



Ancora Heart Announces Expansion of U.S. Early Feasibility Study

CorCinch HFrEF Study Evaluating Safety of AccuCinch Ventricular Repair System in Heart Failure Patients

Santa Clara, Calif.– February 3, 2020 – Ancora Heart, Inc., a company developing a novel therapy to address heart failure, today announced that the U.S. Food and Drug Administration (FDA) has approved an expansion of enrollment in its CorCinch HFrEF Early Feasibility Study (EFS), which is evaluating the AccuCinch® Ventricular Repair System in patients with reduced ejection fraction heart failure (HFrEF). This expansion allows Ancora Heart to double patient enrollment from 15 to 30 patients and add an additional 10 institutions for a total of 25.

“The expansion of the CorCinch HFrEF study further validates the safety data we have seen in our earlier studies of the AccuCinch Ventricular Repair System in heart failure patients,” said Jeff Closs, president and CEO of Ancora Heart. “By increasing the number of participating institutions and patients enrolled, we will be able to continue gaining additional clinical experience in preparation for our pivotal study.”

The transcatheter AccuCinch procedure 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, the AccuCinch procedure may have the potential to reverse the enlargement of the left ventricle. For patients where heart failure has progressed beyond the ability of medications and pacemakers to manage symptoms, minimally invasive percutaneous device therapy with the AccuCinch System may provide an effective treatment option. The AccuCinch system is designed to directly repair the left ventricle of the heart, thereby addressing the fundamental issue in the progression of systolic heart failure.

“Because heart failure is a progressive disease, medication therapy can become less effective over time, leaving patients with few treatment options as their condition worsens,” said Ulrich Jorde, MD, co-principal investigator of the CorCinch HFrEF study and section head of Heart Failure, Cardiac Transplantation and Mechanical Circulatory Support at Montefiore Medical Center in New York. “The data we have gathered so far indicates that the AccuCinch System has the potential to fill this gap in treatment options which, if validated in the pivotal study, would be of great benefit to patients with heart failure.”

“The AccuCinch device is designed to provide structural support to the heart wall so it maintains its ability to pump blood in an efficient manner, providing patients with a new option for improving heart function,” said Azeem Latib, MD, co-principal investigator of the CorCinch HFrEF study and medical director of Structural Heart Interventions at Montefiore Medical Center in New York. “My experience to date with the AccuCinch System has been very positive and I’m excited to continue to build on this progress via this and other clinical studies.”

About Heart Failure

An estimated 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, California, is dedicated to helping people with heart failure feel better and live longer. Ancora Heart has developed the AccuCinch Ventricular Repair 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.

#

Contacts

Ancora Heart:

Bart Beasley, 408-727-1105

bbeasley@ancoraheart.com

or

Media Contact:

Jessica Volchok, 310-849-7985

jessica@merrymancommunications.com

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