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CHF Solutions' Aquadex FlexFlow® Aquapheresis System Receives FDA IDE Approval for Clinical Study for Pediatric Use

EDEN PRAIRIE, Minn., June 29, 2017 (GLOBE NEWSWIRE) -- CHF Solutions, Inc., (fka Sunshine Heart, Inc.) (NASDAQ:CHFS) announced today that researchers in the Stanford University School of Medicine's Department of Pediatrics have received FDA Investigational Device Exemption (IDE) approval to conduct a clinical study to evaluate the safety and effectiveness of CHF Solutions' Aquadex FlexFlow Aquapheresis System for diuretic-resistant fluid overload in children with acute decompensated heart failure. The randomized multi-center, non-blinded clinical study will assess up to 45 children and young adults ages 6 months to 21 years with heart failure and diuretic-resistant fluid overload. Heart failure is the leading cause of death in children with cardiomyopathy and congenital heart disease.

The study seeks to determine whether Aquapheresis therapy is associated with greater weight loss and a non-inferior rate of renal dysfunction compared to optimal medical therapy. In addition, the impact on heart failure symptoms using a novel pediatric heart failure symptoms score developed by the investigators, adverse outcomes and the need for medical management will be evaluated as secondary endpoints. The study is being led by Stanford's Christopher Almond, Associate Professor of Pediatrics (Cardiology), and David Kwiatkowski, Clinical Assistant Professor of Pediatrics (Cardiology).

"We are pleased that the researchers have received FDA approval to proceed with this IDE study," said John Erb, Chairman and CEO of CHF Solutions. "Given the limitations of patient unresponsiveness to diuretic therapies over time, our solution represents a potentially transformative future standard of care. We look forward to the clinical data results and to continuing our efforts to provide patients with additional treatment options for the treatment of heart failure," Mr. Erb concluded.

About CHF Solutions

CHF Solutions, Inc. (NASDAQ:CHFS) is an early-stage medical device company focused on commercializing the Aquadex FlexFlow Aquapheresis System. The Aquadex FlexFlow Aquapheresis 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 objective is to improve the quality of life for patients with heart failure and related conditions. CHF Solutions is a Delaware corporation headquartered in Minneapolis 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 statements the potential for Aquapheresis therapy to be a transformative standard of care for the treatment of fluid overload in heart failure patients and our efforts to evolve ultrafiltration as such, and the receipt of future clinical results. 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, sources of funding for the approved clinical study, the timing and results of the approved clinical study, those risk associated with our ability to execute on our recently announced strategic realignment, 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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