Boston Scientific

FDA Approves Boston Scientific's Express® SD Renal Stent System

First low-profile, pre-mounted stent approved specifically for use in renal arteries

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NATICK, Mass., Dec. 15 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today announced that the U.S. Food and Drug Administration (FDA) has approved the Express® SD Renal Monorail® Premounted Stent System for use as an adjunct to PTRA (percutaneous transluminal renal angioplasty) in certain lesions of the renal arteries. The Express SD System is the first low-profile, pre-mounted stent approved for use in renal arteries in the United States. It is the only FDA-approved renal stent designed to provide additional proximal end support.

"The approval of the Express SD Stent for renal indications provides physicians with an on-label stenting option for use with PTRA in certain patients with renal artery disease," said Krishna Rocha-Singh, M.D., F.A.C.C., of Prairie Cardiovascular Heart Institute in Springfield, Illinois.

"FDA approval for the Express SD Renal Stent is an important step in providing physicians evidence-based technology to facilitate the management of renal artery disease," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "With the addition of the Express SD Renal Stent, Boston Scientific can now offer customers the industry's leading portfolio of products for endovascular treatment of this disease."

Renal artery disease is the narrowing of the main blood supply to the kidneys due to atherosclerosis, or the formation of plaque within the arteries, which can lead to high blood pressure or poor kidney function. The disease can be treated surgically, with medication, or less invasively with angioplasty. Re-narrowing of the arteries can occur after angioplasty, and the use of stenting as an adjunctive treatment option is intended to assist in their re-opening.

Two-year results from the RENAISSANCE clinical trial, which was designed to evaluate the safety and efficacy of the Express SD Renal Stent in hypertensive patients with atherosclerotic renal artery stenosis (RAS), demonstrated a statistically significant improvement in systolic blood pressure and no statistical difference in either diastolic blood pressure or serum creatinine levels from baseline through three years(1). Nine-month results demonstrated a binary restenosis rate of 21.3 percent (23/108), low target lesion revascularization (TLR) rates of 8.1 percent (9/111) and no stent thrombosis (0/100)(2).

The Express SD Renal Stent is designed specifically for treatment of the renal arteries by incorporating additional connections in the proximal end of the stent, which are intended to provide excellent support, especially in lesions occurring at the opening of the renal artery (ostial lesions). Based on Maverick® Monorail® Balloon Catheter technology and Tandem Architecture™ Stent Design, the Express SD Renal Stent is designed to provide strength, precision and deliverability.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of 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 clinical trials, product performance, competitive offerings, procedural volume, overall market size and our market position. 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 thereafter. 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.

(1) Data on File at Boston Scientific
(2) Presented by Dr. Krishna Rocha-Singh at ISET, January 2008

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