Boston Scientific

Boston Scientific Begins Clinical Trial Of Innova™ Peripheral Vascular Drug-Eluting Stent System

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

NATICK, Mass., Oct. 9, 2013 /PRNewswire/ -- 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."

The Innova DES System is an investigational device worldwide and not available for use or sale. To download an image of the Innova DES System click here.

About Peripheral Artery Disease
Peripheral artery disease is a circulatory disorder that results from a build-up of plaque in one or more of the arteries, most often in the legs. As the disease progresses, plaque accumulation may significantly reduce blood flow through the arteries, resulting in pain and increasing disability, with severe cases often leading to amputation of the affected limb. It is estimated that 12-14 percent of the general population is affected by PAD[1].

1. Shammas NW (2007). "Epidemiology, classification, and modifiable risk factors of peripheral arterial disease". Vasc Health Risk Manag 3 (2): 229–34. doi:10.2147/vhrm.2007.3.2.229. PMC 1994028. PMID 17580733

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding markets for our products, clinical trials, regulatory approvals, product performance and competitive offerings. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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