

Ticker Talker

The Mended Hearts, Inc. SOC

South Orange County

Chapter 216 * Chartered 1989

Volume 25, Number 4

www.mendedhearts216.org

April 2015

FOR THE HEART PATIENT AND THEIR FAMILIES

“Algisyl – development of new approach to treat advanced heart failure.”

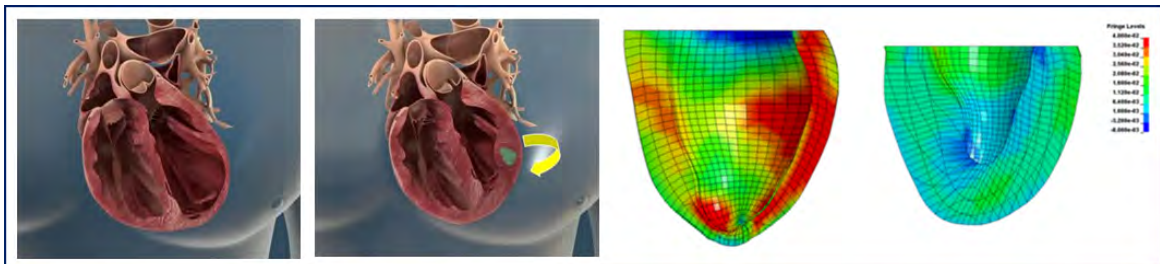
LoneStar Heart, Inc. is a California- and Texas-based start-up company developing medical devices and drugs to restore adequate heart function in patients with Advanced Heart Failure (HF). The company’s lead product, Algisyl®, is now available in Europe and clinical studies are expected to begin in the U.S. in mid-2015.

Algisyl® is an injectable hydrogel that restores adequate heart function in HF patients who have an enlarged left ventricle with low ejection fraction and who continue to have symptoms despite optimal drug treatment (primarily in NYHA Classes III and ambulatory IV). Algisyl® improves cardio-mechanical function, clinical symptoms, and quality of life in a cost-effective procedure that does not conflict with other drug or device therapies.

The administration of Algisyl® involves a procedure known as a mini-thoracotomy that is carried out routinely by cardiac surgeons. In this procedure, depending on the size of the heart, approximately 15 large drops of Algisyl® hydrogel are injected directly into the left ventricle wall. As it sets, the hydrogel thickens the ventricle wall and displaces the inner muscle cells shrinking the ventricle diameter, improving muscle stretch, and reducing wall tension. The hydrogel does not degrade but remains in the muscle as a permanent implant. It is well-tolerated and does not cause inflammatory or other negative reactions. The immediate physiological effects of reshaping the ventricle with Algisyl® lead to sustained improvements in cardiac function and clinical symptoms for most patients.

In development since 2006, Algisyl® has been tested carefully and thoroughly. Results from a controlled randomized study completed in 14 European and Australian centers were recently presented and demonstrated significant improvements for patients treated with Algisyl® in major efficacy endpoints including 6-minute walk test, NYHA classification, quality of life evaluation, and peak-VO₂. Of all of these parameters, peak VO₂, a measure of maximal aerobic capacity, is considered the best indicator of cardiovascular health because it correlates strongly with clinical symptoms as well as morbidity and mortality in HF patients. Patients enrolled in the study continue to be monitored and additional results will be presented in the coming months.

In October 2014, Algisyl® received approval to market in the European Union allowing the Company to broaden product usage and commercialization. Algisyl® is primarily being used in Germany and Italy. In the US, planning and approval procedures are under way with the Food and Drug Administration and with 30 hospitals to begin a randomized clinical study in mid-2015. **Frank Ahmann, President & COO**, will be our speaker.



Algisyl® is implanted into the enlarged left ventricle of HF patients. The effects of this cardiac “plastic surgery” include a decrease in heart muscle tension and ventricle diameter. The effects are shown in the “before and after” models of an actual patient ventricle shown on the right side above. The red color indicates areas of highest stress.

*Don't forget the program starts at 7:00 pm, Wednesday
April 15th at the Conference Center.
Come early for a seat as the program is always very popular
and the public is invited. Refreshments start at 6:30 pm.*

Location:
Mission Hospital Conference Center
26726 Crown Valley Parkway
Mission Viejo, CA