# RenalGuard Shown to Significantly Protect High-Risk Patients Undergoing Coronary Interventional Procedures from Acute Kidney Injury

- *Independent meta-analysis of published clinical studies shows matched hydration using RenalGuard System™ significantly reduces contrast-induced acute kidney injury and need for dialysis*
- *Positive trend seen towards reductions in mortality, stroke and other adverse events*

MILFORD, Mass. — February 28, 2017 - RenalGuard Therapy® holds the potential to provide a new standard-of care for preventing cardiac contrast-agent induced acute kidney injury (CI-AKI) in high-risk patients undergoing percutaneous coronary interventions or transcatheter aortic valve replacement, according to a newly published report and companion editorial in *JACC: Cardiovascular Interventions*.

The report, an independent systematic review and meta-analysis of four previously published randomized controlled clinical trials, found that RenalGuard Therapy was associated with a highly significant reduction of CI-AKI (7.76% vs. 21.43%; $p<0.00001$), a significantly lower need for patient dialysis (0.58% vs. 3.45%; $p = 0.02$), and a consistent positive trend towards lower rates of mortality, post-procedural acute coronary syndrome, stroke, and acute pulmonary edema. Moreover, the analysis found that most of the patients treated with RenalGuard reached a high urine output despite severely depressed kidney function without significant changes in electrolyte balance or any adverse reactions.

The meta-analysis, entitled "Prevention of Contrast-Induced Acute Kidney Injury by Furosemide with Matched Hydration in Patients Undergoing Interventional Procedures," was performed and published by researchers from Cardiocentro Ticino, Lugano, Switzerland and Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS) San Raffaele Scientific Institute, Milan, Italy. The editorial, entitled "High Urine Output with Matched Hydration for CI-AKI Prevention: 'Saus Per Aquam' (Health through Water)," was authored by Antonio L Bartorelli, MD, Centro Cardiologico Monzino, Istituto IRCCS, Milan, Italy and Giancarlo Marenzi, MD, Department of Biomedical and Clinical Sciences "Luigi Sacco", University of Milan, Milan, Italy.

"We are grateful to the authors, whose detailed analysis shows that RenalGuard not only lowers the incidence of CI-AKI, but offers a real benefit for patients and health care payers by significantly reducing the need for dialysis," said Andrew Halpert, President, RenalGuard Solutions™. "This detailed review adds strongly to the growing body of clinical evidence that RenalGuard can significantly lower health care risks arising from the use of medically valuable but potentially toxic contrast agents used today in a variety of diagnostic and interventional coronary procedures. We expect these findings to continue to drive adoption of RenalGuard Therapy in Europe and other areas where it currently available, and we look forward to further adding to these findings through our ongoing U.S. pivotal trial, which we expect to complete around the end of this year."

Mr. Halpert noted that RenalGuard System is currently marketed for use in the cardiac catheterization laboratory in Europe, the Middle East, and South Africa, and that the company expects to file for pre-marketing approval with the U.S. Food and Drug Administration in 2018.

***Economic Impact***

The meta-analysis authors noted that lowering the incidence of CI-AKI, which would also lead to an associated significant reduction in the need for dialysis, could have a strong positive economic impact on health care costs. According to the United Kingdom's National Health Service Kidney Care program, the annual cost of AKI in the UK is estimated at US $700 million to $1 billion per year -- more than the yearly national expenditures related to either breast cancer or lung and skin cancer combined. CI-AKI is associated with higher in-hospital and long-term morbidity and mortality, persistent loss of kidney function, and risk of progression to end-stage renal disease. There are currently no therapies approved in the United States for the reduction of CI-AKI associated with coronary interventional procedures.

***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. 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 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. For further information, please visit the website at http://www.renalguard.com.

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