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**Advanced Cardiac Therapeutics Initiates First-In-Man CE Mark Clinical Trial To Study Innovative Catheter System for the Treatment of Atrial Arrhythmias**  
*World's First Temperature-Sensing Saline Irrigated Ablation Catheter Enables Lesion Control, Is Designed to Improve Patient Outcomes*

LAGUNA BEACH, Calif., March 17, 2011 – Advanced Cardiac Therapeutics, Inc., a developer of innovative temperature-sensing cardiac ablation systems, today announced that the first patients have been enrolled in a first-in-man CE Mark clinical trial of the safety and performance of the company's TEMPASURE™ cardiac ablation catheter. The TEMPASURE system is the world's first RF cardiac ablation catheter to offer both saline irrigation and temperature-sensing technology.

The TEMPASURE system is designed to result in better outcomes for patients by reducing overall procedure time and increasing therapeutic effectiveness, while avoiding rare but serious adverse events. The system's novel passive sensing microwave radiometry technology allows the electrophysiologist to measure the temperature of cardiac tissue at three millimeters depth during the ablation procedure, providing real-time information that enables proper energy delivery and lesion control.

"ACT's novel catheter system directly measures lesion creation through temperature, addressing a longstanding problem for physicians performing irrigated cardiac ablation," said Karl-Heinz Kuck, M.D., head of the Department of Cardiology, St Georg Hospital, Germany, who is co-principal investigator of the trial. "I'm very excited about the promise of this new technology to increase the safety and success of cardiac ablation procedures."

"I found the ACT system straightforward to use, requiring no different handling or training," said Yves Vandekerckhove, M.D., chairman of the Department of Cardiology at Sint Jan Hospital in Bruges, Belgium, who performed the first-ever procedure with the system. "Even in the first few patients, we were able to see clinical therapeutic outcomes that closely matched the temperature measurements. The patients I have treated are doing very well."

"Many years ago, the addition of a thermocouple enabled precise temperature control and temperature mode energy delivery to standard RF catheters. In a similar way, this microwave radiometry technology promises to significantly advance the way we perform irrigated RF ablations for patients with cardiac arrhythmias," said Pedro Brugada, M.D., professor of Cardiology, chairman and scientific director, Cardiovascular Division, UZ Brussel, Brussels, Belgium, the study's co-principal investigator.

The prospective, multi-center, single arm study will enroll up to 30 patients with atrial flutter in Europe and New Zealand. Patients enrolled in the trial will be studied during

ablation, with follow up at seven and 30 days. Operators are blinded to the microwave radiometer signal in the trial procedures, using ACT's catheter in exactly the same way as for current irrigated procedures.

"The initiation of our first-in-man study marks a major milestone for ACT," said Peter van der Sluis, the company's CEO. "We are very excited to soon launch the TEMPASURE temperature-sensing ablation catheter."

Kenneth Carr, Dr. Eng. who pioneered microwave radiometry technology, commented, "It is incredibly exciting to see my life's work proceed to clinical use and directly benefit patients with cardiac arrhythmias."

### **About Cardiac Arrhythmias**

Cardiac arrhythmias occur when the electrical impulses in the heart don't work properly, causing the heart to beat too fast, too slowly or irregularly. Atrial fibrillation and atrial flutter are fast cardiac arrhythmias that can be life-threatening.

### **About Cardiac Catheter Ablation**

Cardiac catheter ablation procedures are used to treat a variety of cardiac arrhythmias including atrial fibrillation and atrial flutter. The procedures involve advancing a catheter into the heart and selectively ablating certain areas of tissue in order to prevent the spread of electrical signals that give rise to the arrhythmia. The temperature of the tissue during ablation is critical – lower temperatures are ineffective, and temperatures that are too high can result in dangerous over-heating. Saline irrigation ensures that lesions are created safely and are effective deeper inside the cardiac tissue. However, the inclusion of irrigation negates the effectiveness of conventional thermometry.

### **About the TEMPASURE Cardiac Ablation Catheter**

ACT's technology enables, for the first time, measurement of tissue temperature with a saline-irrigated RF catheter. The TEMPASURE cardiac ablation catheter continuously measures temperature at three millimeters depth below the heart wall surface using VERITAS™ Technology, a proprietary microwave radiometry system. The TEMPASURE system is designed to improve patient outcomes by providing electrophysiologists with real-time validation information and greater control in lesion creation.

### **About Advanced Cardiac Therapeutics**

Headquartered in Laguna Beach, Calif., privately held Advanced Cardiac Therapeutics, Inc. specializes in advanced irrigated cardiac catheter ablation systems with proprietary temperature-sensing technology for the treatment of patients with cardiac arrhythmias. For more information visit [www.actmed.net](http://www.actmed.net).

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