

## **MEDIA ADVISORY for March 6, 2006**

### **UNLOAD Trial Evaluating Heart Failure Therapies to be Featured in Late-Breaking Clinical Trial Presentations at 2006 American College of Cardiology Scientific Session**

#### **Pioneering randomized multi-center trial compared the immediate and long-term effects of treatments for congestive heart failure patients**

**WHAT:** Maria Rosa Costanzo, M.D., Midwest Heart Foundation, Lombard, Illinois, and principal investigator of the UNLOAD\* clinical trial, will present the results of this trial at the 2006 American College of Cardiology (ACC) 55<sup>th</sup> Scientific Session Conference in Atlanta. This prospective, randomized multi-center trial compared the immediate and long-term effects of early ultrafiltration alone, versus intravenous diuretics alone, on weight loss, symptoms and hospitalizations of patients with decompensated heart failure and fluid overload. In heart failure patients, an inefficient heart can lead to a buildup of excess fluid which accumulates in the lungs, liver and extremities, causing shortness of breath, decreased function of vital organs and swelling of the extremities, e.g. legs. In the UNLOAD study, 200 patients were enrolled at 28 sites and patient outcomes were documented from enrollment until 90 days after discharge.

The ultrafiltration therapy used in the trial was administered via the Aquadex FlexFlow™. Designed to safely and predictably remove excess salt and water from fluid-overloaded patients, the Aquadex FlexFlow is a sophisticated mechanical system that can remove up to one liter of excess fluid from the body in two hours, or more than a gallon in eight hours. The system received marketing clearance from the U.S. Food and Drug Administration in 2002 and is in use at many leading medical institutions.

\* UNLOAD (or UltrafiltrationN versus IV Diuretics for Patients HospitaLized for Acute Decompensated Congestive Heart Failure)

**WHY:** Heart failure is a condition that affects approximately five million Americans and is responsible for one million annual hospitalizations, which surpasses the number of hospitalizations due to all forms of cancer and heart attacks combined. More than 500,000 new cases of heart failure are diagnosed each year. The estimated economic burden of heart failure care is in excess of \$28 billion in the United States. Due to prolonged hospitalizations and high readmission rates, many hospitals often lose more than \$1,000 for each heart failure admission.

**WHEN/WHERE:** Dr. Costanzo will discuss the results of the UNLOAD study at:

- **8:00 a.m. ET press conference at ACC, Sunday, March 12, in Room B 203**
- **9:15 a.m. ET presentation on Tuesday, March 14, in Room 102, Hall B**  
**Georgia World Congress Center**  
**852 Andrew Young International Boulevard**  
**Atlanta, Georgia**

**INTERVIEW OPPORTUNITIES:** Requests for interviews with Dr. Costanzo as well as John Erb, chief executive officer of CHF Solutions, can be submitted in advance by contacting Nancy Johnson, 612-455-1745, njohnson@psbpr.com; or Kristen Spargo, (612) 455-1741, kspargo@psbpr.com, Padilla Speer Beardsley, Minneapolis.

**CHF SOLUTIONS BACKGROUND:** CHF Solutions (ACC Booth No. 1032), based in Brooklyn Park, Minn., is a privately held manufacturer of innovative medical devices for cardiac care. For additional information about CHF Solutions, and the Aquadex FlexFlow, visit [www.chfsolutions.com](http://www.chfsolutions.com).

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