SentreHEART aMAZE Trial Receives FDA Approval for Stage II Expansion Based on 100 Subject Interim Safety and Performance Analysis

REDWOOD CITY, Calif.--(BUSINESS WIRE)-- SentreHEART, Inc., the manufacturer of the LARIAT® Suture Delivery Device (LARIAT) for percutaneous left atrial appendage (LAA) closure announces FDA approval to expand to Stage II of the aMAZE Trial. The approval comes as a result of pre-specified analysis of adjudicated safety and performance results from initial 100 enrolled subjects by independent Data Monitoring Committee (DMC) and FDA.

The aMAZE Trial aims to assess improved outcomes in the treatment of atrial fibrillation (AFib) when the LARIAT is used to close the left atrial appendage (LAA) in adjunct to Pulmonary Vein Isolation (PVI) catheter ablation in those patients that suffer from drug-refractory, persistent and long-standing persistent AFib. The Trial is designed in two sequential stages, with data from both stages used in primary endpoint analyses. Stage I intended to monitor the adjudicated safety and performance results of the LARIAT in the first 100 consecutively enrolled subjects against pre-specified criteria, as assessed by an independent Data Monitoring Committee. With Stage II approval, SentreHEART will expand the aMAZE trial to 65 centers across the United States and limited International locations.

“The LARIAT procedure, when combined with PVI, may offer improved outcomes for patients with persistent and long-standing persistent AFib, compared with PVI alone,” stated aMAZE Study Co-Chairs Dr. David Wilber of Loyola University and Dr. DJ Lakkireddy of the University of Kansas. “FDA approval to expand to Stage II is an important step forward toward completion of this pivotal study.”

AFib is an irregular, rapid heartbeat or 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 sustained arrhythmia and a major global public health problem due to its associated morbidity, including stroke and heart failure, diminished quality of life, and increased mortality. Approximately 33.5 million individuals worldwide suffer from AFib, with close to 5 million new cases occurring each year.

Studies have demonstrated the LARIAT not only closes the LAA mechanically[1] but may also isolate electrical activity[2] within the LAA. Having a non-implant option that may both electrically and mechanically isolate the LAA is a potentially important addition to the treatment armamentarium for clinicians treating patients with persistent or longstanding persistent AFib. The LARIAT has the potential to permanently eliminate the LAA as a source of AFib and nidus for thrombus.

Unlike other LAA implant solutions for AFib, the aMAZE Trial seeks to potentially treat the underlying disorder of AFib by mechanically and electrically isolating the base of the LAA in a single step using the percutaneous, non-implant LARIAT suture delivery device.

“We are pleased with both the DMC and FDA’s endorsement of the aMAZE Trial’s interim safety and performance which allow us to expand to Stage 2 of the Trial. With FDA’s approval, we can seamlessly expand to additional centers and continue patient enrollment without interruption,” stated Russell Seiber, President & CEO of SentreHEART, Inc. “The aMAZE Trial is groundbreaking in its therapeutic potential to improve outcomes in patients with AFib and we look forward to completing the trial with our strong clinical investigator partnerships.”

ABOUT THE aMAZE TRIAL (www.amazetrial.com)

The aMAZE Trial is an FDA IDE-approved, prospective, multi-center, randomized controlled Trial evaluating the LARIAT Suture Delivery Device (LARIAT) for Left Atrial Appendage (LAA) closure adjunctive to Pulmonary Vein Isolation (PVI) catheter ablation for the treatment of persistent and long-standing persistent atrial fibrillation (AFib). The objective of the AMAZE Trial is to demonstrate that the LARIAT for LAA closure, plus a pulmonary vein isolation (PVI) ablation will lead to a reduced incidence of recurrent AFib compared to PVI alone, with a high safety profile. The Trial will enroll up to 600 total subjects.

PVI Catheter ablation is the standard of care in the management of drug-refractory symptomatic AFib. However, the success rates of PVI ablation are less than ideal, especially in patients with persistent AF[3]. Current data suggests that a single ablation procedure of the pulmonary veins (PV) for treating AFib results in long-term success rates of only 20%-40%. The LAA has been known to play a role in triggering recurrence of AFib after treatment with PVI catheter ablation, and is the source of most stroke-causing blood clots (thrombus) in AFib patients.

About SentreHEART, Inc.

SentreHEART is a privately owned medical device company based in Redwood City, CA. Founded in 2005, SentreHEART has developed innovative technology for remote delivery of suture for closure of anatomic structures including the left atrial appendage. SentreHEART is the only company that offers both percutaneous and surgical options for immediate and complete LAA closure without the need for an implant.

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

3. 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

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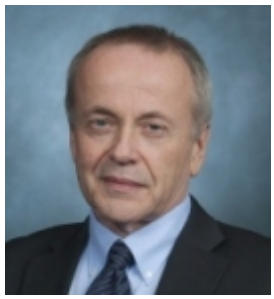
Smart Multimedia Gallery



David J. Wilber, MD, FAHA, FACC Loyola University Hospital (Photo: Business Wire)

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