

CHF Solutions Announces First Commercial Shipments of Aquadex Systems to Brazil, following Regulatory Approval

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EDEN PRAIRIE, Minn., Oct. 29, 2020 (GLOBE NEWSWIRE) -- CHF Solutions (Nasdaq: CHFS), a medical device company dedicated to changing the lives of patients suffering from fluid overload, today announced it has shipped the first commercial orders of its Aquadex SmartFlow™ system tcBrazil, following approval from the Brazilian Health Surveillance Agency, commonly known as ANVISA. CHF Solutions has partnered with Bragenix Ltda, to serve patients in Brazil. These shipments expand the company's worldwide sales outreach into South America and the largest market in the region.

"The expansion of Aquadex™ into the Brazilian market demonstrates our commitment to providing physicians and medical staff throughout the world with effective solutions for treating fluid overload," said John Erb, CEO of CHF Solutions. "Regulatory approval of Aquadex in Brazil was rapidly obtained, highlighting the impact ultrafiltration therapy can have on patients suffering from fluid overload due to heart failure, cardiovascular surgery and other critical care conditions."

"The Aquadex system provides a simple and predicable method for removing excess fluid from patients suffering from heart failure, COVID-19 and other critical care conditions," said Mario Padovani, Managing Director of Bragenix. "We are excited to partner with CHF Solutions and bring this life-saving therapy to Brazil."

It is estimated that approximately 3.9 million individuals in Brazil suffer from heart failure. CHF Solutions further estimates that there are approximately 470,000 hospitalizations each year for heart failure, of which approximately 290,000 patients experience fluid overload with less than optimal diuretic response.

Ultrafiltration with Aquadex allows clinicians to remove excess fluid from the body at a very customizable and gentle rate. The device can remove up to 500 mL of fluid per hour, in increments of 10 mL/hr, enabling providers to customize their treatment approach specific to the patient being treated.

¹ Stevens B., et. al. The Economic Burden of Heart Conditions in Brazil, Health Economics and Social Policy, Deloitte Access Economics, Australia, 2016.

About CHF Solutions

CHF Solutions, Inc. (Nasdaq: CHFS) is a medical device company dedicated to improving the lives of patients suffering from fluid overload with its novel ultrafiltration therapy system. 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 Bragenix Ltda

Bragenix is focused on identifying innovative technologies in the medical, hospital, commercial and industrial areas and providing sustainable products of proven international quality to the Brazilian market.

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 regarding the use of the Aquadex system in Brazil. 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.

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