



New Study Demonstrates Feasibility of Using RenalGuard-Guided Diuretic Therapy for Acute Heart Failure Patients

Late-Breaking Presentation at European Society of Cardiology Heart Failure 2018 Shows Potential of Treatment to Help Clinicians Manage Patient Fluid Balance

MILFORD, Mass. – May 29, 2018 – RenalGuard Solutions™, Inc., a medical device company focused on innovative fluid management technologies for the cardiac and vascular markets, today announced new clinical study results demonstrating the feasibility of using RenalGuard®-Guided Diuretic Therapy to optimize fluid management in Acute Decompensated Heart Failure (ADHF) patients while alleviating related symptoms. Study results were presented during a late-breaking presentation at the European Society of Cardiology Heart Failure (ESC-HF) conference in Vienna.

“We are thrilled to reveal late-breaking data that demonstrates a promising step towards a new therapy for patients suffering from Acute Decompensated Heart Failure. RenalGuard’s fluid management technology may precisely enable the controlled decongestive therapy that ADHF patients need,” said Jim Dillon, CEO of RenalGuard Solutions. “Our Guided Diuretic Therapy (GDT) has the potential to establish a new front-line standard of care for heart failure patients, allowing physicians to maximize fluid removal while protecting patients from the potential negative impact of excessive fluid loss. At ESC-HF we have experienced overwhelming interest and attendance in our Late Breaking Clinical Trial presentation and Satellite Symposium entitled ‘*Problems and optimization of volume management in patients with acute heart failure*,’ as well as numerous inclusions in Acute Heart Failure presentations.”

ADHF is a sudden onset of heart failure symptoms, which typically include difficulty breathing (dyspnea), swelling in the extremities, and fatigue. Current treatment for ADHF includes diuretic therapy that aims to restore healthy fluid levels in the kidneys and throughout the body. Diuretic therapy can be unpredictable and lose effectiveness as a patient’s condition worsens. In some patients, diuretics can trigger a condition called “diuretic resistance,” which blunts the function of diuretics and can worsen the severity of fluid overload, potentially resulting in acute kidney injury. RenalGuard-Guided Diuretic Therapy is designed to allow clinicians to increase the dose of diuretics without increasing the risk of diuretic resistance, enabling safe and effective removal of excess fluid from ADHF patients and alleviation of symptoms.

“Clinicians need new options to help manage our patients who are hospitalized with Acute Decompensated Heart Failure,” says Piotr Ponikowski, professor of cardiology at Wroclaw Medical University, 4th Military Hospital in Wroclaw, Poland, and one of the lead investigators for this study. “The results of this study are encouraging as they show clinicians were able to achieve a safe rate of fluid loss by inducing high-urine rates and maintaining intravascular volume using RenalGuard-Guided Diuretic Therapy.”

About the Study

This first-in-human clinical trial evaluated nine patients hospitalized for ADHF. Patients underwent 24 hours of standard diuretic therapy with intravenous furosemide, followed by 24 hours of diuretics in conjunction with RenalGuard-Guided Diuretic Therapy. Study results showed a significant improvement in breathing patterns and diuretic efficiency among patients treated with RenalGuard-Guided Diuretic Therapy, creating a more than two-and-a-half-fold increase in the amount of urine they produced. Average urine output measured over 24 hours of standard diuretic therapy was 1,961 mL. Over the next 24 hours, RenalGuard-Guided Diuretic Therapy was applied in conjunction with diuretic therapy, and average urine output increased to 4,771 mL ($p < 0.01$). The average change in estimated kidney function at 30 days after the trial, measured using the glomerular filtration rate, showed an average increase of 8 percent, with three patients demonstrating an increase of more than 25 percent.

About RenalGuard-Guided Diuretic Therapy

RenalGuard-Guided Diuretic Therapy is designed to manage fluids, thereby optimizing diuretic therapy for heart failure patients, and may relieve a number of symptoms related to heart failure. By enabling precise and predictable management of a patient's fluid levels, RenalGuard-Guided Diuretic Therapy has the potential to give clinicians better control over diuretic therapy. More information showing how RenalGuard-Guided Diuretic Therapy works can be viewed in the following animation: <https://vimeo.com/272079141/f0dac273dc>

About RenalGuard Solutions, Inc.

RenalGuard Solutions, Inc. is a medical device company focused on innovative fluid management technologies for the cardiac and vascular markets. The company's lead product, RenalGuard®, is a platform technology designed to precisely manage fluid levels and improve care for a wide range of patients. Originally developed to reduce the risk of contrast-induced nephropathy (CIN), the RenalGuard platform has potential applications in other disease areas, including heart failure. The CIN-RG RenalGuard pivotal study is underway in the United States to support a planned Premarket Approval submission with the Food and Drug Administration in 2018. For further information, please visit the company's website at <https://www.renalguard.com/> and follow us on Twitter at [@RenalGuard](https://twitter.com/RenalGuard).

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