

Two Laser Balloon "Live Cases" Shed New Light on Direct Visualization and PV Ablation

A Tipping Point for CardioFocus

Marlborough, MA, 1/19/11 CardioFocus announced today that two "live cases" using its Endoscopic Ablation System were recently conducted. The first live case was a satellite transmission performed at Centro Cardiologico Monzino in Milan, Italy and broadcast to the 16th Annual Boston Symposium on Atrial Fibrillation on January 13, 2011 in Boston MA. Several prominent physicians, recognized as pioneers in the transcatheter treatment of atrial fibrillation, served as moderators for this exciting educational presentation and provided current and historical perspective on the performance of ablation procedures designed to isolate pulmonary veins.

The second live case was performed at St. Georg Hospital, in Hamburg, Germany, by Prof. Karl-Heinz Kuck on January 19th, 2011. Both live cases demonstrate the continued interest of leading catheter ablation experts to gain a real time view of the anatomy they are treating to enable durable pulmonary vein isolation.

Steve Sagon, President & CEO of CardioFocus said, "These two live cases provide CardioFocus with a unique opportunity to be seen by electrophysiologists and healthcare professionals from around the world. Now that the company has obtained CE Mark approval for the latest version of our equipment, we have received requests from multiple well-respected arrhythmia treatment centers in Europe."

The rate of acute isolation of the pulmonary veins has been reported by CardioFocus clinical investigators at over 99% in published, peer reviewed articles. While nearly all of the pulmonary veins were isolated during the procedure, 78% of veins were isolated on the very first attempt using endoscopic guidance. Chronic pulmonary vein isolation has also been reported to be near 90% when assessed at 3 months. According to Burke Barrett, CardioFocus Vice President of Clinical and Regulatory Affairs, "We expect to see more scientific studies published and further presentations on the CardioFocus Endoscopic Ablation System technology throughout the year, including the commencement of the company's US IDE pivotal study in the first half of 2011."

Although the company has received requests from leading arrhythmia treatment centers in Europe and around the world, CardioFocus plans to continue a highly disciplined launch of the Endoscopic Ablation System. This launch began in late 2010 and will continue at key sites in Europe in 2011.

Two years after the initiation of clinical research, approximately 250 patients have been treated under multiple research protocols. More than 150 patients were treated in the EU and almost 100 patients were enrolled in a US feasibility clinical trial. To date, physicians have performed visually guided ablation procedures at 16 different medical centers world-wide.

The scientific information discussed in this news release related to our product is preliminary and investigative. The CardioFocus Endoscopic Ablation System is not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the system. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

CONTACT: CardioFocus, Marlborough MA, USA

Maria Shepherd+1 (617) 548-9892 (media)