



CHF Solutions receives 510(k) clearance for Aquadex SmartFlow™ system in Pediatric Patients Weighing 20kg or More

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EDEN PRAIRIE, Minn., Feb. 26, 2020 (GLOBE NEWSWIRE) -- CHF Solutions (Nasdaq: CHFS) today announced FDA 510(k) clearance in the U.S. of its next generation Aquadex SmartFlow console for use in adult and pediatric patients who weigh 20kg or more. The console is a simple, gentle, and smart solution for treatment of patients suffering from hypervolemia (fluid overload).

In a retrospective, multi-center study, 32 pediatric patients weighing over 20 kgs and predominantly suffering from hypervolemia were treated with the Aquadex system and 97% (31/32) survived to the end of therapy.¹

"For many types of pediatric patients, the available therapies require very high relative extracorporeal blood volumes, which can be challenging," said Stuart Goldstein, M.D., Professor of Pediatrics and Director, Center for Acute Care Nephrology at Cincinnati Children's Hospital Medical Center and a paid consultant of CHF Solutions. "The Aquadex SmartFlow system allows us to initiate therapy with excellent hemodynamic stability due to the low extracorporeal volume of 35ml. In addition, the hematocrit monitoring feature helps caregivers maintain appropriate fluid balance in their patients."

"With the approval of the Aquadex SmartFlow, traditionally underserved pediatric patients will benefit from ultrafiltration therapy that has shown positive clinical results and has strong interest from pediatric hospitals," said John Erb, chairman and CEO of CHF Solutions. "FDA clearance for pediatric patients is a significant milestone for the company and the result of strong execution from our team."

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 innovation. The company is focused on developing, manufacturing, and commercializing the Aquadex SmartFlow systems 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 the Aquadex SmartFlow System

The Aquadex SmartFlow system is a clinically proven therapy that provides 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 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a healthcare provider, within an outpatient or inpatient clinical setting, under physician prescription, both of whom 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 clinical use of the Aquadex SmartFlow system in adult and pediatric patients weighing 20kg or more. 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

-or-

Bret Shapiro
Managing Partner
CORE IR
516-222-2560
brets@coreir.com
www.coreir.com

1. <https://cjasn.asnjournals.org/content/early/2019/08/27/CJN.03240319>

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