



ENDOSENSE BEGINS ENROLLMENT IN EFFICAS STUDY SERIES

GENEVA – May 10, 2010 – [Endosense](#), a Swiss medical technology company focused on improving the efficacy, safety and reproducibility of catheter ablation for the treatment of cardiac arrhythmias, has announced it has enrolled the first patients in EFFICAS I, the first study of the EFFICAS series. These patients were enrolled in Na Homolce Hospital, Prague, Czech Republic and treated by Petr Neuzil, M.D. and Vivek Reddy, M.D.

EFFICAS is a study series intended to demonstrate that 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 without a force sensor.

EFFICAS I and EFFICAS II are single arm, multi-center, prospective pilot studies that will assess the effectiveness of catheter ablation with and without the use of contact force control. In EFFICAS I, physicians will perform the procedure with the TactiCath without having access to contact force measurements; however, the contact forces applied will be recorded. In EFFICAS II, physicians will take full advantage of the TactiCath contact force control features, with the ability to objectively influence their ablation technique during lesion creation. The endpoint for EFFICAS I will be the occurrence of reconnection areas in the pulmonary vein isolation (PVI) lines, relative to the contact forces applied; endpoints for EFFICAS II will include reduction in PVI reconnection as compared to EFFICAS I.

Outcomes data from EFFICAS I and II will help in the design of future, larger, EFFICAS studies with clinical endpoints.

“The EFFICAS study series represents a very rigorous and thoughtful approach to evaluating the comparative clinical effectiveness of contact force control in the catheter ablation treatment of cardiac arrhythmias,” said Karl-Heinz Kuck, M.D.,

Asklepios Klinik St. Georg, Hamburg. “EFFICAS I and II will lay an important foundation for achieving this goal while also yielding valuable incremental insights that can be immediately applied to current clinical practice.”

Added Eric Le Royer, president and chief executive officer of Endosense, “Unique in its focus and depth, the EFFICAS series will provide a definitive measure of the clinical value and superiority of force control in the catheter ablation treatment of cardiac arrhythmias. These studies add to a growing library of robust clinical research designed to establish uncompromising scientific validation of the TactiCath. We are confident that this validation will make contact force control the standard of care in the electrophysiology lab.”

The TactiCath force-sensing ablation catheter and the TactiSys™ system are indicated for the treatment of atrial fibrillation (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 reproducibility 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.

MEDIA CONTACT/U.S.:

Laura Nobles
Nobles Communications
310-795-0497
laura@noblescommunications.com

MEDIA CONTACT/EUROPE:

Danièle Castle
Genevensis
+41 22 779 06 20
info@genevensis.com

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