Medtronic News

Medtronic Announces Global Drug-Eluting Balloon Study

International Research Program Will Collect and Assess Safety and Efficacy Data on IN.PACT Admiral(TM) Drug-Eluting Balloon in Treatment of Peripheral Artery Disease

MINNEAPOLIS & LONDON, Apr 17, 2012 (BUSINESS WIRE) --In conjunction with the Charing Cross International Symposium (CX34), which concludes today in London, Minneapolis-based Medtronic, Inc. (NYSE: MDT) announced its plans for the imminent start of the IN.PACT Global SFA clinical study, an international research program to evaluate the treatment of peripheral artery disease using the company's IN.PACT Admiral *(TM)* drug-eluting balloon.

The purpose of this prospective, multicenter study is to collect and assess safety and efficacy data on the Medtronic IN.PACT Admiral drug-eluting balloon for the treatment of atherosclerotic disease in the superficial femoral (SFA) and/or popliteal arteries. This study calls for enrolling up to 1,500 "real world" patients at up to 80 sites in numerous countries and will allow lesions of any length.

Steering committee members for the Medtronic IN.PACT Global SFA clinical study thus far include Drs. Gunnar Tepe (Germany), Marc Bosiers (Belgium), Do Dai Do (Switzerland), Peter Gaines (UK), Alvaro Razuk (Brazil) and Gary Ansel (USA).

"By enrolling 1,500 unselected patients within the setting of a robust and controlled trial design like this, the Medtronic IN.PACT Global SFA study not only will provide first-of-its-kind results and insights on the role of drug-eluting balloons, but will also offer better and deeper understanding on 'real-world' fem-pop disease, pattern and its multiple variables," said Dr. Tepe, chief of radiology at Klinikum Rosenheim in Germany and chairman of the IN.PACT Global SFA steering committee. "The initiation of a study of these proportions and structure marks a major milestone in the advancement of peripheral artery disease therapy in general and provides further proof of a company committed to invest in clinical research that generates the data physicians need to be confident that their patients are receiving the best care."

The Medtronic IN.PACT Global SFA clinical study is a major component of the company's global clinical program for its line of drug-eluting balloons. The 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.

Recently, results of a registry evaluating the IN.PACT Admiral drug-eluting balloon in the SFA were published in the *Journal of the American College of Cardiology (JACC): Cardiovascular Interventions* (March 2012). The independent study, titled "Clinical Evaluation of a Paclitaxel-eluting Balloon for Treatment of Femoro-popliteal Arterial Disease: Twelve Month Results from a Multicenter Italian Registry," was led by Dr. Antonio Micari of Maria Eleonora Hospital in Palermo, Italy, and was the first study of its kind to measure quality of life (QoL) improvements when using a drug-eluting balloon to treat patients with peripheral artery disease.

The study showed that use of the IN.PACT Admiral drug-eluting balloon in 105 patients at 12 months resulted in an 83.7 percent primary patency rate and a target lesion revascularization rate of 7.6 percent. Additionally, the trial resulted in statistically significant QoL improvements across multiple endpoints, including walking distance and shift in Rutherford classification.

Medtronic IN.PACT drug-eluting balloons received 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 IN.PACT Admiral drug-eluting balloon is limited to investigational use under an investigational device exemption (IDE) granted by the U.S. Food and Drug Administration (FDA) and is currently being studied in the Medtronic IN.PACT SFA II clinical study.

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.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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