Multi-Center, Retrospective Study Evaluates Use of Ultrafiltration Therapy with Aquadex FlexFlow® System in Pediatric Patients

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EDEN PRAIRIE, Minn., Sept. 24, 2019 (GLOBE NEWSWIRE) -- CHF Solutions, Inc. (Nasdaq:CHFS) today announced the publication of a multi-center, retrospective study in the Clinical Journal of the American Society of Nephrology[1] evaluating the use of hemofiltration and ultrafiltration therapy with the company's Aquadex FlexFlow system in pediatric patients. The Aquadex FlexFlow system is not yet cleared by FDA for use in pediatric patients.

The study, titled "Kidney Support in Children Using an Ultrafiltration Device," included 117 patients in three weight categories: <10 kgs; 10-20 kgs; and >20 kgs, suffering from volume overload, acute kidney injury or end-stage kidney disease. All patients across the three weight categories were treated with the Aquadex FlexFlow system, using one of the following three modalities: slow continuous ultrafiltration (SCUF); continuous veno-venous hemofiltration (CVVH); or prolonged intermittent kidney replacement therapy, based on patient condition.

The primary outcome was survival to the end of therapy. In patients weighing over 20 kgs (n=32), 97% survived to the end of therapy. In patients weighing between 10-20 kgs (n=13), 100% survived to the end of therapy. In patients weighing under 10 kgs (n=72), 60% survived to the end of therapy.

"We report the first multi-center experience in pediatrics in which we use an ultrafiltration device to provide kidney support therapy in younger patients," said David Askenazi, M.D., M.S.P.H., Professor of Pediatrics at the University of Alabama Birmingham/Children's of Alabama. "For many of the types of patients in the study, available therapies require very high relative extracorporeal blood volumes, which can be challenging. With the use of an ultrafiltration device with a small blood volume, we were able to initiate therapy with excellent hemodynamic stability."

As previously announced, the company will be hosting a conference call and webcast with investigators from the study tomorrow, September 25, at 1:00 pm Eastern Time. To access the live webcast, please visit the Investors page of the CHF Solutions website at http://ir.chf-solutions.com or access the webcast directly at http://ir.chf-solutions.com/events. Alternatively, you may access the live conference call by dialing (877) 303-9826 (U.S.) or (224) 357-2194 (international) and using conference ID: 6985754. An audio archive of the webcast will be available following the call on the Investor page at http://ir.chf-solutions.com/events.

About CHF Solutions
CHF Solutions, Inc. (Nasdaq:CHFS) is a medical device company focused on developing, manufacturing and commercializing the Aquadex FlexFlow system for aquapheresis therapy. The Aquadex FlexFlow system is a clinically proven therapy that provides a safe, effective, and predictable method of removing excess sodium and 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 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. CHF Solutions expects to submit an application to the FDA requesting a modification to the 510(k) clearance for the Aquadex FlexFlow system to include pediatric patients above 20kg in the near future. The company is dedicated to changing the lives of patients suffering from fluid overload through science, collaboration, and innovative. 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.

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. 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.

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

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

MEDIA
Jules Abraham
JQA Partners, Inc.
917-885-7378
jabraham@jqapartners.com

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