



ENDOSENSE COMPLETES ENROLLMENT IN TOCCASTAR IDE STUDY OF ITS TACTICATH® FORCE-SENSING ABLATION CATHETER

GENEVA – June 13, 2012 - [Endosense](#), a pioneer and leader in force-sensing technology focused on improving the efficacy and safety of catheter ablation for the treatment of cardiac arrhythmias, has announced enrollment completion in the TOCCASTAR clinical study. TOCCASTAR is a prospective, randomized, multi-center investigational device exemption (IDE) trial designed to evaluate the safety and effectiveness of the company's TactiCath force-sensing ablation catheter in patients with symptomatic paroxysmal atrial fibrillation (AF).

TOCCASTAR study investigators enrolled 300 patients at 17 centers across the United States and Europe. All patients were randomized on a one-to-one basis for treatment with the TactiCath or a control radiofrequency catheter approved by the U.S. Food and Drug Administration (FDA) for treating paroxysmal AF.

The TOCCASTAR study will evaluate the safety and effectiveness of the TactiCath based on 12-month follow-up data from the index procedure. The primary effectiveness endpoint is a non-inferiority comparison of treatment success as defined by both acute procedural success and chronic freedom from symptomatic paroxysmal AF, atrial tachycardia and atrial flutter; the safety endpoint is a non-inferiority comparison of early onset device-related serious adverse events. Secondary endpoints include a superiority comparison of procedural effectiveness related to the use of the contact-force sensor.

“Contact-force sensing in the context of a radiofrequency ablation catheter represents a significant enhancement to the tools available to electrophysiologists treating AF. The idea that we can deliver intra-cardiac lesions with full knowledge of the quality of the electrode-tissue interface is very appealing,” said Dr. Vivek Reddy, TOCCASTAR principal investigator and director of the Cardiac Arrhythmia Service, The Mount Sinai Medical Center, New York. “When complete, TOCCASTAR will provide the first randomized comparison of treatment safety and success between a conventional radiofrequency catheter and one with contact-force sensing capability. Through the use of this important diagnostic feature, we are gaining singular insights into the challenges and techniques that define optimal cardiac ablation therapy.”

Endosense expects to use the results of the TOCCASTAR study to support a Premarket Approval Application (PMA) to the FDA in the third quarter of 2013.

“The completion of enrollment in TOCCASTAR is an exciting milestone that not only puts Endosense closer towards our goal of offering contact-force sensing to U.S. electrophysiologists and their AF patients, but also further cements Endosense’s leadership in the field,” said Hendrik Lambert, vice president of clinical affairs at Endosense. “We are grateful to our investigator group and external support teams for their enthusiasm and commitment to ensuring the highest study standards. We look forward to completing follow-up and reporting on the outcome of this landmark trial and to the potential of expanding commercialization of the TactiCath worldwide.”

About Endosense

Founded in Geneva in 2003, Endosense is a medical technology company focused on improving the efficacy, safety and accessibility of catheter ablation for the treatment of cardiac arrhythmias. The company pioneered the use of contact-force measurement in catheter ablation with the development of the TactiCath, the first force-sensing ablation catheter to give physicians a real-time, objective measure of contact force during the catheter ablation procedure. Endosense is backed by Edmond de Rothschild Investment Partners, Neomed, Gimv, VI Partners, Sectoral Asset Management, Ysios Capital Partners and Initiative Capital Romandie. For more information, visit www.endosense.com.

Caution: In the United States, the TactiCath is an investigational device. Limited by Federal (or United States) law to investigational use.

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