Cardiac Dimensions Announces Australian Therapeutic Goods Administration's Approval of the Carillon System for the Treatment of Functional Mitral Regurgitation

KIRKLAND, WA – September 2, 2020 — Cardiac Dimensions®, a leader in the development of innovative, minimally invasive treatments for functional mitral regurgitation (FMR) in patients with heart failure, today announced the Therapeutic Goods Administration (TGA) has approved its Carillon Mitral Contour System®. The Carillon System is a right heart transcatheter mitral valve repair (TMVr) device designed to treat the primary cause of FMR in patients with mitral regurgitation grades 2+, 3+ and 4+.

"We would like to thank the Therapeutic Goods Administration for their partnership in the review and approval of the Carillon System in Australia," said Rick Wypych, Chief Executive Officer and President of Cardiac Dimensions. "This is a significant milestone as Australian patients with heart failure can now be treated earlier in their disease state with a minimally invasive treatment for mitral regurgitation."

An estimated 26 million people, worldwide, suffer from heart failure[i] and of those, approximately 70 percent have FMR. Heart failure is a significant clinical and economic burden with direct and indirect costs expected to grow to $70 billion by 2030.[ii]

"The availability of the Carillon System is an extremely exciting advancement for the medical community as this technology has the potential to help millions of patients suffering from heart failure and FMR," commented David Kaye, MD, Director of Cardiology at The Alfred Hospital, Melbourne, Australia. "The Carillon System provides a new, non-surgical method to correct a fundamental problem with the mitral valve in patients with heart failure. This approach has been shown to reduce mitral regurgitation and to favorably impact the left ventricle (LV). This is significant because a reduction in LV enlargement in heart failure is known to be associated with positive patient outcomes."

The Carillon System is placed using a non-surgical, minimally invasive (catheter-based) technique in a vein on the outside of the heart that is adjacent to the mitral valve. This procedure is designed to reshape the mitral valve, reduce valve leakage, and thus reduce mitral regurgitation and induce favorable remodeling.

The TGA's approval was based on the combined efficacy and safety results from several Cardiac Dimensions' studies including the most recent REDUCE FMR study. Treatment with the Carillon Mitral Contour System in these studies consistently demonstrated a significant decrease in regurgitant volume and left ventricular volumes. These changes were associated with reduced heart failure symptoms and improved quality of life.

"M.H. Carnegie & Co. and Hostplus, a large investor in our medical device initiative, recognized early on the importance of the Carillon System to patients and have been a significant supporter of the therapy and the company during their journey," said Mark Carnegie of M.H. Carnegie & Co. "We're excited now that the company has approval in Australia and look forward to the benefits it brings this underserved patient population."

About the Carillon Mitral Contour System®

The Carillon System offers a simple right heart approach to transcatheter mitral valve repair (TMVr) designed to reshape the anatomy and function of the mitral apparatus from the coronary sinus. Distal and proximal anchors, connected by a shaping ribbon, utilize the heart's venous anatomy to cinch the mitral apparatus, without compromising the valve or future treatment options.[iii, iv] The Carillon System is designed to treat the primary cause of functional mitral regurgitation (FMR) in patients with MR grades 2+, 3+ and 4+ and is the first and only device to demonstrate a reduction in regurgitant volume and favorable left ventricular remodeling in a randomized sham-controlled clinical trial of percutaneous valve therapy.[v, vi, vii] The Carillon System is CE-marked (0344) and has been implanted in over 1,200 patients in the U.S., Europe, Australia, Turkey and the Middle East. The Carillon System is currently being studied in The CARILLON Trial pivotal trial and limited to investigational use in the United States.

About Cardiac Dimensions

Cardiac Dimensions is a leader in the development of innovative, minimally invasive treatments to address heart failure and related cardiovascular conditions. Privately held, the company's lead investors include Aperture Venture Partners, Arboretum Ventures, HostPlus, Life Sciences Partners, Lumira Ventures and M.H. Carnegie & Co. Cardiac Dimensions is headquartered in Kirkland, Washington and has operations in the United States, Australia and Germany. For more information, visit cardiacdimensions.com.

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