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Mount Sinai First In Nation to Ablate Atrial Fibrillation Using New Visually-Guided Balloon Catheter

(New York, NY – September 18, 2009) Physicians at The Mount Sinai Medical Center in New York became the first in the U.S. to ablate atrial fibrillation using a visually-guided laser balloon catheter. The procedure was performed September 15 by Vivek Y. Reddy, MD, Professor of Medicine and Director of the Cardiac Arrhythmia Service at Mount Sinai Heart, and his colleague, Srinivas R. Dukkupati, MD, Director of Mount Sinai's Experimental Electrophysiology Laboratory.

The procedure marks the first time the device—the “Endoscopic Ablation System” manufactured by CardioFocus Inc.—has been used in human clinical trials in this country. Dr. Reddy is the principal investigator for the national study.

Approximately six million U.S. adults have been diagnosed with atrial fibrillation (AFib), a condition characterized by a rapid and irregular heart beat that can cause serious complications, including stroke, palpitations, fainting and early death. AFib diagnosis has increased over the past two decades and the condition now accounts for one-quarter of all strokes in the elderly.

“This new device has the potential to make AFib ablation more reliable, more reproducible, and more consistent for patients with paroxysmal [intermittent] atrial fibrillation,” said Dr. Reddy. “The technology which is currently available leads to widely variable success rates, depending largely on physician skill and experience with the procedure. This visually-guided system with a rotating laser design has the potential to simplify AFib ablation and make it available to more patients than ever, before their paroxysmal AFib becomes chronic [continuous] AFib.”

Dr. Valentin Fuster, Director of Mount Sinai Heart and Chair of the European American Guidelines on atrial fibrillation, said, "Such an advance in the treatment of atrial fibrillation is another small step forward to cure the disease without the need for chronic medication."

Paroxysmal (intermittent) AFib is caused by irregular electrical signals that come from pulmonary veins that drain blood from the lungs to the heart. During a standard AFib ablation procedure, physicians use spot catheters to cauterize heart tissue in a point-by-point manner to encircle these pulmonary veins; this creates a ring of scar tissue to electrically isolate the pulmonary veins, thereby preventing the irregular electrical signals from causing AFib. But this is a technically complicated procedure since unlike open heart surgery, physicians cannot directly see the tissue that is being cauterized. Despite using various cardiac mapping systems, problems often arise because the scar tissue that is created is not continuous, allowing the abnormal electrical signals to continue to pass into the heart and cause recurrence of AFib.

The new balloon catheter device used by the Mount Sinai Heart team features a built-in camera that allows the physicians to directly see the heart tissue that needs to be ablated. They can then guide an internal laser in a continuous arc around the origin of the vein, creating more uniform scar tissue. "By directly seeing the tissue that we are ablating, there is less chance of a gap in the encircling ablation line," said Dr. Dukkipati.

The patient was a 58-year old man with a history of paroxysmal AFib. He had been treated with a number of drugs which failed to control the AFib, so he continued to have symptoms including palpitations (feeling of a fast heartbeat), and shortness of breath. Therefore, he elected to undergo a catheter ablation procedure to eliminate his symptoms. The procedure was performed in a cardiac catheterization laboratory and did not require surgery or cardiopulmonary bypass.

Drs. Reddy and Dukkipati joined Mount Sinai Heart in August 2009 to focus on building the institution's services for treating heart-rhythm disorders. Last month, they were the first in the U.S. to perform left atrial appendage occlusion as an alternative to Coumadin therapy on an AFib patient using a non-surgical, catheter-based suture delivery system.

Dr. Vivek Reddy, the principal investigator on this study, receives financial compensation for conducting training cases from CardioFocus, Inc., the study sponsor.

About The Mount Sinai Medical Center

The Mount Sinai Medical Center encompasses The Mount Sinai Hospital and Mount Sinai School of Medicine. The Mount Sinai Hospital is one of the nation's oldest,

largest and most-respected voluntary hospitals. Founded in 1852, Mount Sinai today is a 1,171-bed tertiary-care teaching facility that is internationally acclaimed for excellence in clinical care. Last year, nearly 50,000 people were treated at Mount Sinai as inpatients, and there were nearly 450,000 outpatient visits to the Medical Center.

Mount Sinai School of Medicine is internationally recognized as a leader in groundbreaking clinical and basic science research, as well as having an innovative approach to medical education. With a faculty of more than 3,400 in 38 clinical and basic science departments and centers, Mount Sinai ranks among the top 20 medical schools in receipt of National Institute of Health (NIH) grants. For more information, please visit www.mountsinai.org.

About CardioFocus, Inc.

CardioFocus, Inc. is a venture-backed medical device company based in Marlborough, Massachusetts. The company is developing, manufacturing and investigating proprietary, disposable fiber optic catheters for the visualization of the cardiac anatomy and the treatment of cardiac arrhythmias such as atrial fibrillation. The company's propriety Endoscopic Ablation System (EAS) is a novel device that combines real-time, full color, endoscopic visualization and guidance with the delivery of therapeutic light energy to perform pulmonary vein isolation for the treatment of atrial fibrillation. For more information, visit www.cardiofocus.com.

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