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FOR IMMEDIATE RELEASE

**CHF SOLUTIONS INITIATES MULTI-CENTER
CLINICAL TRIAL OF AQUAPHERESIS™ THERAPY**

**Large-Scale Study Will Evaluate Unique Aquapheresis Therapy Versus Conventional Diuretic
Therapy for the Treatment of Fluid-Overloaded Patients**

BROOKLYN PARK, MINN. – JULY 8, 2004 – CHF Solutions, Inc., a private medical device manufacturer, announced today that enrollment has begun in a large clinical trial to evaluate its unique Aquapheresis™ therapy compared with traditional diuretic therapy. Administered via CHF Solutions' Aquadex™ System 100, Aquapheresis is designed to safely and predictably remove excess fluid from fluid-overloaded patients. In heart failure patients, an inefficient heart can lead to a buildup of excess fluid, causing swollen legs and arms, fatigue, and eventually severe and life-threatening shortness of breath. Aquapheresis with the Aquadex System 100 technology is commercially available in the United States, having received 510(k) marketing clearance from the U.S. Food and Drug Administration in June 2002.

The trial is called the **U**ltrafiltration **N** versus IV Diuretics for Patients Hospitalized for **A**cute **D**ecompensated Congestive Heart Failure (UNLOAD) and will compare the long-term safety and efficacy of treatment with the Aquadex System 100 technology to conventional pharmaceutical therapy (i.e. intravenous diuretics) in hospitalized heart failure patients with fluid overload. The UNLOAD trial is a prospective, randomized and controlled study that will enroll 200 patients at as many as 20 U.S. clinical sites. Researchers will document patient outcomes at three months to evaluate longer-term improvements. CHF Solutions expects to announce clinical trial results in the fourth quarter of 2005.

“We are committed to advancing the Aquadex System 100 as a treatment for fluid overload for all patients and physicians who struggle with the disappointing performance of current fluid overload treatments,” said John Erb, president and chief executive officer of CHF Solutions. “Currently, 39 percent of heart failure patients are discharged from the hospital as ‘improved, but still symptomatic.’ We see an

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obvious need to provide physicians with a simple and dependable way to remove fluid and genuinely improve patients' quality of life. This large-scale trial is an exciting milestone for CHF Solutions, and we are especially pleased that Midwest Heart Specialists is leading this study."

"As a major cardiovascular institute, we care for many heart failure patients, and we have treated many patients with the Aquadex System 100 since it first became available in 2002," said principal investigator Maria Rosa Costanzo, M.D., Midwest Heart Specialists, Chicago. "The UNLOAD study is the first randomized, prospective trial to critically test the use of diuretics for fluid overload in heart failure patients. Despite the mounting evidence of diuretics' detrimental effects, they remain the most commonly used therapy for heart failure. I view the UNLOAD trial not merely as a comparison between two treatments but rather as an opportunity to explore novel concepts in heart failure physiology and treatment."

"The UNLOAD trial will test the hypothesis that fluid reduction by Aquapheresis can be performed without the hazards inherent in high-dose loop diuretics," said Paul Sobotka, M.D., CHF Solutions' chief medical officer. "We have worked closely with heart failure and cardiovascular experts to design this trial. The positive results of previous Aquadex System 100 studies suggest that treatment with our system can have sustained clinical benefits. The Aquadex System 100 makes it possible to challenge conventional and historical reliance on a class of drugs which have escaped careful clinical examination."

About Aquapheresis and the Aquadex System 100

Today's ultrafiltration has advanced so far beyond previous ultrafiltration technologies that CHF Solutions refers to this new therapeutic modality as Aquapheresis. By mechanically removing a predetermined amount of fluid specified by the physician, Aquapheresis is the safe and predictable removal of excess fluid that eliminates the uncertainty, unpredictability and side effects often associated with diuretics. Aquapheresis, by means of an advanced device called the Aquadex System 100, is a simple, transportable procedure that can be performed in virtually any clinical setting.

The Aquadex System 100 is a technologically sophisticated mechanical system that can remove up to four liters (one gallon) of excess fluid from the body in eight hours. The system is highly automated and easy to use. Standard catheters inserted into peripheral or central veins connect the patient to the Aquadex System 100. There is no clinically significant impact on electrolytes, heart rate or blood chemistry. Conventional diuretic treatment typically takes several days to achieve significant fluid reduction and can be associated with a negative impact on blood chemistry, blood pressure or heart rate. In a substantial number of cases, diuretic therapy fails to remove adequate amounts of fluid.

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Fluid Overload and Heart Failure

Fluid overload is a common medical problem that can derive from a variety of causes, including renal failure, post-surgical fluid overload, metabolic disease and congestive heart failure. Patients with heart failure represent the largest group of fluid-overloaded patients. Heart failure is the progressive inability of the heart to pump enough blood to support the vital organs. Deterioration of the heart muscle leads to decreased pumping capacity, elevated stress on the heart and increased fluid retention.

In the United States alone, an estimated five million people suffer from heart failure, with 550,000 new diagnoses and 3.1 million hospital admissions annually—at a cost of more than \$23 billion.

About CHF Solutions

CHF Solutions, based in Brooklyn Park, Minn., is a privately held manufacturer of innovative medical devices for cardiac care. The company's mission is to provide medical practitioners with innovative and proprietary solutions that enable the treatment of patients with unmet clinical needs. For additional information about CHF Solutions, Aquapheresis, and the Aquadex System 100, visit www.chfsolutions.com.

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