



Ancora Heart Announces Positive Interim Analysis from Study of First-of-Its-Kind Heart Failure Therapy

Encouraging Initial Safety and Compelling Early Efficacy Data Presented at TCT 2018

Santa Clara, Calif. — September 24, 2018 — Ancora Heart, Inc., a company developing a novel therapy to address heart failure, today announced positive clinical data from the company's recently expanded U.S. early feasibility study evaluating the safety of the investigational AccuCinch® Ventricular Repair System designed for the treatment of heart failure and functional mitral regurgitation (FMR). The data was presented at the 30th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

The transcatheter AccuCinch therapy has the potential to treat heart failure and FMR patients in whom the disease has progressed beyond the ability for medications and pacemakers to manage symptoms, or for whom the risks of open-heart surgery are too high. Unlike current technologies that replicate surgical procedures to replace or repair an otherwise-normal mitral valve, the AccuCinch system is designed to repair the left ventricle of the heart *directly*, to address the fundamental issue in the progression of systolic heart failure.

An interim analysis from the first cohort of 16 patients with heart failure and FMR was presented in two sessions at the meeting by Dan Burkhoff, M.D., Ph.D., of the Cardiovascular Research Foundation (CRF), and separately by Mark Reisman, M.D., Clinical Professor of Medicine, Section Head for Interventional Cardiology, and Director of Cardiovascular Emerging Therapies at University of Washington Medical Center.

"These preliminary efficacy data suggest that repairing the enlarged left ventricle with the AccuCinch system may not only reduce mitral regurgitation but may also improve heart function. The results are highly encouraging, and we look forward to continuing to study the device's many potential benefits in this study and future studies," said Jeff Closs, president and CEO of Ancora Heart. "Our goal is to show that a therapy focused on the ventricle will make a real difference in both quality and length of life for heart failure patients."

The initial data from the study, which continues to enroll patients and add trial sites, suggest a favorable safety profile with consistent procedural safety at 30 days, including no major adverse cardiac events and no device-related deaths. Preliminary efficacy data also at 30-day follow-up demonstrated a reduction in left ventricular volume by an average of 29%. Ejection fraction (EF), a measure of blood flowing out of the left ventricle, improved on average from 30% to 42%. In addition, mitral regurgitation grades and regurgitant volumes were both substantially reduced across this cohort.

"We are seeing consistent procedural success and promising safety results with AccuCinch, which is unique in its ventricular approach," said Dr. Burkhoff. "Early efficacy data indicate a mitral regurgitation reduction similar to transcatheter therapies focused on the mitral valve. However, the additional substantial improvement in LVESV and EF in patients treated with the AccuCinch system, which in general is also improving over time, suggests the device may be reshaping the left ventricle, and fundamentally improving heart function. We look forward to continuing to evaluate AccuCinch in this study."

About Heart Failure and Functional Mitral Regurgitation

About 6.5 million U.S. adults live with heart failure, a condition in which the heart's muscles slowly weaken and lose their ability to pump enough oxygen-rich blood to the body.¹ Up to 74 percent of people with heart failure also suffer from FMR, a condition caused when the left ventricle of the heart becomes enlarged to the point where it pulls the mitral valve leaflets apart and allows blood to flow backwards into the left atrium.² Heart failure and FMR patients suffer from debilitating symptoms including persistent exhaustion, trouble breathing, confusion and loss of memory. There is no cure for heart failure or FMR, and about half of people who develop heart failure die within five years of diagnosis.

About Ancora Heart

Ancora Heart, Inc., based in Santa Clara, Calif., is dedicated to helping people with heart failure feel better and live longer. Ancora Heart has developed the AccuCinch System, an investigational therapy designed to repair the enlarged left ventricle targeting the underlying cause of heart failure. The AccuCinch heart failure treatment was created to benefit the millions of patients who otherwise have no minimally invasive option available to them. For more information visit www.ancoraheart.com.

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¹ Benjamin E.J., Blaha M.J., Chiuve S.E., et al. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. *Circulation* 2017; 135: pp. e146-e603

² Al-Amri, H. S., Al-Moghairi, A. M., & El Oakley, R. M. (2011). Surgical treatment of functional mitral regurgitation in dilated cardiomyopathy. *Journal of the Saudi Heart Association*, 23(3), 125–134. <http://doi.org/10.1016/j.jsha.2011.04.001>