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PLC Systems Provides Update on Japanese Approval Process for RenalGuard®

First Step in Process to Secure Approval for Full RenalGuard® Study in Japan Completed

MILFORD, Mass., Jan. 5, 2012 /PRNewswire/ -- PLC Systems Inc. (OTC: PLCSF), a company focused on innovative medical device technologies, announced today that Dr. Ichiro Michishita, a leading Japanese cardiologist, has successfully completed two cases utilizing RenalGuard® for the prevention of Contrast-Induced Nephropathy (CIN) at Yokohama Sakae Kyosai Hospital, Yokohama, Japan. This is the first step in the process to secure regulatory approval for RenalGuard in Japan.

Dr. Michishita, Director of the hospital's Cardiovascular Division, a leading Japanese expert in CIN prevention, has worked with the Japanese Ministry of Health, Labor and Welfare (MHLW) to outline a process for RenalGuard evaluation and approval in Japan. The first step, now completed, was the initial experience of two patients. Dr. Michishita will meet with the Ministry in February to present these findings and request approval for the previously-agreed upon 60 patient study that could begin as early as April 2012 with Dr. Naoto Inoue, who is the director of Cardiovascular Center of Sendai Kousei Hospital, as the co-investigator. The investigators expect to complete that study within 8-10 months. Once the study is concluded, the results will be submitted to the MHLW, as part of a package for ***shonin*** approval from the agency. Completion of this process, if successful, would allow the importation of RenalGuard for sales and marketing in Japan.

Mark R. Tauscher, President and Chief Executive Officer of PLC, said, "We are absolutely delighted by the positive experience of these initial cases utilizing RenalGuard in Japan. Dr. Michishita's leadership in CIN prevention is paving the way for the clinical study that hopefully will lead to the approval by the MHLW to allow us to begin selling RenalGuard in Japan. The Japanese market is arguably the second largest market in the world for RenalGuard, based upon the number of cath lab procedures and patients undergoing these procedures with existing at-risk conditions for CIN. We await approval of the larger patient study shortly, and following the successful completion of the trial, approval for the start of sales and marketing of RenalGuard in Japan, launching a major new phase in RenalGuard's adoption."

Dr. Michishita noted, "I am very pleased that the very first cases utilizing RenalGuard in Japan to prevent CIN were successful. I am very impressed with the ease of use of the system, and how it works to maintain the fluid balance of the body. Once it is approved by the MHLW, I believe that RenalGuard will be a great benefit for patients undergoing PCI requiring contrast media."

Contrast-Induced Nephropathy

CIN is a major and growing problem due to the increasing number of older patients, diabetics and patients with pre-existing renal impairment – all of whose conditions make them at risk for CIN when they require interventional procedures that use radiographic contrast media. More than 7 million such imaging procedures occur worldwide each year, and it is estimated that 15-20% of those patients are 'at risk' of acquiring CIN. CIN is the third most common cause of in-hospital acute renal failure. It is associated with significant in-hospital mortality rates, and increases in long-term mortality rates, major in-hospital adverse cardiac events, and increased risk of renal dialysis therapy. All of these lead to prolonged hospital stays and increased medical costs. Estimated mortality rates for patients who acquire CIN may be as high as 35%.

About RenalGuard

RenalGuard is based on data that shows that initiating and maintaining high urine output during imaging procedures allows the body to rapidly eliminate toxins in contrast media, reducing their harmful effects. RenalGuard is a fully-automated, real-time matched fluid replacement device intended for interventional cardiology and radiology patients undergoing imaging procedures using contrast media.

About PLC Systems

PLC Systems Inc., headquartered in Milford, Mass., is a medical device company focused on innovative technologies for the cardiac and vascular markets. PLC's newest product, RenalGuard, has been developed to help prevent the onset of Contrast-Induced Nephropathy (CIN) in at-risk patients undergoing certain cardiac and vascular imaging procedures. The Product is CE-marked and is being marketed in Europe and selected countries around the world. Two investigator-sponsored European studies have demonstrated RenalGuard's effectiveness at preventing CIN. RenalGuard is being studied in a pivotal trial in the U.S., as required for approval by FDA.

This press release contains "forward-looking" statements. For this purpose, any statements contained in this press release that relate to prospective events or developments are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will" and similar expressions are intended to identify forward-looking statements. Our statements of our objectives are also forward-looking statements. While we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release. Actual results could differ materially from those indicated by such forward-looking statements as a result of a variety of important factors, including that we may not receive necessary regulatory approvals to market our RenalGuard product or that such approvals may be withdrawn, the U.S. clinical trial for RenalGuard may not be completed in a timely fashion, if at all, or, if this clinical trial is completed, it may not produce clinically significant or meaningful results, the RenalGuard product may not be commercially accepted, operational changes, the need for additional financing, competitive developments may affect the market for our products, regulatory approval requirements may affect the market for our products, and additional risk factors described in the "Forward Looking Statements" section of our Annual Report on Form 10-K for the year ended December 31, 2010, a copy of which is on

file with the SEC.

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