Medtronic News

Medtronic Initiates Landmark U.S. Drug-Eluting Balloon Study

First Patients Treated in Clinical Trial of Novel Medical Device Involving Interventions for Lower-Extremity Peripheral Artery Disease

MINNEAPOLIS, Apr 13, 2012 (BUSINESS WIRE) --Expanding its commitment to developing innovative treatments for cardiovascular disease and the evidence to support their adoption, Medtronic, Inc. (NYSE: MDT) announced today the start of the Medtronic IN.PACT SFA II study, the company's first U.S. clinical trial for its line of IN.PACT drug-eluting balloons.

The first patients in this landmark study were treated this week by Dr. Ash Jain at Washington Hospital in Fremont, Calif., and Dr. Brian Bigelow at St. Vincent Hospital in Indianapolis; Dr. Monica Hunter at Christ Hospital in Cincinnati is planning to treat a patient in the study as early as next week. Drs. Jain, Bigelow and Hunter are the principal investigators at their respective trial site.

Peripheral artery disease is estimated to affect eight to 12 million people in the United States alone. A prevalent form of cardiovascular disease, lower-extremity peripheral artery disease is a prime cause of claudication (ischemic leg pain) and immobility, critical limb ischemia and amputations.

The Medtronic IN.PACT SFA II study will evaluate the safety and effectiveness of the company's IN.PACT Admiral drug-eluting balloon in the treatment of peripheral artery disease in the superficial femoral artery and/or proximal popliteal artery. Specifically, the trial will examine the effect of this novel device for treating *de novo* and non-stented restenotic atherosclerotic lesions in these vessel beds.

The Medtronic IN.PACT SFA II study is a prospective, multicenter randomized controlled trial that will involve several hundred patients at up to 55 U.S. sites. Patients will be randomized 2:1 to treatment with either Medtronic's IN.PACT Admiral drug-eluting balloon (study arm) or a traditional non-coated angioplasty balloon (control arm).

The principal investigators of the Medtronic IN.PACT SFA II study are interventional cardiologist Dr. John Laird, professor of medicine at the University of California Davis and medical director of the UC Davis Vascular Center, and vascular surgeon Dr. Peter Schneider, chief of the vascular therapy division at Kaiser Foundation Hospital and Hawaii Permanente Medical Group in Honolulu.

"Drug-eluting balloons represent an exciting and innovative therapy in the advancement of peripheral artery disease treatment," said Dr. Laird. "The concept of delivering an anti-restenotic agent to the vessel while leaving nothing behind is very attractive."

"Medtronic is a leader in the development of this novel drug-delivery device, and I am excited to partner with the company on IN.PACT SFA II. Dr. Schneider and I would also like to congratulate our colleagues at Washington Hospital, St. Vincent Hospital and Christ Hospital for being the first activated sites in this landmark study."

Once complete, data from the Medtronic IN.PACT SFA II study will be combined with those from the Medtronic IN.PACT SFA I study -- currently underway in Europe and led by principal investigator Dr. Gunnar Tepe, chief of radiology at Klinikum Rosenheim in Germany -- and is intended to support a premarket approval (PMA) application to the U.S. Food and Drug Administration (FDA). The combined enrollment in the two Medtronic studies -- IN.PACT SFA I and II -- is expected to total approximately 450 patients.

Ultimately, Medtronic's global IN.PACT clinical program will include 24 studies involving approximately 4,000 patients and 200 sites across more than 80 countries worldwide. Through these company-sponsored and physician-initiated studies, Medtronic

IN.PACT drug-eluting balloons will be investigated thoroughly for the treatment of arterial disease in coronary and peripheral vessel beds. To date, seven of these studies have completed enrollment and 10 others have begun enrollment.

"As treatment of peripheral artery disease has moved to endovascular as a primary option, we are constantly seeking out more effective technologies for our patients," said Dr. Schneider. "As data accumulates around the world, drug-eluting balloons may someday play a major role in treating narrowed arteries in the lower extremities. Dr. Laird and I are privileged to help assess this exciting new option for U.S. patients."

Medtronic's IN.PACT drug-eluting balloons feature a proprietary coating called FreePac that is a formulation of paclitaxel and urea, an excipient that facilitates absorption of the drug into the vessel wall. They received the CE *(Conformite Europeenne)* mark in 2008 and 2009 and are available in many countries around the world. They are not commercially available in the United States; the Medtronic IN.PACT Admiral drug-eluting balloon is limited to investigational use under an investigational device exemption (IDE) granted by the FDA.

More information about the Medtronic IN.PACT SFA II clinical study is available online at www.inpactsfa2.com.

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

ABOUT MEDTRONIC
Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

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