

FDA Grants Approval to Extend U.S. Enrollment and Clinical Trial Ablation Frontiers Uses Novel Technology in Treatment of Chronic Atrial Fibrillation Patients

Carlsbad, Calif. -- January 16, 2008 - Ablation Frontiers, Inc. today announced the expansion of enrollment in the first ever U.S. Investigational Device Exemption (IDE) clinical trial for interventional treatment of chronic atrial fibrillation (AF). Approval from the US Food and Drug Administration (FDA) to proceed with the pivotal phase of the study is based on the review of an initial feasibility segment completed in August 2007. Completion of the clinical trial, which will compare the safety and efficacy of tailored ablation therapy against traditional pharmaceutical regimens, will support a pre-market approval (PMA) application to the FDA.

Having received FDA approval to enter the pivotal phase of the trial in the fourth quarter of 2007, several patients have already been randomized into the study. Initial US treatment sites included The Lahey Clinic and Medical Center in Burlington, Massachusetts. Their first patient, with a three year history of continuous AF, was successfully treated and returned home the next day with a normal heart rhythm. After the two-hour and ten-minute procedure, Dr. Gregory Michaud had the following enthusiastic comment, "I am really excited about this new technology. It has two advantages that are immediately apparent. One, the catheters are simpler to use than the traditional "point-by-point" catheters, thus reducing the time it takes to complete complex left atrial procedures. Second, the depth of the radiofrequency energy lesions is controllable, which makes damage to collateral structures, such as the esophagus, less likely."

The Ablation Frontiers Cardiac Ablation System, being evaluated in this clinical study, was developed under the guidance of Drs. Fred Morady and Hakan Oral, at the University of Michigan. Designed to be a versatile tool kit for mapping and ablating areas of the heart where AF is most prevalent, the Cardiac Ablation System combines a novel radiofrequency (RF) energy source with a series of anatomically-designed catheters. The Ablation Frontiers system is also unique because it does not require expensive 3D navigation or robotic steering equipment that can make these types of procedures longer and more complicated.

About the TTOP AF Trial

The study, known as the **T**ailored **T**reatment of **P**ermanent **A**trial **F**ibrillation (**TTOP AF**), uses an approach that allows cardiologists to customize their treatment strategy and potentially shorten procedure times, improve patient outcomes, and reduce recurrence of the disease. "The pivotal phase of the TTOP AF trial is designed to demonstrate the clinical safety and efficacy of our Catheter Ablation System as compared to current drug options," said Ablation Frontiers'

Chief Executive Officer, Keegan Harper. "Based on positive clinical outcomes of our multi-center European study, as well as our ongoing commercial experience in Europe, we believe that the TTOP AF trial will show striking clinical benefits made possible by our technology. We have already demonstrated in numerous procedures in Europe that we can greatly reduce procedure times with our technology."

Patients will initially be randomized into two treatment groups; one group receiving ablation therapy, and the other group – called the control arm – receiving commonly used drug treatments. For every two patients initially receiving an ablation, one will be randomly assigned to the control arm. The trial allows patients in the control arm to receive an ablation if they do not respond to drug therapy. At the conclusion of the study, Ablation Frontiers will submit a Pre-Market Approval (PMA) application to the FDA for marketing the Catheter Ablation System in the US.

About Atrial Fibrillation

Atrial fibrillation remains the most commonly diagnosed cardiac arrhythmia, or irregular heart rhythm, affecting approximately ten million people worldwide. As the U.S. population ages, it is likely that the incidence of AF will dramatically increase over the next several decades, with an estimated six percent of the current U.S. population over age 60, and ten percent of the population over age 80, affected by the condition. AF is a leading cause of stroke and when left untreated can significantly reduce quality of life and lead to stroke, heart failure and death.

Patients with AF today are generally treated with pharmaceutical drug regimens or surgery in more severe cases. Currently, no minimally invasive, catheter-based procedures have been approved by the FDA to treat AF, although an estimated 50,000 procedures will be performed this year. The currently available "tip catheter" approaches are based on a decade-old technology originally designed to treat irregular heart rhythms other than AF.

About Ablation Frontiers

Ablation Frontiers is an emerging, venture-backed medical device company based in Carlsbad, California. The company received \$21.8 million Series C financing in June 2007, led by the Novartis Venture Fund, to drive clinical development and market expansion for their novel Cardiac Ablation System. Founded in 2004, the company is focused on developing and commercializing innovative products for the treatment of cardiac arrhythmias. In late 2006, Ablation Frontiers received the CE Mark to begin marketing in the European Union with its portfolio of anatomical-based catheters and a multi-channel RF generator. To learn more about the company, visit www.ablationfrontiers.com