CHF Solutions submits 510(k) application for Use of Aquadex FlexFlow® System with Pediatric Patients

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EDEN PRAIRIE, Minn., Oct. 01, 2019 (GLOBE NEWSWIRE) -- CHF Solutions, Inc. (Nasdaq:CHFS) today announced that it has submitted an application to the FDA requesting for 510(k) clearance of the Aquadex FlexFlow system to include pediatric patients who weigh 20kg or more. Subject to FDA review, the company expects clearance for this pediatric population by the end of the year.

“We are excited to have achieved this significant milestone in our corporate strategy to make the Aquadex FlexFlow technology available to pediatric patients,” said John L. Erb, chairman and CEO of CHF Solutions. “Following FDA clearance, we look forward to expanding use for these most vulnerable patients, who have limited alternative solutions.”

“We are pleased with CHF Solutions’ commitment to taking the regulatory steps to support our efforts in delivering this therapy to pediatric patients,” said Dr. Stuart L. Goldstein, Director of the Center for Acute Care Nephrology at Cincinnati Children's Hospital Medical Center. “Devices like this will address a significant unmet need in the treatment options available to children.”

About CHF Solutions
CHF Solutions, Inc. (Nasdaq:CHFS) is a medical device company dedicated to changing the lives of patients suffering from fluid overload through science, collaboration, and innovative technology. The company is focused on developing, manufacturing, and commercializing the Aquadex FlexFlow system for ultrafiltration therapy. 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.

About Aquadex FlexFlow® System
The Aquadex FlexFlow system is a clinically proven therapy that provides a safe, effective, and predictable method of removing excess 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 for extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. The company has submitted an application to the FDA requesting for 510(k) clearance of the Aquadex FlexFlow system to include pediatric patients who weigh 20kg or more. All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.

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 use of the Aquadex Flex Flow system in pediatric patients and the likelihood and timing of receipt of FDA clearance. 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.

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