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BIOTRONIK GmbH & Co. KG
Woermannkehre 1
12359 Berlin
Tel +49 (0) 30 68905-1400
Fax +49 (0) 30 68905-1940
press@biotronik.com
www.biotronik.com

BIOTRONIK launches largest worldwide Clinical Trial using wireless Home Monitoring technologies

Lake Oswego, OR - February 29, 2008 – BIOTRONIK, the pioneer in remote monitoring technologies for patients with cardiac devices, announced today the launch of the landmark IMPACT Study (The **IMPACT** of BIOTRONIK Home Monitoring Guided Anticoagulation on Stroke Risk in Patients with Implanted ICD and CRT-D devices). The first patient was enrolled at the Thoracic & Cardiovascular Institute in Lansing, MI, USA, which marks the start of this large international, prospective, randomized trial. IMPACT will investigate whether the risk of stroke can be reduced in patients with cardiac devices and asymptomatic atrial fibrillation (AF) by early detection of these arrhythmias utilizing BIOTRONIK's Home Monitoring technologies and a predefined anticoagulation plan.

Dr. Castellani, Principal Investigator at the Thoracic & Cardiovascular Institute in Lansing, MI commented: "We are very pleased to be enrolling the first patient in this important study which will further explore the potential benefits of remote Home Monitoring solutions. Studying the use of immediate detection of AF frequency and duration of AF episodes to guide anticoagulation in patients with a wide variety of stroke risks, will provide important information on the potential stroke reduction in this population."

The IMPACT study will enroll over 2,700 patients from 100 clinical centers worldwide and will utilize the BIOTRONIK's Lumax family of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT-Ds) with BIOTRONIK's exclusive Home Monitoring solutions. Lumax ICD and CRT-D devices are part of BIOTRONIK's most technologically advanced tachycardia product portfolio with the ability to detect episodes of AF, including the frequency and duration, even before the presence of clinical symptoms. The IMPACT study will further contribute to guidelines regarding anticoagulation for patients with AF and provide information on whether early anticoagulation in patients with AF documented by remote monitoring of cardiac device data can reduce the stroke and systemic embolism rate in this patient population. Remote monitoring of cardiac device data may be particularly relevant in patients with asymptomatic AF by allowing timely intervention as compared to conventional periodic in-office evaluation.

Dr. Halperin, Professor of Medicine and Director of Clinical Cardiology Services, Mount Sinai Medical Center, New York, NY, and IMPACT Steering Committee Co-Chair commented: "The IMPACT study is the first large randomized trial to evaluate the clinical utility of remote Home Monitoring technologies for the long-term management of patients, with implanted cardiac devices, at risk of developing AF and stroke. The study results will indicate how often these arrhythmias would otherwise go unnoticed and, perhaps more importantly, help us to better understand the relationship between AF and stroke events". Dr. Ip, Thoracic & Cardiovascular Institute, Lansing, MI, and IMPACT

Steering Committee Co-Chair added: "Additionally, this is the largest prospective clinical trial to investigate the risk of stroke in patients who have frequent episodes of AF. The data from this important study will improve our anticoagulation strategy in patients with AF".

The IMPACT study was designed by an independent steering committee comprised of internationally renowned Electrophysiologists, Cardiologists and Neurologists to ensure the clinical validity of the study protocol. A Clinical Events Committee, Data Safety Monitoring Board and study statistician are all operationally independent of BIOTRONIK, the study sponsor. IMPACT is registered on clinicaltrials.gov.

"BIOTRONIK is proud to sponsor this important study which reaffirms our commitment to scientifically meaningful trials." said Jake Langer, President, BIOTRONIK, Inc.

"BIOTRONIK is investing in clinical research that can make a significant difference in patient outcomes."

About BIOTRONIK GmbH & Co. KG

As one of the worlds leading cardiovascular medical device companies, with several million implanted devices, BIOTRONIK is present in all world markets. Known for having its finger on the pulse of the medical community, BIOTRONIK helps to assess the challenges physicians face, and provides the best solutions, be they cardiac implants, minimal invasive devices or other products and services ranging from diagnosis to electrotherapy and vascular intervention or therapy management. Quality, innovation, and reliability define BIOTRONIK and its growing success, and deliver confidence and peace of mind to physicians and their patients worldwide.

Contact:

Katerina de Metz
Senior Manager, Clinical Studies
BIOTRONIK, Inc.
Telephone: +1-503-675-2169

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