PLC Systems Provides Update on Japanese Approval Process for RenalGuardÃ‚®

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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
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