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BIOTRONIK congratulates Endosense on the FDA IDE approval of the TOCCASTAR clinical trial and first patient enrollment

Important achievement for [TactiCath](#)¹—a novel technology for treating atrial fibrillation

BERLIN, January 13, 2011—BIOTRONIK SE Co. & KG highlights two key milestones toward receiving premarket approval (PMA) of the [TactiCath](#), a novel technology for treating atrial fibrillation (AF): FDA IDE (investigational device exemption) approval and the first patient enrollment of the TOCCASTAR ([TactiCath Contact Force Ablation Catheter Study for Atrial Fibrillation](#)) clinical trial.

TactiCath is an irrigated radio frequency (RF) contact force ablation catheter. Since January 2010, commercialization efforts have led to significant appreciation of the advantages of contact force-sensing by the electrophysiology community. BIOTRONIK is proud to partner with the TactiCath manufacturer, Endosense, as the exclusive distributor for all major markets outside of the United States, Japan and Asia.

A major challenge that physicians face when they treat patients with AF is manipulating the ablation catheter in the highly variable anatomy of the left heart with precisely the right amount of force to effectively ablate cardiac tissue without causing damage.

“The unique TactiCath technology provides physicians with objective measures of contact force—reliably and in real-time,” commented Marlou Janssen, Global Vice President of Marketing and Sales at BIOTRONIK. “Early clinical data suggests it helps to reduce redo procedures in AF ablation, which would subsequently lead to improved efficacy, safety and reproducibility of the therapy.”

At up to 30 centers in the United States and Europe, TOCCASTAR will randomize 300 patients with paroxysmal AF on a one-to-one basis with the TactiCath or a catheter approved by the FDA for paroxysmal AF. The first enrollment in the TOCCASTAR clinical trial was at Na Homolce Hospital, Prague, Czech Republic by study investigator Petr Neuzil, M.D..

The [TactiCath](#) is a second-generation device with a solid scientific background established by the excellent results of its preclinical and clinical research programs. The TOCCATA clinical trial, for which European CE mark was granted, established safety and effective performance of the device and has shown that contact force varies significantly from operator to operator and from ablation site to ablation site. It has raised the expectation that contact force technology has the potential to improve the outcome of AF ablation procedures.

About BIOTRONIK SE & Co. KG

As one of the world's leading manufacturers of cardiovascular medical devices, with several million devices implanted, BIOTRONIK is represented in over 100 countries by its global workforce of more than 5600 employees. Known for having its finger on the pulse of the medical community, BIOTRONIK assesses the challenges physicians face and provides the best solutions for all phases of patient care, ranging from diagnosis and treatment to patient management. Quality, innovation and reliability define BIOTRONIK and its growing success—and deliver confidence and peace of mind to physicians and their patients worldwide.

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

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