



Ancora Heart Enrolls First Patient in U.S. Early Feasibility Study of First-of-Its-Kind Investigational Heart Failure Therapy

Study is first in the world to evaluate a transcatheter therapy designed to improve left ventricular function for heart failure patients with reduced ejection fraction

Santa Clara, Calif.—May 30, 2019—Ancora Heart, Inc., a company developing a novel therapy to address heart failure, today announced the first patient was enrolled in a U.S. early feasibility study evaluating the AccuCinch[®] Ventricular Repair System as a treatment for patients with reduced ejection fraction systolic heart failure (HFrEF).

The first patient was enrolled at UPMC Pinnacle Harrisburg by Hemal Gada, MD, MBA, interventional cardiologist, medical director of the structural heart program and Mubashir Mumtaz, MD, FACS, FACC, chief of cardiothoracic surgery and surgical director of structural heart.

“We are pleased to participate in this study because it is the first in the world to evaluate a transcatheter therapy for heart failure that seeks to restore quality of life and longevity by directly improving left ventricular heart function,” said Gada.

This is the second U.S. early feasibility study evaluating the safety of the AccuCinch system, and it will enroll up to 15 patients from heart centers across the country. In May 2018, Ancora Heart announced the U.S. Food and Drug Administration (FDA) allowed the expansion of patient enrollment in the initial study evaluating the AccuCinch system in patients with heart failure and functional mitral regurgitation (FMR). These two AccuCinch studies are enrolling patients simultaneously and are being conducted under the same investigational device exemption approved by the FDA.

“Enrolling the first patient in this heart failure study is a significant milestone in our mission to profoundly improve the care and quality of life of heart failure patients,” said Jeff Closs, president and CEO of Ancora Heart. “We believe the preliminary data from our initial AccuCinch feasibility study suggests that repairing the enlarged left ventricle directly may fundamentally improve heart function. We are thrilled to have the opportunity to better understand AccuCinch’s potential benefits in this currently underserved patient population with HFrEF.”

The transcatheter AccuCinch therapy is designed to complement and enhance the existing care cardiologists provide to further manage symptoms and slow, or stop, the progression of heart failure. For some patients, AccuCinch may have the potential to reverse the enlargement of the left ventricle. For patients where heart failure has progressed beyond the ability for medications and pacemakers to manage symptoms, non-surgical percutaneous device therapy with AccuCinch may provide an effective treatment option. The AccuCinch system is designed to repair the left ventricle of the heart *directly*, thereby addressing the fundamental issue in the progression of systolic heart failure.

About Heart Failure

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 Heart failure patients suffer from debilitating symptoms including persistent exhaustion, trouble breathing, confusion and loss of memory. About half of heart failure patients have an enlarged left ventricle, the main pumping chamber of the heart, which causes more stress on the heart

and leads to reduced pumping efficiency. Current heart failure treatments only partially address the enlarged left ventricle and up to 50 percent of people who develop heart failure die within five years of diagnosis.¹

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