Cardiac DimensionsÃ‚® Receives CE Mark Approval for Enhanced CARILLONÃ‚® Mitral Contour Systemâ„¢

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KIRKLAND, Wash., Sept. 29, 2011 /PRNewswire/ -- Cardiac Dimensions®, Inc. today announced that it has received Conformite Europeenne (CE) Mark approval for a newly enhanced version of its CARILLON® Mitral Contour System™, a novel therapy for treating heart failure patients suffering from functional mitral regurgitation (FMR). Receipt of the CE Mark enables Cardiac Dimensions to initiate a commercial launch of the enhanced device in Europe, which the Company noted will begin in 2012.

The CE Mark approval follows the successful completion of the AMADEUS and TITAN clinical trials of the CARILLON system, which demonstrated significant reduction in FMR and significant improvement in functional capacity and quality of life. An additional trial with the enhanced version of CARILLON, called TITAN II, was recently initiated to further the clinical experience.

"We are delighted to have achieved this critical milestone, which allows us to distribute CARILLON throughout Europe," said Rick Stewart, President and Chief Executive Officer of Cardiac Dimensions. "We believe CARILLON's novel approach to addressing FMR holds significant promise for the millions of heart failure patients who suffer from this debilitating and progressive condition. The CE Mark approval of CARILLON is a reflection of our rapidly growing clinical experience, which suggests that this device is uniquely positioned to reverse the course of heart failure in this largely under-addressed patient population. Also, we are pleased to have the opportunity to further substantiate our initial clinical experiences through the commencement of the TITAN II trial."

Janusz Lipiecki, M.D., of Clinique Pole Sante Republique in Clermont Ferrand, France, one of the TITAN and TITAN II investigators, commented: "FMR secondary to left ventricular dilatation is associated with poor prognosis and high rates of mortality. As a new treatment option, CARILLON offers compelling and uniq
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[1] http://www.bio-medicine.org/medicine-technology-1/Cardiac-Dimensions-AE-Receives-CE-Mark-Approval-for-Enhanced-CARILLON-AE-Mitral-Contour-System-u2122-20721-1/