Boston Scientific

# Boston Scientific Announces CE Mark and FDA Approval of NC Quantum Apex™ Balloon Catheter

NATICK, Mass., May 25 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced CE Mark and U.S. Food and Drug Administration (FDA) approval of its NC Quantum Apex™ PTCA Dilatation Balloon Catheter. The Company plans to launch the product in European markets this week and in the U.S. next month.

The NC Quantum Apex Catheter is a high-performance, post-dilatation balloon catheter developed specifically to address physicians' needs in optimizing coronary stent deployment. It represents the next generation of balloon catheter technology, and is designed to deliver enhanced performance through the use of a new Bi-Segment™ Inner Shaft for improved trackability and a re-designed tip for greater flexibility(1). It is available in a wide array of balloon diameters from 2.0 to 5.0 mm, with balloon lengths ranging from 6 to 30 mm. The Monorail® catheter platform will be available worldwide and both the Monorail and Over-the-Wire (OTW) catheter platforms will be available in the U.S.

Jean Fajadet, M.D., Director of the Interventional Cardiology Unit, Clinique Pasteur, Toulouse, France was the first physician to treat patients with the new balloon catheter. "The NC Quantum Apex Catheter performed very well, offering a noticeably lower profile, excellent trackability and effective post-dilatation," said Dr. Fajadet. "It features an innovative design and impressive performance that should benefit interventional cardiologists and their patients."

Bruce Brodie, M.D., Interventional Cardiologist, Moses Cone Heart and Vascular Center, and Chairman, LeBauer Cardiovascular Research Foundation, Greensboro, North Carolina, and Principal Investigator of the POSTIT study was one of the first physicians in the U.S. to use the NC Quantum Apex Catheter. "Results from the POSTIT clinical study showed that more than 70 percent of coronary stents are not optimally deployed by a stent delivery balloon alone," said Dr. Brodie. "The use of IVUS with an adjunctive post-dilatation balloon makes it twice as likely that a stent will be optimally deployed. The NC Quantum Apex Catheter is a great addition to the available post-dilatation balloons, making it easier for physicians to achieve optimal stent deployment."

"As the leader in balloon catheters and drug-eluting stents, Boston Scientific continues to innovate and improve on the best-in-class products we currently deliver to our physician customers," said Hank Kucheman, Executive Vice President and President of Boston Scientific's Cardiology, Rhythm and Vascular Group. "The next-generation NC Quantum Apex Catheter is another example of our leadership, offering improved performance over the industry standard Quantum™ Maverick® and providing enhanced treatment options for our physicians and their patients."

PTCA dilatation catheters are used in coronary angioplasty and stenting procedures to open arteries blocked by atherosclerosis, which if left untreated can cause heart attack and stroke. Coronary artery disease represents the leading cause of death in the United States and Europe, accounting for more than 870,000 U.S. deaths each year and 1.95 million deaths annually in Europe(2).

The NC Quantum Apex Catheter is the latest innovation from Boston Scientific designed to improve the management of patients with coronary artery disease undergoing percutaneous coronary intervention (PCI). Boston Scientific offers a broad range of devices intended to optimize PCI procedures, including ultrasound imaging to assess lesions, and balloon catheters and drug-eluting stents to reopen blocked arteries. This comprehensive portfolio supports physicians' efforts to achieve safe and effective outcomes for their patients.

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.

(1) Trackability, tip flexibility and recross bench testing compared the NC Quantum Apex and Quantum Maverick catheters.

(2) Source: http://www.americanheart.org/downloadable/heart/1166712318459HS_StatsInsideText.pdf

**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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