Medtronic News

Medtronic Stent Resulted in 90% Freedom from Reinterventions in Narrowed Leg Arteries at 12 Months in International Study

New Clinical Data Presented for First Time at Medical Meetings in U.S. and Europe Show Durable Vessel Patency in Treating Atherosclerotic Lesions of Superficial Femoral Artery

MINNEAPOLIS--(BUSINESS WIRE)--Feb. 8, 2012-- Consistent with its commitment to developing better treatments for peripheral arterial disease (PAD), Medtronic Inc. (NYSE:MDT) today announced the one-year results of an international study of the Complete SE (self-expanding) vascular stent for the treatment of atherosclerosis in the superficial femoral artery (SFA). The device is investigational in the United States.

As presented for the first time at ISET and LINC in January, the Complete SE SFA study demonstrated a primary patency rate of 73.1 percent, a major adverse event rate of 11.0 percent and a target lesion revascularization (TLR) rate of 9.4 percent at 12 months of patient follow-up. The TLR rate, a patient-centric measure of symptom-driven reintervention, means that more than 90 percent of study subjects at the one-year time-point had not required another procedure to treat the target lesion.

The Complete SE SFA study was a prospective, single-arm trial that enrolled 196 subjects (with a total of 213 lesions) at 28 sites in the United States and Europe.

Approved by the U.S. Food and Drug Administration (FDA) under an investigational device exemption (IDE), the study evaluated the safety and efficacy of the Complete SE stent in treating lesions of the SFA, including the proximal popliteal artery (PPA), with the primary endpoints assessed at 12 months: major adverse events for safety and primary patency for efficacy. All study subjects were determined to have symptomatic, ischemic PAD involving the SFA/PPA.

The principal investigators of the study are Dr. John Laird of UC Davis Medical Center in the United States and Prof. Dr. Dierk Scheinert of the University of Leipzig Heart Center in Germany.

“The strong performance of the Complete SE vascular stent in this rigorously conducted clinical trial is encouraging,” said Dr. Laird, who presented the results at this year’s International Symposium on Endovascular Therapy (ISET) in Miami and the Leipzig Interventional Course (LINC) in Germany. “The investigators found the device easy to use in treating SFA lesions of varying complexity, which is indicative of clinical practice.”

Study subjects showed statistically significant improvements in all measures of clinical and functional effectiveness, such as Rutherford Category, mean ABI/TBI, and Walking Assessment. These improvements were achieved despite the enrollment of patients with moderately or severely calcified lesions (91.0%), diabetes (45.4%), and a Rutherford Category rating of 3 or higher (66.8%) at baseline.

More than 80 percent of study subjects had achieved a Rutherford Category value of 0 or 1, the favorable end of the 0–6 scale, at 30 days, and that benefit persisted through six months and one year of follow-up. Treatment with the Complete SE stent also resulted in highly significant positive shifts in mean ABI/TBI scores at six and 12 months, with more than 60 percent of study subjects improving by at least 0.15 over the follow-up period. On Walking Assessment measures, impairment improved by 36.8 percent, distance by 32.4 percent, speed by 21.8 percent and stair climbing by 23.3 percent.

The Complete SE stent, which is commercially approved by the FDA for use in the iliac arteries, is Medtronic’s flagship self-expanding peripheral vascular stent, known for its innovative delivery system that enables exceptional deployment accuracy. Medtronic also plans to seek FDA approval for the SFA indication.

“Our commitment to building the clinical evidence to advance peripheral interventional therapies takes many forms,” said Tony

Semedo, vice president and general manager of the Endovascular Therapies business at Medtronic. “The Complete SE SFA study is a prime example. We are also devoting significant resources to building a strong clinical foundation for the use of drug-eluting balloon technology to treat atherosclerosis in the lower extremities.”

The superficial femoral artery (SFA) runs under the skin of the upper leg and carries blood to the lower extremities, from the thigh to the toes. In patients whose SFA narrows (usually due to the accumulation along the inner wall of the artery of fatty deposits called plaque), the flow of oxygenated blood to the lower extremities becomes restricted, with consequences ranging from leg pain while walking (claudication) to limb loss (amputation).

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias.

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.

Source: Medtronic Inc.

Medtronic Inc.
Joseph McGrath, 707-591-7367
Public Relations
Jeff Warren, 763-505-2696
Investor Relations

---

https://news.medtronic.com/2012-02-08-Medtronic-Stent-Resulted-in-90-Freedom-from-Reinterventions-in-Narrowed-Leg-Arteries-at-12-Months-in-International-Study