Meta-Analysis Shows RenalGuard Offers Dramatic Benefit for Preventing Contrast-Induced Acute Kidney Injury in Patients Undergoing Cardiovascular Interventions

RenalGuard Significantly Reduced AKI Rates in Patients at Moderate to High Risk, as well as Significantly Decreased Deaths, Dialysis, and Major Adverse Cardiovascular Events

New Meta-Analysis of RenalGuard Therapy(R) Includes 3 Studies Showing RenalGuard Protects from AKI during TAVR

MILFORD, Mass. — September 13, 2017 - A new meta-analysis suggests that the use of the RenalGuard System® reduces the rate of contrast-induced acute kidney injury (CI-AKI) compared to standard intravascular volume expansion in moderate-to-high-risk patients with chronic kidney disease who are undergoing cardiac interventional procedures. The study, published in the *Journal of Interventional Cardiology*, also found that RenalGuard significantly reduces rates of all-cause mortality, progression to renal replacement (dialysis), and Major Adverse Cardiovascular and Cerebrovascular Events (MACCE), both short- and long-term. The meta-analysis included 10 studies, four of which were randomized controlled trials, and was conducted by Anand Prasad, M.D., FACC, FASCI, RPVI and colleagues of the Department of Medicine, Division of Cardiology, University of Texas Health Science Center at San Antonio. Of a total of 1,585 patients, 698 were enrolled in the four randomized trials, and 887 belonged to the remaining patient registries included in the analysis.

Results showed that use of RenalGuard was associated with a significant risk reduction for CI-AKI compared to controls (standard volume expansion) (RR: p.30, 95% CI: 0.18-0.50, P<0.01). Incidence of CI-AKI in RenalGuard treated patients was 7.7% versus 23.6% in the control group (P<0.01). The use of RenalGuard was also associated with decreased mortality (RR:0.43, 95%CI: 0.18-0.99, P=0.05, dialysis (RR: 0.20, 95%CI: 0.06-0.61, p=0.01), and MACCE (RR: 0.42, 95%CI: 0.26-0.65, P<0.01) compared to the control.

"Acute kidney injury following contrast administration has been linked to significantly worsened patient outcomes, including increased need for dialysis, adverse events and mortality," said RenalGuard Chief Executive Officer Jim Dillon. "We thank the authors of this study, whose detailed analysis shows that RenalGuard provides greater benefit to patients and health care providers than volume expansion, not only by lowering the incidence of CI-AKI and reducing the need for dialysis, but improving patient outcomes by furthermore decreasing patient mortality and the incidence of costly major adverse cardiovascular events."

"This meta-analysis is the first to incorporate the three studies that reported significant reductions in the incidence of AKI post- transcatheter aortic valve replacement (TAVR)," said RenalGuard Chief Technology Officer Andrew Halpert. "Kidney injury following TAVR is one of the strongest predictors of long-term mortality post procedure. RenalGuard's demonstrated

reduction in rates of AKI in these patients will helps Edwards and Medtronic and the rest of the TAVR manufacturers as they seek to expand the indicated population for TAVR valves. We expect these findings to continue to drive adoption of RenalGuard Therapy in the growing TAVR market, as well as all of the other applications where RenalGuard has been found to reduce the incidence of CI-AKI."

The RenalGuard system is currently marketed for use in the cardiac catheterization laboratory in markets where it is approved, including a number of countries in Europe and the Middle East. The company expects to conclude its Pivotal US trial before the end of this year and file for pre-marketing approval with the U.S. Food and Drug Administration in 2018.

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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