



ENDOSENSE COMPLETES ENROLLMENT
IN EFFICAS I CLINICAL STUDY

GENEVA – February 15, 2011 – Endosense, a Swiss medical technology company focused on improving the efficacy, safety and accessibility of catheter ablation for the treatment of cardiac arrhythmias, has announced enrollment completion in the EFFICAS I clinical study. EFFICAS is a study series intended to demonstrate that, in patients with paroxysmal atrial fibrillation (AF), the use of contact force control during cardiac ablation utilizing the company’s TactiCath® force-sensing catheter results in superior outcomes as compared to ablations performed with a standard catheter.

EFFICAS I is a 45-patient, single-arm, prospective, multi-center European clinical trial designed to demonstrate the correlation between contact forces applied during pulmonary vein isolation (PVI) and AF treatment efficacy at three months. The endpoint for the study is the occurrence of reconnection (or “gap”) areas in the PVI lines, relative to the contact forces applied during lesion formation. While investigators perform the procedure with the TactiCath, they are blinded to contact force measurements; however, the contact forces applied are recorded. Patients are re-assessed with a mapping catheter at three months to identify potential gaps in the PVI lines. Contact force parameters from initial procedures are then analyzed to determine the relationship with lesion formation.

“We believe that the data from EFFICAS I will greatly advance the scientific understanding of contact force and the role it plays in the catheter ablation treatment of AF, as the data will allow us to better identify those force parameters that will deliver optimal patient outcomes,” said Eric Le Royer, president and chief executive officer of Endosense. “This study is yet one more proof point illustrating Endosense’s leadership and commitment to clinical research of contact force in catheter ablation.”

The next study in the EFFICAS series is EFFICAS II, in which investigators will take full advantage of the real-time, objective TactiCath contact force control features to improve their ablation technique during lesion creation. Endpoints for EFFICAS II will include reduction in PVI gaps as compared to EFFICAS I. Outcomes data from EFFICAS I and II will help in the design of future, larger EFFICAS randomized studies with clinical endpoints. EFFICAS II enrollment is currently underway.

“The EFFICAS studies represent a scientifically rigorous approach to quantifying the importance of contact force in catheter ablation,” said Karl-Heinz Kuck, M.D., Asklepios Klinik St. Georg, Hamburg. “Never before have we looked at each ablation point with such level of detail. A preliminary analysis of the 24 patients who have completed their three-month follow-up indicates some truly groundbreaking findings. We look forward to communicating the results to our fellow electrophysiologists, as we believe these studies will result in actionable recommendations that will have a meaningful impact on catheter ablation effectiveness.”

The TactiCath force-sensing ablation catheter and the TactiSys™ system are indicated for the treatment of AF and supraventricular tachycardia (SVT). BIOTRONIK is the exclusive distributor of the TactiCath in Europe, Latin America, Canada, Africa and the Middle East. The TactiCath is not yet available in the United States.

About the TactiCath

Endosense’s TactiCath is the first and only force-sensing ablation catheter to give physicians a real-time, objective measure of contact force during the catheter ablation procedure. It has undergone considerable pre-clinical and clinical testing, the results of which have created a solid foundation of evidence supporting the feasibility, safety and value of contact force sensing during catheter ablation. The TactiCath has the potential to improve the effectiveness, safety and reproducibility of catheter ablation treatment of cardiac rhythm disorders, including AF.

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 has pioneered the use of contact force measurement in catheter ablation, with the development of its proprietary Touch+®

sensor technology. Endosense's flagship product is 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.

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

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