



## **Ancora Heart Expands Enrollment of U.S. Early Feasibility Study for the AccuCinch System for Left Ventricular Repair**

*Study Evaluates Safety of First-of-Its-Kind Therapy Designed to Directly Target Systolic Heart Failure*

SANTA CLARA, Calif. – May 14, 2018 – Ancora Heart, Inc., a company developing a novel therapy to address heart failure, today announced the expansion of the company’s U.S. feasibility study to evaluate the investigational AccuCinch® Ventricular Repair System designed for the treatment of heart failure and functional mitral regurgitation (FMR).

Ancora has received approval from the U.S. Food and Drug Administration (FDA) to enroll a second group of subjects and expand to 15 heart centers across the United States.

“We are pleased that the FDA has approved expansion of this study, as it will allow us to continue to gather valuable clinical information about AccuCinch,” said Jeff Closs, president and CEO of Ancora Heart. “We are encouraged by our early clinical experience and interest from new heart centers to participate in the study.”

The AccuCinch procedure is intended to directly repair the enlarged left ventricle, targeting the underlying cause of heart failure. This minimally invasive procedure is designed to reduce the size of the left ventricle, improve left ventricular function, and reduce symptoms of heart failure, with the goal of improving quality of life for patients.

“Today there is an enormous unmet need for effective treatment options for patients with heart failure, as many patients either do not undergo or may not benefit from traditional surgical approaches,” said Paul Sorajja, M.D., Roger L. and Lynn C. Headrick Family Chair for Valve Science Research at the Minneapolis Heart Institute Foundation® Valve Science Center, and principal investigator for the study at Minneapolis Heart. “Early results suggest that AccuCinch has the potential to be the first therapy of its kind to treat dysfunction of the left ventricle and indicate this approach may address the shortcomings of current heart failure and FMR treatments.”

The 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, AccuCinch is designed to repair the left ventricle directly to enable proper mitral valve function.

### **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.<sup>1</sup> 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

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<sup>1</sup> 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

and allows blood to flow backwards into the left atrium.<sup>2</sup> 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.<sup>1</sup>

### **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 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](http://www.ancoraheart.com).

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<sup>2</sup> 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.isha.2011.04.001>