Study Confirms RenalGuard Efficacy for Dramatically Lowering Risk of Contrast-Induced Acute Kidney Injury

Results of New Clinical Study in Japanese Patient Population Presented at European Society of Cardiology Annual Congress

MILFORD, Mass. — August 29, 2017 - New clinical research confirms the ability of RenalGuard® to dramatically lower the risk of contrast-induced nephropathy (CIN) compared to the risk predicted by validated Mehran CIN scores for patients with kidney impairment who are exposed to contrast agents as part of cardiac catheterization procedures. Moreover, 58 patients undergoing such procedures with RenalGuard support experienced no serious adverse events. Results of the RESPECT KIDNEY study of RenalGuard, conducted in Japan, were presented today by Dr. Hiromasa Katoh on behalf of the study investigators at the European Society of Cardiology Annual Congress 2017 in Barcelona, Spain.

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. In the reported study, investigators Dr. Tsuyoshi Nozue, Dr. Ichiro Michishita at the Yokohama Sakae Kyosai Hospital and Dr. Kazuki Horie and Dr. Naoto Inoue at Sendai Kosei Hospital incorporated RenalGuard into the treatment of 58 patients with severe renal dysfunction and coronary artery or peripheral artery disease who were undergoing catheterization procedures using iodinated contrast. Primary endpoint for the study was the combined incidence of CIN and serious in-hospital therapy-related adverse events.

Results of the study showed a markedly lower incidence of CIN in RenalGuard treated patients, compared to values predicted by the Mehran CIN risk scores:

Low Risk Patients (Risk Score ≤ 5%)	Predicted RESPECT Study	7.5% 0% (0/3 patients)
Moderate Risk Patients (Risk Score 6-10%)	Predicted RESPECT Study	14% 0% (0/15)
High Risk Patients (Risk Score 11-15%)	Predicted RESPECT Study	26.1% 9.4% (3/32)
Very High Risk Patients (Risk Score ≥ 16%)	Predicted RESPECT Study	57.3% 25.0% (2/8)
Overall	Predicted RESPECT Study	26.1% 8.6% (5/58)

Renal function of the patients who did sustain CI-AKI returned to baseline within a month of their procedure. A spike in serum creatinine post-procedure has been associated with an increased incidence of long-term adverse outcomes and mortality.

"We are very gratified by the findings of this clinical study which continue to underscore the benefits offered by RenalGuard therapy for reducing the risks of CIN in patients with kidney impairment, thus better enabling them to receive potentially life-saving cardiac interventional therapies," said Jim Dillon, Chief Executive Officer of RenalGuard Solutions. "We look forward to the completion of our U.S. pivotal study of RenalGuard around year end, and the potential ability to offer this therapy to the U.S. market 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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