Late-Breaking REMEDIAL III Clinical Trial Presented at TCT Shows RenalGuard Therapy's Automated, Personalized Hydration Superior in Preventing Contrast-Induced Acute Kidney Injury

- 700 patient, multicenter, randomized, investigator driven clinical trial
- Met primary endpoint: onset of CI-AKI defined by rise in serum creatinine > 25% or 0.5 mg/dl and/or pulmonary edema
- 10.3 % of patients developed CI-AKI and/or pulmonary edema using LVEDP vs. 5.7% using RenalGuard
- One month post-treatment: 12% of patients developed major adverse events using LVEDP vs. 7.1% using RenalGuard

MILFORD,MA – October 03, 2019 – RenalGuard Solutions™, a pioneering medical device company focused on protecting patients from acute kidney injury (AKI), announced today that a late-breaking clinical trial found the company's RenalGuard Therapy® superior to the POSEIDON method in preventing contrast-induced acute kidney injury (CI-AKI) for patients with kidney disease who undergo interventional procedures. Results of the 700 patient, randomized, investigator-driven REMEDIAL III trial were presented at the TCT 2019 meeting held in San Francisco September 25-29.

The contrast used in interventional procedures injures the kidney in a number of ways, including direct toxicity, blocking oxygen delivery to the kidney, and increasing fluid loss. RenalGuard Therapy, a technology used with more than 23,000 patients, is designed to protect patients from these insults by inducing and maintaining high urine output. A number of clinical trials found that the high urine output induced by RenalGuard Therapy reduces the incidence of CI-AKI.

"Contrast-induced acute kidney injury is a powerful predictor of unfavourable early and late outcomes," according to the authors of the REMEDIAL II trial. CI-AKI also accounts for approximately 10% of all causes of hospital-acquired renal failure and increases length of stay.

The REMEDIAL III trial was designed to evaluate the ability of the two most successful patient "tailored hydration regimens" to protect at-risk patients from CI-AKI by comparing RenalGuard Therapy with left ventricular end-diastolic pressure (LVEDP)-guided hydration (the "POSEIDON" method).

The data showed RenalGuard Therapy to be superior to LVEDP-guided hydration for the prevention of CI-AKI, as demonstrated by a significantly lower incidence of CI-AKI and/or pulmonary edema, and a lower incidence of major adverse events one month post-treatment. Overall 10.3% of patients (36/351) treated with LVEDP-guided hydration developed CI-AKI and/or pulmonary edema, compared with 5.7% (20/351) of patients treated with RenalGuard Therapy. One month post-treatment, 12% of patients (44/351) treated with LVEDP suffered major adverse events including dialysis, sustained kidney damage, acute pulmonary edema, and death vs. 7.1% (21/351) treated with RenalGuard Therapy.

The investigators concluded that RenalGuard Therapy is superior to the LVEDP-guided hydration regimen to prevent the composite of CI-AKI and/or acute pulmonary edema in high-risk patients.

"RenalGuard Therapy has once again been proven to be the most effective means of preventing acute kidney injury in at risk patients," said Dr. Howard Levin, RenalGuard Solutions Chief Medical Officer. "In comparing RenalGuard® to the POSEIDON protocol, Dr. Briguori selected the most aggressive comparison possible. His finding that RenalGuard provided superior CI-AKI protection provides the strongest evidence to date to support the use of RenalGuard Therapy in at-risk patients. "

"We congratulate Dr. Briguori and his team on completing the largest study to date involving the RenalGuard System™", said RenalGuard President and CEO Jim Dillon. "A growing body of clinical evidence shows that core vital organs are protected by both the RenalGuard system and affiliate company Reprieve Cardiovascular's automated diuresis system. Both of these targeted therapies correct fluid imbalances to optimize outcomes for the growing population of patients with cardiac and renal disease."

About RenalGuard Therapy®

RenalGuard Therapy measures a patient's urine output and automatically adjusts hydration on an individual basis to induce high urine rates, which have been shown to protect the kidney from a range of insults. The system has been used with more than 23,000 patients. A growing body of clinical evidence demonstrates RenalGuard's ability to protect patients from AKI and CIN following catheterization procedures when compared to the standard of care. RenalGuard is CE-marked and is sold in Europe and other countries via a network of distributors. For further information and clinical trial results, please visit the company's website at https://www.renalguard.com.

About RenalGuard Solutions, Inc.

Milford, MA-based RenalGuard Solutions, Inc. is a medical device company focused on innovative technologies for the cardiac and vascular markets. The company's RenalGuard Therapy is designed to prevent surgery- or procedure-induced acute kidney injury (AKI), as well as contrast-induced nephropathy (CIN) for at-risk patients undergoing interventional procedures using contrast. RenalGuard Solutions, Inc. and Reprieve Cardiovascular, Inc. are subsidiaries of parent company CardioRenal Systems, Inc. For more information, please visit www.renalguard.com, and follow us on Twitter https://twitter.com/RenalGuard

About Reprieve Cardiovascular's Guided Diuretic Therapy

Reprieve Cardiovascular's Guided Diuretic Therapy is designed to manage fluids during diuretic therapy for patients with Acute Decompensated Heart Failure (ADHF) and may relieve a number of symptoms related to this condition. The therapy has the potential to enable precise and predictable management of a patient's fluid levels, guarding against dangerous fluid imbalances and enabling better control over diuretic therapy, thus increasing diuretic efficiency. 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. For more information please visit www.reprievecardio.com and follow us on Twitter https://twitter.com/ReprieveCardio

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