



CHF Solutions Announces Data Demonstrating Benefit of Aquadex Therapy for Treatment of Heart Failure and COVID-19

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EDEN PRAIRIE, Minn., Oct. 07, 2020 (GLOBE NEWSWIRE) -- CHF Solutions (Nasdaq: CHFS), a medical device company dedicated to changing the lives of patients suffering from fluid overload, today announced data from a retrospective study and a case study supporting the benefit of Aquadex™ therapy in the treatment of heart failure. These data were presented at the 24th Annual Scientific Meeting of Heart Failure Society of America.

The real-world retrospective study of 335 patients treated with the Aquadex FlexFlow® System, “10 years of real world data with UF for ADHF patients,”¹ compared previous RCT trials with ultrafiltration (UF) and demonstrated that UF compares favorably in reducing heart failure (HF) rehospitalizations, renal function response, and weight/volume loss. Specific results included:

- Substantial mean fluid removal (14.58 liters) and weight loss (15.63 lbs), which was sustained at 1-2 weeks post follow-up.
- Improvement in reduced HF rehospitalization rates at 30, 90 days, and 1 year of 12.4%, 14.9%, 27.3% respectively.
- Mean serum creatinine (sCr) increase of +0.07-0.11 mg/dl recorded at time of stopping therapy, discharge, and follow up.
- On average, patients had 1.74 fewer hospitalizations for HF in the year following UF when compared to the year preceding UF.
- Major bleeding, defined as requiring discontinuation of anticoagulation, was 3.6 %

In comparison to previous randomized control trials focused on UF (AVOID², CARRESS³, DOSE⁴, and UNLOAD⁵), patients in this study were older with worse renal function and greater HF hospitalizations in the year preceding UF therapy. The ability to adjust the rate of fluid removal with the Aquadex system is believed to be a major contributor to favorable outcomes. The study was conducted by Abington Hospital – Jefferson Health in Abington, Pennsylvania and funded by CHF Solutions.

The case study, “Outpatient Ultrafiltration to Prevent Hospital Readmissions During COVID-19 Pandemic in Diuretic Intolerant Patient: Case Study,”⁶ involved the successful outpatient treatment of a 70-year-old female with heart failure with preserved ejection fraction and pre- and post-capillary pulmonary hypertension. This patient did not respond to outpatient therapies and diuretics and experienced multiple hospitalizations due to recurrent congestion. Given the patient’s co-morbidities and high-risk status, the patient received UF treatment with the Aquadex SmartFlow™ system in an outpatient setting to avoid exposure to COVID-19. Over the course of 4 days, a total of 4950 ml of isotonic fluid was removed. The patient showed immediate improvement in clinical symptoms and was effectively stabilized in the outpatient setting at Advocate Good Samaritan Hospital in Downers Grove, Illinois.

“We are pleased with the results of these two studies confirming the benefits of Aquadex therapy in the treatment of heart failure patients, as demonstrated in previous studies and clinical observations, and the effectiveness of use in the outpatient setting to limit exposure to COVID-19,” said John Erb, Chairman and CEO of CHF Solutions. “We thank the teams at Abington Hospital – Jefferson Health and Advocate Good Samaritan Hospital for furthering data on the benefits of ultrafiltration.”

1. <https://www.chf-solutions.com/aquadex-smartflow-system/clinical-evidence/>
2. AVOID-HF Trial: <https://pubmed.ncbi.nlm.nih.gov/26519995/>
3. CARRESS-HF Trial: <https://www.nejm.org/doi/full/10.1056/NEJMoa1210357>
4. DOSE Trial: <https://pubmed.ncbi.nlm.nih.gov/21366472/>
5. UNLOAD Trial: <https://pubmed.ncbi.nlm.nih.gov/17291932/>
6. <https://www.chf-solutions.com/aquadex-smartflow-system/clinical-evidence/>

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 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 use of Aquadex therapy in the treatment of heart failure and COVID-19. 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 expectations regarding the potential impacts of the COVID-19 pandemic on our business operations, 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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