective decongestion.” [2] This study showed no evidence that ultrafiltration is inferior for decongestion or worse post-discharge clinical outcomes.

“In the past, we have received some criticism regarding the increase in creatinine levels with ultrafiltration, such as with the Aquadex FlexFlow® system, and our response has been that the ultimate benefits outweighed potential risks. This analysis is yet another study that supports this assertion, with the added information that increases in serum creatinine levels were associated with superior decongestion and recovery of renal function at 60-days even in the presence of renal tubule injury biomarkers,” commented John Erb, chairman and chief executive officer of CHF Solutions. "This study is further validation of our long-held position that ultrafiltration therapy has the potential to significantly improve outcomes in heart failure patients, with the added advantages of reducing rehospitalizations and providing less impact on the healthcare system as a whole. We are very proud of our technology and are pleased to share this data with medical professionals interested in maximizing patient outcomes in the heart failure setting.”

About CHF Solutions

CHF Solutions, Inc. (NASDAQ:CHFS) is a medical device company focused on developing, manufacturing and commercializing the Aquadex FlexFlow system for aquapheresis therapy. The Aquadex FlexFlow system is a clinically proven therapy that provides a safe, effective and predictable method of removing excess sodium and fluid from patients suffering from fluid overload. The Aquadex FlexFlow system is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies. The company's vision is to improve the lives of fluid overloaded patients through science, collaboration, and innovative medical technology. CHF Solutions is a Delaware corporation headquartered in Minneapolis, Minnesota with wholly owned subsidiaries in Australia and Ireland. The company has been listed on the Nasdaq Capital Market since February 2012.

Forward-Looking Statements

Certain statements in this release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding the clinical performance of the Aquadex FlexFlow system. 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 commercialization 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://www.ncbi.nlm.nih.gov/pubmed/31163974

[2] https://www.ncbi.nlm.nih.gov/pubmed/29671929

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