SentreHEART Receives FDA Approval for the AMAZE Trial to Evaluate LARIAT Ligation of the Left Atrial Appendage as Adjunctive Treatment for Atrial Fibrillation

June 25, 2015

REDWOOD CITY, Calif.- SentreHEART, Inc., the manufacturer of the LARIAT Suture Delivery Device, today announced that it has received approval for an Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration (FDA) to begin enrollment in a clinical study of the LARIAT Suture Delivery Device. The randomized, controlled clinical study, known as the AMAZE Trial, will evaluate the use of the LARIAT device for the ligation, or closure, of the left atrial appendage (LAA) as an adjunctive treatment to ablation in patients with persistent or longstanding persistent atrial fibrillation (AFib).

"The LAA is an important site for atrial fibrillation initiation and persistence, and its exclusion using the LARIAT device as an adjunct to conventional ablation could be a major breakthrough in decreasing recurrence in patients with persistent atrial fibrillation," said Dhanunjaya Lakkireddy, M.D., FACC, FHRS, professor of medicine, director, Center for Excellence in AF and Complex Arrhythmias, University of Kansas Medical Center. "The AMAZE trial is rigorously designed and we believe will further validate the mechanical and electrical isolation benefits of the LARIAT device, which has the potential to become a standard of care in treating persistent or longstanding persistent atrial fibrillation."

Recent studies have demonstrated that the LARIAT device not only closes the LAA mechanically,[1] but can also isolate electrical activity within the LAA[2], a known trigger for AFib[3]. The objective of the AMAZE Trial is to demonstrate that the LARIAT for LAA closure, plus a PVI ablation will lead to a reduced incidence of recurrent AFib compared to PVI alone, with a high safety profile.

The study is comprised of two stages. The overall study plan is to enroll a maximum of 600 persistent or longstanding persistent AFib patients who are candidates for PVI catheter ablation at up to 50 centers. The first stage of the AMAZE Trial will enroll up to 175 patients at 15 centers.

"The left atrial appendage has been accurately termed our most lethal human attachment," stated James L. Cox, MD, the pioneering surgeon who developed the gold-standard Cox-maze procedure as a cure for AFib. "The LARIAT is the only percutaneous device that can provide the electromechanical isolation of the myocardium of the LAA by devascularization and, when combined with PVI ablation, would seem to be the one most likely to improve catheter ablation outcomes for AFib."

AFib is an irregular heartbeat, a rapid heartbeat, or a quivering of the upper chambers of the heart, called the atria, due to a malfunction in the heart's electrical system. It is the most common heart rhythm disorder in the United States, affecting more than 3 million people.[4] By not getting enough oxygen to the body, AFib can lead to heart and valve diseases, sleep apnea, and chronic fatigue. In addition, atrial fibrillation can lead to two potentially life- threatening conditions: stroke and congestive heart failure.

PVI catheter ablation is the standard of care interventional treatment for patients with persistent and longstanding persistent AFib; however, not all electrical activity originates from the pulmonary veins. The LAA has been known to play a role in triggering recurrence of AFib after treatment with PVI catheter ablation,[5] and is the source of most stroke-causing blood clots (thrombus) in AFib patients.[6]

“SentreHEART was fortunate to be able to work closely with leading electrophysiologists and the FDA to ensure the AMAZE Trial would address the most relevant clinical questions and endpoints required to advance the treatment of percutaneous solutions for persistent AFib,” said Russell Seiber, CEO of SentreHEART. “Our objective is to address improved treatment strategies for AFib of which the left atrial appendage plays a critical role in the restoration and maintenance of normal sinus rhythm, as well as protection against thromboembolism. The AMAZE Trial is key to fulfilling our commitment to developing clinical evidence that could greatly improve the lives of patients with atrial fibrillation.”

ABOUT LARIAT SUTURE DELIVERY DEVICE

The LARIAT Suture Delivery Device is indicated for suture placement and knot tying in surgical procedures where soft tissues are being approximated and/or ligated with a pre-tied polyester suture. SentreHEART received FDA 510(k) clearances for the LARIAT in 2006, 2009 and 2014. The LARIAT device also has CE Mark approval in Europe.

ABOUT SENTREHEART

SentreHEART is a privately owned medical device company based in Redwood City, CA. Founded in 2005, SentreHEART has developed technology for remote delivery of suture for closure of anatomic structures.

[1] Bartus K, et al. Percutaneous Left Atrial Appendage Suture Ligation Using the LARIAT Device in Patients with Atrial Fibrillation. J Am Coll Cardiol 2013 Jul 9;62(2):108-18

[2] Han FT, et al. The Effects of LAA Ligation on Electrical Activity. Heart Rhythm. 2014 May; 11(5):864-70

[4] *Waktare JEP. Atrial fibrillation. Circulation. 2002; 106: 14–16.*

[5] Tilz, R.R., et al., *Catheter ablation of long-standing persistent atrial fibrillation: a lesson from circumferential pulmonary vein isolation.* J Cardiovasc Electrophysiol, 2010. **21**(10): p.1085-93

[6] Manning WJ. Atrial fibrillation, transesophageal echo, electrical cardioversion, and anticoagulation. Clin Cardiol. 1995; 18: 58,114.

Contacts
SentreHEART, Inc.
Leslie J. Hines, 650-241-6003
LHines@sentreheart.com