Cardiac Dimensions Announces DRG Reimbursement Code for Carillon® Mitral Contour System® in Germany

With Reimbursement in Place and Positive Late-Breaking Data, Company Expects Continued Growth in Germany

Kirkland, Wash. – October 18, 2018 – Cardiac Dimensions, a leader in the development of innovative, minimally invasive treatment modalities to address heart failure and related cardiovascular conditions, today announced that InEK, the German Institute for the Hospital Remuneration System, has granted a permanent DRG (Diagnosis Related Group) code covering reimbursement for the company's Carillon Mitral Contour System to treat patients with functional mitral regurgitation (FMR) in Germany. The new reimbursement becomes effective January 1, 2019.

Previously, the Carillon System had been available in limited volumes under the Neue Untersuchungs- und Behandlungsmethoden (NUB) program. The DRG approval will allow every eligible patient in Germany to have access to the Carillon procedure.

"With this reimbursement in place and following the positive late-breaking clinical data from REDUCE FMR presented last month at TCT, we expect to see significant growth in Germany, the largest market in which the Carillon Mitral Contour System is currently available," said Gregory D. Casciaro, President and CEO of Cardiac Dimensions. "We are pleased that this decision means many more people will now benefit from Carillon therapy."

Data presented at the Transcatheter Cardiovascular Therapeutics (TCT) Conference in San Diego last month showed that the REDUCE FMR clinical trial met its primary endpoint, demonstrating a statistically significant reduction in regurgitant volume at one year in patients who received the Carillon Mitral Contour System versus the control cohort, consisting of patients under guideline-directed medical therapy who underwent a sham procedure. The reduction represented a 22% reduction in regurgitation in the treatment group, compared to an overall increase of 8% in regurgitation in the control group ($p=0.03$). Study patients, the imaging core lab, and the clinical assessors were blinded as to the patients' randomization group through the one-year follow-up period of the study.

"This positive decision is good news for patients in need of mitral valve repair due to FMR," said Prof. Michael Haude, M.D., Director of the Department of Internal Medicine I, Cardiology, Lukas Krankenhaus Neuss, who has been treating patients with the Carillon System since the Amadeus study in 2007. "The Carillon System provides an important option for patients that is easy to use and that can be used to treat patients earlier in the progression of their disease to prevent worsening quality of life."

The company announced last month that it had enrolled its first patient in the pivotal CARILLON Trial, a multi-center, double-blinded, randomized controlled trial expected to randomize 450 patients at up to 75 centers in North America and Europe.

Functional mitral regurgitation occurs when the left ventricle of the heart is enlarged, dilating (stretching) the valve opening (annulus) and causing a backward flow of blood into the atrium. Left untreated, FMR contributes to heart failure – a chronic, progressive condition that weakens the heart

and makes everyday activities difficult. The Carillon System addresses the underlying mechanical problem of FMR with a catheter-based alternative to medications and invasive surgery.

About the Carillon Mitral Contour System

The Carillon Mitral Contour System is an innovative minimally invasive treatment for people diagnosed with FMR. The Carillon System is designed to offer physicians a safe and easy-to-use option to treat patients earlier in their disease diagnosis, including those with lesser degrees of FMR (2+ MR grade), to slow disease progression and prevent worsening quality of life. The Carillon System treats the dilated mitral annulus, the underlying mechanical problem of FMR, with a catheter-based alternative to medications and invasive surgery. The Carillon System is a minimally invasive approach that offers patients annular reduction, while keeping adjunctive therapy options open.

To date, approximately 900 patients have been treated with the Carillon System throughout the world. Commercially, the Carillon System has CE Mark and is available in certain European markets as well as other key geographies including Turkey, Italy and The Netherlands. Clinical data from three completed studies of the Carillon System (AMADEUS, TITAN, and TITAN II) were the basis for the CE Mark demonstrating safety and performance. The recently released REDUCE FMR data is expected to assist with expanding reimbursement and usage in additional geographies such as Poland, France, United Kingdom and Australia. Additionally, the CARILLON Trial, the randomized sham-controlled U.S. pivotal IDE study, continues to enroll patients at centers in the U.S. and Europe.

About Cardiac Dimensions

Cardiac Dimensions is a leader in the development of innovative, minimally invasive treatment modalities to address heart failure and related cardiovascular conditions. Left untreated, FMR contributes to heart failure – a chronic, progressive condition that weakens the heart and makes everyday activities difficult. The Carillon System addresses the underlying mechanical problem of FMR with a catheter-based alternative to medications and invasive surgery. Cardiac Dimensions has operations in Kirkland, Washington; Sydney, Australia and Frankfurt, Germany.

The Carillon Mitral Contour System is an investigational device in the U.S. For more information, please visit www.cardiacdimensions.com.

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Media Contact:
Rick Wypych
rwypych@cardiacdimensions.com
(425) 605-5910