Boston Scientific

FDA Approves Boston Scientific's Express® LD Iliac Stent System

NATICK, Mass., March 11 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved its Express® LD Iliac Premounted Stent System for use in iliac arteries. The Express LD Iliac Stent is the first and only low-profile, premounted, balloon-expandable stent approved by the FDA for use in treating iliac artery disease. The Company said it plans to launch the product immediately in the United States.

The Express LD Iliac Stent is designed to be highly deliverable, and its Tandem Architecture™ Stent Design is engineered to balance strength, flexibility and conformability.

Atherosclerotic iliac disease occurs when plaque builds within the arteries that supply blood to the legs, which can lead to poor blood flow, leg pain and other complications. The disease can be treated with medication, surgery or angioplasty.

"Boston Scientific's Express LD Iliac Stent incorporates a flexible stent design and is engineered for improved deployment accuracy, two critical treatment components," said Barry Katzen, M.D., F.A.C.R, F.A.C.C., of Baptist Cardiac and Vascular Institute in Miami. "With an approved iliac indication, the Express LD Stent offers physicians a less-invasive alternative to surgery for our patients suffering from iliac artery disease."

"The Express LD Iliac Stent offers an attractive option for physicians treating the iliac arteries," said Joe Fitzgerald, Senior Vice President and President of Boston Scientific's Endovascular Unit. "This approval reinforces our leadership in the treatment of peripheral artery disease and adds to our portfolio of peripheral vascular stent indications, which includes the Carotid WALLSTENT® Endoprosthesis for carotid artery disease and the Express® SD Stent for renal artery disease."

The Express LD Iliac Stent has received CE Mark approval and is currently approved for iliac use in a number of international markets.

"I have found that the benefits of a balloon-expandable stent like the Express LD Iliac Stent can be extremely important when working in atherosclerotic iliac lesions," said Luc Stockx, M.D., of Limburgs Vaatcentrum Ziekenhuis, Belgium. "Deployment accuracy and radial strength can play crucial roles in these types of procedures, and the Express LD Stent is designed to deliver both."

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 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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