Protégé GPS Self-Expanding Peripheral Stent System Receives FDA Approval for Use in Treating Iliac Artery Stenosis

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DUBLIN -- March 18, 2015 -- Medtronic plc (NYSE: MDT) today announced that its Protégé(TM) GPS(TM) self-expanding peripheral stent system has received approval from the U.S. Food and Drug Administration (FDA) for the treatment of stenotic lesions of the common and external iliac arteries.

The news follows the nine-month results of the DURABILITY Iliac study, which were presented at the 2014 VIVA conference in Las Vegas. The results demonstrated the safety and effectiveness of the Protégé GPS peripheral stent system in the treatment of stenotic lesions of the common and external iliac arteries. The prospective, multi-center, non-randomized clinical study demonstrated 95.8 percent nine-month primary patency (the ability for the treated artery to remain open) by Kaplan-Meier analysis and 98.6 percent freedom from target vessel revascularization (no repeat procedure).

"When used for iliac angioplasty and stenting, the Protégé GPS self-expanding peripheral stent system demonstrated excellent patency rates even in difficult-to-treat calcified lesions," said Dr. Peter Faries, co-national principal investigator of the DURABILITY Iliac study, Mount Sinai School of Medicine, New York. "Data from the DURABILITY Iliac study confirms the safety and effectiveness of the Protégé GPS stent. It is gratifying to see that the FDA has approved this stent for the iliac indication."

Iliac stenosis occurs when plaque builds up in the iliac artery, which can block the blood supply to the entire leg. As a result, patients with iliac artery stenosis can experience pain that can limit mobility.

The Protégé GPS self-expanding peripheral stent system allows physicians to treat iliac artery lesions and restore blood flow with large diameter stents through a low, 6F profile delivery system. The stent is cut from a nitinol tube into an open lattice design and has tantalum radiopaque markers at the proximal and distal ends of the stent. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, outward force to restore patency.

"The Protégé GPS self-expanding peripheral stent system is designed to enhance delivery, deployment and visibility during peripheral vascular procedures," said Mark Turco, M.D., medical director of the Aortic and Peripheral Vascular business at Medtronic. "This new indication will provide physicians with enhanced device options when treating complex iliac artery disease."

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 diseases 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 plc (www.medtronic.com), headquartered in Dublin, Ireland, 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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