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French Study Demonstrating Safety of RenalGuard® During Kidney Transplantation Presented at International Conference on Kidney

MILFORD, MA -- (Marketwired) -- 11/14/16 -- RenalGuard Solutions™, Inc., an innovative renal protection company, today announced that Nicolas Viallet, MD, Nephrologist, Felix Guyon University Hospital, St Denis, Reunion Island, France, presented the results of his investigator-sponsored pilot study on the use of RenalGuard® during kidney transplantation, "[Forced diuresis with matched hydration by RenalGuard after kidney transplantation](#)," at the International Conference on Kidney, September 29 - 30, Orlando, Florida. The study, the first of its kind, demonstrated that the use of RenalGuard Therapy® with post-transplant kidney patients was relatively safe, and resulted in higher urine rates.

The study, which took place between December 2013 and September 2014, evaluated eleven kidney transplant patients who were given forced diuresis by Furosemide with matched hydration using RenalGuard during the first 36 hours post transplantation (DF group). These patients were retrospectively compared to eleven similar patients who had spontaneous diuresis (DS group). The DF group had an average urine output of 265 (154-350) ml/h versus 69 (51-107) ml/h in the DS group.

The diuresis quantification by RenalGuard appeared strongly correlated with the nurse measurement ($R^2 = 0.96$, $p < 0.001$). Real-time matched hydration allowed no significant change in patients' weights. Three patients from the DF group had major hyperglycemia when using glucose 5% as compensation, but modifications to the infusion of glucose prevented this in subsequent patients. Hypokalemia was more frequent in the DF group. There was no difference observed in renal function.

In his abstract, Dr. Viallet noted, "We have observed that RenalGuard System™ helps to achieve a high diuresis while simultaneously balancing urine output and venous fluid infusion to maintain euvolemia in patients with compromised kidney function. This strategy has revealed to be beneficial to prevent contrast-induced acute kidney injury in these patients. We hypothesize it could be extended to kidney transplantation as a reno-protective action to prevent delayed graft function. This study is the first step in developing proof for this theory.

"This is the first observation of the RenalGuard experience in renal transplant patients. We felt it important to focus on both the safety and efficacy of incorporating the protocol into this procedure," he continued. "It is a good initial step that helps guide future use of RenalGuard in this area."

"Our focus continues to be on the adoption of RenalGuard by cardiac catheterization labs

for patients at high-risk of developing acute kidney injury, but this study offers an opportunity to extend the use of our device and RenalGuard Therapy into additional important patient populations," said Andrew Halpert, President, RenalGuard Solutions, Inc. "We look forward to learning of the results of more in-depth studies by Dr. Viallet and his team."

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. This study is the first in to examine the use of RenalGuard in kidney transplant patients. 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. Our lead product, RenalGuard, is designed to protect patients from acute kidney injury (AKI), including contrast-induced AKI. Two investigator-sponsored studies in Europe have demonstrated RenalGuard's effectiveness at preventing CI-AKI in at-risk patients. RenalGuard is CE-marked and is being sold in Europe and certain countries around the world via a network of distributors. The CIN-RG RenalGuard pivotal study is underway in the U.S. to support a planned Premarket Approval filing with the U.S. Food and Drug Administration. For further information, please visit the website at www.RenalGuard.com.

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