Boston Scientific Begins Clinical Trial of Peripheral Vascular Drug-Eluting Stent System

PR Newswire

MAJESTIC Trial to Study Self-Expanding DES System Designed to Treat Superficial Femoral Artery (SFA) Lesions

Launching a key clinical trial expected to serve as the foundation for global regulatory approvals, a physician in Auckland, New Zealand has performed the first patient implant of the Boston Scientific Corporation (NYSE: BSX) Innova™ Drug-Eluting Stent (DES) System.

The MAJESTIC trial—designed to evaluate the safety and performance of the first Boston Scientific peripheral drug-eluting stent system—is projected to enroll 55 patients across 15 centers in Europe, Australia and New Zealand. The Innova DES System reflects more than a decade of Boston Scientific experience in drug-eluting technologies.

The Innova DES System is designed to restore blood flow in arteries above the knee, specifically the SFA and proximal popliteal artery (PPA). The stent features a unique drug-polymer combination, intended to facilitate optimal release of the drug and prevent restenosis (narrowing) of the vessel. The first implant was performed by Andrew Holden, M.D., director of Interventional Radiology at Auckland City Hospital, Auckland, New Zealand.

"The complex anatomy of the superficial femoral artery above the knee and the

dynamic forces created by flexion of the knee create a challenging environment for implants like stents, leading to the potential risk of stent fracture and higher rates of restenosis," said Professor Stefan Muller-Hulsbeck, M.D., PhD, deputy chairman Vascular Center Diako Flensburg and Head of the Dept. of Diagnostic and Interventional Radiology / Neuroradiology, Academic Hospitals Flensburg, Germany. "The Innova DES System combines the benefits of the clinically-proven drug Paclitaxel with architecture and stent design purpose-built for use in the SFA and PPA. The deliverability, flexibility and durability in combination with the anti-restenotic characteristics of the Innova DES System make it ideal for use treating lesions in these critical arteries."

Professor Muller-Hulsbeck serves as principal investigator of the MAJESTIC trial.

The Innova DES System consists of a Paclitaxel-coated, Nitinol, self-expanding stent loaded on an advanced, low-profile delivery system. The innovative stent architecture features a closed-cell design at each end of the stent for more consistent deployment, and an open-cell design along the stent body for improved flexibility and fracture resistance. Deployment accuracy is facilitated by a tri-axial catheter shaft designed to provide added support and placement accuracy.

"Millions of patients around the world suffer the debilitating effects of peripheral artery disease (PAD), including amputation and an elevated risk for major cardiovascular events," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "The Innova DES System builds upon the Boston Scientific leadership in both peripheral vascular devices and drug-eluting technologies, and we look forward to bringing this meaningful innovation forward to improve outcomes for patients with PAD."

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