Initial Clinical Results Show Feasibility and Safety of RenalGuard Use to Reduce Risk of Cardiac Surgery-Associated Acute Kidney Injury

Results of Phase 1 Pilot Study Published in British Medical Journal's Publication openheart

MILFORD, Mass. — October 12, 2017 - A first-in-man, feasibility study of the use of the RenalGuard System® in patients undergoing cardiopulmonary by-pass surgery shows the potential of RenalGuard Therapy® to safely reduce the incidence of acute kidney injury (AKI) in the cardiac surgery setting.

The 10-patient pilot study was conducted by investigators at the Heart and Lung Centre, New Cross Hospital in Woverhampton, United Kingdom and published online in the journal *openheart*, a publication of the *British Medical Journal.*

All of the patients, who were undergoing cardiopulmonary by-pass surgery, were at increased risk of developing AKI. RenalGuard Therapy was initiated for all patients prior to the beginning of the procedure, and continued for 6-12 hours after the patient was transferred to the cardiac intensive care unit (CICU). The median intensive care stay was 1.5 days. None of the patients enrolled in the study developed AKI within 36 hours of surgery, despite one patient developing cardiac tamponade 8 hours postoperatively and one patient developing paralytic ileus. One patient, however, was 'electively' hemofiltered on day 2 after developing acute right ventricular failure. Additionally, one patient developed stroke 1 week postoperatively. The authors report that they did not believe these adverse events were related to the use of the RenalGuard System.

The investigators concluded that: "The RenalGuard system can be used successfully in patients undergoing cardiac surgery with CPB and may reduce the incidence of AKI in at-risk patients." Acute kidney injury is the most common major complication of cardiac surgery, with an incidence rate ranging from 5-42% for the more than 2 million cardiac surgeries performed worldwide each year. AKI complicates patient recovery, adds significantly to recovery time and the cost of care, and places patients at an increased risk of death that can remain high for as long as 10 years after surgery even in those who recover full renal function. To date, no preventive strategies have been shown in clinical trials to reduce the occurrence of cardiac surgery-associated AKI.

"We are very gratified by the results of this pilot study of RenalGuard in the cardiac surgery setting, which show this technology's promise in this new application as a means to protect a very high-risk population from cardiac surgery-associated AKI," said RenalGuard Solutions President and Chief Executive Officer, Jim Dillon. "We look forward to further exploring the use of the RenalGuard System to reduce the incidence of AKI in this patient population."

About RenalGuard Therapy

RenalGuard measures a patient's urine output and automatically infuses hydration fluid based on that urine output. The system is designed to induce high urine rates, which have been shown to protect the kidney from a range of insults. A number of studies have demonstrated RenalGuard's ability to protect patients from AKI following catheterization procedures when compared to the standard of care, including: MYTHOS, which found RenalGuard to be superior to overnight hydration; REMEDIAL II, which found RenalGuard to be superior to sodium bicarbonate hydration; Protect-TAVI, which reported a significant reduction in post-procedural acute kidney injury (AKI) following transcatheter aortic valve replacement (TAVR) when using RenalGuard during the procedure, compared to standard therapy; and AKIGUARD, which showed significant improvement in long-term outcomes when using RenalGuard vs. standard therapy.

About RenalGuard Solutions, Inc.

RenalGuard Solutions, Inc. is a medical device company focused on innovative technologies for the cardiac and vascular markets. The company's lead product, RenalGuard®, is designed to protect patients from acute kidney injury (AKI), including contrast-induced AKI. Investigator-sponsored studies in Europe have demonstrated RenalGuard's effectiveness at preventing CI-AKI in at-risk patients. RenalGuard is CE-marked and is sold in Europe and certain countries around the world via a network of distributors. The CIN-RG RenalGuard pivotal study is underway in the United States to support a planned Premarket Approval filing with the U.S. Food and Drug Administration in 2018. For further information, please visit the company's website at http://www.renalguard.com.

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