CHF Solutions Announces Meta-Analysis Demonstrates Ultrafiltration is Better than Diuretic Therapy for the Management of Volume Overload in ADHF

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EDEN PRAIRIE, Minn., Dec. 15, 2020 (GLOBE NEWSWIRE) -- CHF Solutions (Nasdaq: CHFS), a medical device company dedicated to changing the lives of patients suffering from fluid overload, today announced a meta-analysis published in *Heart Failure Reviews* concludes that ultrafiltration (UF) increases fluid removal and weight loss and reduces rehospitalization and the risk of worsening heart failure in congestive patients, suggesting ultrafiltration as a safe and effective treatment option for volume-overload heart failure patients.

When hospitalized, 88% of patients with acute decompensated heart failure (ADHF) are treated with diuretics, yet many have suboptimal responses (diuretic resistance, electrolyte imbalances, deteriorating renal function). One in four of patients are re-hospitalized within 30 days. [1]

The article, “Ultrafiltration is better than diuretic therapy for volume-overloaded acute heart failure patients: A meta-analysis,” included eight randomized controlled studies involving 801 ADHF patients. The authors investigated possible advantages of UF compared to diuretic treatment regarding fluid removal, weight loss, rehospitalization for heart failure and all-cause mortality. Data from the analysis demonstrated:

- UF was statistically better than diuretics in terms of increased fluid removal and weight loss.
- UF resulted in statistically significant decreases in worsening heart failure.
- A reduction of heart failure rehospitalization with the use of UF was sustained between 30 days and 1 year.
- No statistically significant difference between therapies in renal impairment and all-cause mortality.
- UF is a safe and effective treatment option for volume-overloaded ADHF patients.

“While most patients with heart failure are treated with diuretics, only part of them attain the desired pharmacological targets, and a significant portion of patients display suboptimal response with persistent overhydration, poor outcomes and high hospital readmission rates,” said Dr. Claudio Ronco, Full Professor at the University of Padova, Italy and Director of the International Renal Research Institute of Vicenza and Department of Nephrology at San Bortolo Hospital in Vicenza, Italy. "As demonstrated by this recent publication, the only chance to adequately manage overhydration in several patients is to use extracorporeal mechanical ultrafiltration. With this technique, fluid management becomes easy and effective with marginal or absent unwanted effects. The treatment results in a lower rate of hospitalization and improved quality of life for heart failure patients.”

Conclusions from this meta-analysis are consistent with findings from the real-world retrospective study of 335 patients treated with the Aquadex FlexFlow® System, presented at the 24th Annual Scientific Meeting of Heart Failure Society of America. Data demonstrate that UF is safe and effective, comparing favorably in reducing heart failure rehospitalizations, renal function response, and weight/volume loss.[2]

“Our mission is to improve outcomes for people suffering from fluid overload, and this meta-analysis further demonstrates how ultrafiltration is capable of doing so,” said John Erb, Chairman and CEO of CHF Solutions. “This analysis is a welcome addition to the growing list of evidence supporting the numerous benefits of ultrafiltration and the Aquadex™ technology.”

1. Wobbe, B., Wagner, J., Szabo, D.K., et. al. Ultrafiltration is better than diuretic therapy for volume-overloaded acute heart failure patients: a meta-analysis. Heart Fail. Rev. (2020) https://doi.org/10.1007/s10741-020-10057-7

2. https://www.chf-solutions.com/aquadex-smartflow-system/clinical-evidence/

About Meta-analysis
A meta-analysis is a statistical analysis that combines study data from multiple independent studies (e.g. randomized studies) with a specific question, which aims to generate statistical significance and an average effect. A key benefit of a meta-analysis is that the aggregation of data leads to a higher statistical power, and more robust point estimate than is possible from an individual study.

About CHF Solutions
CHF Solutions, Inc. (Nasdaq: CHFS) is a medical device company dedicated to improving the lives of patients suffering from fluid overload with its novel ultrafiltration therapy system. 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 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 use of the Aquadex SmartFlow system to treat pediatric patients. 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.

CONTACTS

INVESTORS:
Claudia Napal Drayton
Chief Financial Officer, CHF Solutions, Inc.
952-345-4205
ir@chf-solutions.com

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

MEDIA:
Jessica Stebing
Health+Commerce
260-336-6202
jstebing@healthandcommerce.com

Source: CHF Solutions, Inc.