

Clinical Data from Reprise Cardiovascular's Successful First-in-Human Therapy for Acute Heart Failure Presented

Personalized Volume Management System : 2nd generation automated fluid management technology

MILFORD, MA – December 13, 2019 – [Reprise Cardiovascular](#)[®], a pioneering medical device company focused on improving outcomes for patients suffering from acute decompensated heart failure (ADHF), today announced the results of the first-in-human clinical trial with the company's second generation device, the Personalized Volume Management System (PVM). The study demonstrated that the fully automated fluid management system resulted in safe, effective, efficient and long-lasting decongestion for patients with Acute Heart Failure. The results were presented today at the Device Therapies in Heart Failure (D-HF 2019) meeting in Paris, France.

The 15-patient clinical trial was designed to determine whether the Reprise Personalized Volume Management System could more efficiently and safely achieve reductions in net volume and AHF symptoms.

Data highlights:

- Average net fluid removal: -5.9 L/therapy, normalized to -4.5 L/24 hr.
- Average weight loss after mean treatment duration of 31 hrs: -6.8 kg.
- Average weight loss of -5.7 kg (from baseline) was maintained at 30-day follow-up in 12 patients who completed the 30-day follow-up.
- Average sodium removal was -798 mmol per therapy, normalized to -611 mmol/24 hr.
- No re-hospitalization of patients who have completed the 30-day follow-up.
- No significant adverse events were reported.

Device benefits for AHF treatment:

- The Reprise Personalized Volume Management System, designed to speed fluid removal and symptom relief with the lowest effective diuretic dose for each patient, automatically tailors diuretic dosing.
- **"Set and forget"** convenience.
- Provides personalized fluid management to prevent hypotension and the activation of salt- and water-retaining renal mechanisms.

"We're very encouraged by these first in man results with our new Personalized Volume Management System," said Reprise Cardiovascular Chief Medical Officer Howard Levin, M.D. "The trends in all of the core metrics that matter to heart failure physicians and patients, including length of stay, weight reduction, and re-hospitalization point in a positive direction. We look forward to continuing this clinical

work to support the adoption of PVM as a standard of care for improved treatment of patients with ADHF.”

About ADHF

ADHF is a sudden onset of heart failure symptoms, which typically include difficulty breathing (dyspnea), swelling in the extremities, and fatigue. The signs and symptoms of fluid overload are responsible for 90% of heart failure hospital admissions. Current treatment for ADHF includes diuretic therapy that aims to restore healthy fluid levels in the kidneys and throughout the body. Standard diuretic therapy, however, can be unpredictable and lose effectiveness as a patient’s condition deteriorates. In some patients, diuretics can trigger a condition called “diuretic resistance,” which blunts the function of diuretics and can exacerbate the severity of fluid overload, potentially resulting in acute kidney injury.

About Reprise Cardiovascular’s Personalized Volume Management System

Reprise Cardiovascular’s Personalized Volume Management System, a second-generation automated fluid management system, is designed to better manage diuretic therapy for patients with Acute Decompensated Heart Failure (ADHF) and may relieve a number of symptoms related to this condition. The therapy is designed to enable more precise, predictable and efficient management of a patient’s fluid levels, guarding against dangerous fluid imbalances and enabling better control over diuretic therapy. Potential benefits include speeding decongestion while protecting core organ function, reducing symptoms of congestive heart failure such as shortness of breath, ascites, and swelling, reduced time in hospital, reduced readmission rates, and a better quality of life for patients.

About Reprise Cardiovascular

Reprise Cardiovascular is a pioneering medical device company focused on automated fluid management technologies for acute heart failure treatment. The company’s Reprise technology is being investigated as an innovative fluid management treatment that provides clinicians with the ability to precisely control a patient’s fluid volume and may enable improved cardiac care with safe, effective decongestion of acutely decompensated heart failure patients (ADHF). Reprise Cardiovascular, Inc. and RenalGuard Solutions, Inc. are subsidiaries of parent company CardioRenal Systems, Inc. For more information, visit www.reprivecardio.com and follow us on Twitter at @RepriseCardio.

Please visit us at our D-HF 2019 booth.

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